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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

Commission file number: 001-38097

CALLIDITAS THERAPEUTICS AB

(Exact name of registrant as specified in its charter and translation of Registrant's name into English)

Sweden
(Jurisdiction of
Incorporation or Organization)

Kungsbron 1, D5
SE-111 22 Stockholm, Sweden
(Address of principal executive offices)

Renée Aguiar-Lucander
Calliditas Therapeutics AB
Kungsbron 1, D5
SE-111 22 Stockholm, Sweden
Tel: +46 (0) 8 411 3005
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(Name, telephone, e-mail and/or facsimile number and address of company contact person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol:	Name of each exchange on which registered:
American Depositary Shares, each representing two common shares, quota value SEK 0.04 per share	CALT	Nasdaq Global Select Market
Common shares, quota value SEK 0.04 per share *		Nasdaq Global Select Market*

* Not for trading, but only in connection with the registration of the American Depositary Shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act: None.
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

As of December 31, 2023, 59,580,087 common shares were outstanding, including common shares represented by American Depositary Shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b 2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐	Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b2 of the Exchange Act). Yes ☐ No ☒

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INTRODUCTION

Unless otherwise indicated or the context otherwise requires, all references in this annual report to the terms "Calliditas Therapeutics AB," "Calliditas Therapeutics," "Calliditas," "the company," "we," "us" and "our" refer to Calliditas Therapeutics AB and its wholly owned subsidiaries.

We own various trademark registrations and applications, and unregistered trademarks, including, as of March 31, 2024, CALLIDITAS (registered in the European Union, or EU, in the United States and in other countries), CALLIDITAS THERAPEUTICS (registered in the United States), TARPEYO® (registered in the EU, in the United States, and registered or pending in other countries) and NEFECON (registered in the EU, in the United States, and in other countries). The trademark registrations for Kinpeygo®, previously owned by us, were transferred to our partner STADA Arzneimittel AG, or STADA. All other trade names, trademarks and service marks of other companies appearing in this annual report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this annual report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

TARPEYO is the brand name used in the United States for our product developed under the name Nefecon, and Kinpeygo is the brand name used in the United Kingdom, or UK, and EU. In general, in this annual report we use "Tarpeyo" to describe the product commercialized in the United States, "Kinpeygo" to describe the product commercialized in the UK and EU, "NEFEGAN" to describe the product to be commercialized in Singapore and "Nefecon" for all other purposes, including for the conditionally approved product in China and the global Nefecon product franchise. Approved product encompasses TARPEYO, Kinpeygo and Nefecon as conditionally approved in China and related territories.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "is designed to," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue," "ongoing or the negative of these and similar expressions identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements and opinions contained in this annual report are based upon information available to our management as of the date of this annual report and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements contained in this annual report include, but are not limited to, statements about:

- the timing, scope or likelihood of regulatory filings and approvals with respect to the global Nefecon franchise and our current and future product candidates, including setanaxib;
- our TARPEYO sales and commercialization efforts and their results;
- our commercialization partners' Kinpeygo and Nefecon sales and commercialization efforts and their results;
- the timing, progress and results of development plans for global Nefecon franchise and our current and future product candidates;
- our ability to secure payor approval of TARPEYO for its patient population on acceptable terms;
- the ability of our commercialization partner to secure payor approval for Kinpeygo and Nefecon for its patient population on acceptable terms;
- the potential attributes and benefits of our approved product and our other product candidates and their competitive position with respect to alternative treatments;
- the potential benefit of the European Commission's conditional approval and hybrid marketing authorization application pathway, orphan drug status or designation and related market exclusivity for our products and product candidates, and equivalent foreign provisions;
- the timing and results of our interim readout of setanaxib in the TRANSFORM study, a Phase 2b clinical trial, and the determination of which dose of setanaxib could be used for a potential Phase 3 study;
- our ability to successfully identify and develop our current and future product candidates and build our product pipeline, including strategic acquisitions;
- the impact of the macroeconomic environment, political and geopolitical tension and other world events on our business and clinical trials, including on the supply of API or other relevant components required for Nefecon and our current and future product candidates;
- our expectations regarding the size and growth of the potential market and patient populations for the global Nefecon franchise and our current and future product candidates, if approved;
- our manufacturing, commercialization and marketing capabilities and strategy;

- the rate and degree of market acceptance and clinical utility of our approved product and our present or future product candidates;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals, including sales and marketing personnel;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our competitive position, and developments and projections relating to our competitors and our industry;
- our plans to enter into collaborations for commercialization of our products, product candidates or any future product candidates;
- whether we are classified as a passive foreign investment company for current and future periods;
- our estimates regarding expenses, revenue, capital requirements and needs for additional financing; and
- the impact of laws and regulations.

You should refer to the section of this annual report titled "Item 3.D.—Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this annual report and the documents that we reference in this annual report and have filed as exhibits to the annual report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Information regarding market and industry statistics contained in this annual report is included based on information available to us that we believe is accurate. Forecasts and other forward-looking information obtained from this available information is subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous material and other risks and uncertainties, including those described in "Item 3.D.—Risk Factors" in this annual report. The principal risks and uncertainties affecting our business include the following:

- We are substantially dependent on the commercial success of the global Nefecon franchise. If we are unable to successfully commercialize Nefecon or experience significant delays in doing so, our business will be materially harmed.
- If we are unable to successfully complete clinical development of, obtain regulatory approval for and successfully commercialize the global Nefecon franchise and our present or future product candidates, or experience significant delays in doing so, our business will be materially harmed.
- The regulatory approval processes of the FDA, EC and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain acceptance for filing and regulatory approval for any of our products or present or future product candidates, our business will be substantially harmed.
- The use of proteinuria as a surrogate endpoint to support initial approvals of Nefecon is a novel approach in nephrology.
- Our clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.
- The results of early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in a clinical trial may not be indicative of results obtained when these trials are completed or in later-stage trials.
- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may be impacted as additional patient data become available and are subject to audit and verification procedures that could result in material changes in the conclusions based on the final analysis of the complete data set.
- The target patient population of Nefecon for the treatment of IgAN is small and has not been definitively determined, and if the number of treatable patients for Nefecon or our present or future product candidates is lower than expected, our potential product sales revenues and our ability to achieve profitability would be compromised.
- We were not involved in the early development of setanaxib; therefore, we are dependent on third parties having properly conducted setanaxib's preclinical research, manufacturing control and clinical development.
- We face significant competition for our drug discovery, development and commercialization efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.
- If we fail to develop and commercialize other product candidates in addition to Nefecon, such as setanaxib, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.
- We have only recently begun commercialization of the global Nefecon franchise and we have never previously commercialized a product. We may lack the necessary expertise, personnel and resources to successfully commercialize Nefecon or any other approved products on our own or together with suitable partners.
- We have incurred significant losses since our inception and anticipate that we will continue to incur operating losses for the near future.
- We may need substantial additional funding in order to fund our operations. Failure to obtain this necessary capital at acceptable terms and when needed may force us to delay, limit or terminate certain or all of our operations and pursuit of our growth strategy.

- We have a limited operating history as a commercial company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

- We have entered into agreements with third parties to develop and commercialize Nefecon in jurisdictions outside the United States, if approved in such jurisdictions, and we plan to enter into additional agreements in the future with respect to any of our present or future product candidates that receive approval. If we are unable to establish and maintain such collaborations, we may not be successful in our commercialization efforts. If our commercialization partners do not to satisfy their obligations or are unsuccessful, we could be adversely affected.

- We expect to continue to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

- Our business is subject to economic, political, regulatory and other risks associated with international operations.

- We have identified material weaknesses in our internal control over financial reporting. If our remediation of these material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.

- We are dependent on third parties to manufacture and distribute our products.

- Healthcare reform initiatives, unfavorable pricing regulations, and changes in reimbursement practices of third-party payers or patients' access to insurance coverage could affect the pricing of and demand for our products.

- We may be unable to successfully integrate new products or businesses we may acquire.

- We may become involved in litigation matters, which could result in substantial costs, divert management's attention and otherwise have a material adverse effect on our business, operating results or financial condition.

- We may not have sufficient insurance to cover our liability in any current or future litigation claims either due to coverage limits or as a result of insurance carriers seeking to deny coverage of such claims.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the US Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs. This report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors including the risks described below and elsewhere in this annual report and our other SEC filings. See "Special Note Regarding Forward-Looking Statements" above.

Risks Related to the Development and Commercialization of Our Product Candidates

We are substantially dependent on the commercial success of the global Nefecon franchise. If we are unable to successfully commercialize Nefecon or experience significant delays in doing so, our business will be materially harmed.

We have sold Nefecon in the United States (marketed under the brand name TARPEYO) only since January 2022 and our commercial partner in Europe, STADA, launched Kinpeygo in Germany in October 2022 and in Greece under a Special Import License since June 2023. Our net sales for the year ended December 31, 2023 were SEK 1,206.9 million, of which TARPEYO net sales amounted to SEK 1,075.8 million. We do not know whether such revenue levels will increase or be maintained in the future. Other than Nefecon, which has been granted full approval in the United States, conditional marketing authorization in the EU and the UK, and conditional approval for sale in Macau in October 2023, China in November 2023 and Singapore in March 2024, we currently have no products approved for commercial sale. Our success as a company is substantially dependent on our ability to generate revenue from sales of the global Nefecon franchise, which will depend on many factors including, but not limited to, our ability to:

- maintain full approval of TARPEYO in the US;
- execute our sales and marketing strategies for TARPEYO;
- maintain and manage the necessary sales, marketing and other capabilities and infrastructure that are required to continue to successfully commercialize TARPEYO in the US;

- achieve, maintain and grow market acceptance of the global Nefecon franchise and demand for TARPEYO;
- establish or demonstrate in the medical community the safety and efficacy of Nefecon as compared to marketed products and product candidates currently in clinical development;
- secure payor approval of TARPEYO for the patient population on acceptable terms;
- offer TARPEYO at competitive prices as compared to alternative options, and our ability to achieve a suitable profit margin on our sales of TARPEYO;
- adapt to additional changes to the label for TARPEYO in the US that could place restrictions on how we market and sell it, including as a result of adverse events observed in NefIgArd or other studies;
- obtain and deliver adequate and timely supplies of Nefecon, which may in the future be adversely affected by factors relating to pandemics, geopolitical tension, global supply chain disruptions and other world events;
- comply with applicable legal and regulatory requirements;
- deliver Nefecon to our partners in a timely manner;
- maintain necessary state pharmaceutical distribution licenses and permits required for the sale of TARPEYO and a pharmacovigilance system satisfying applicable legal and regulatory requirements;
- maintain our arrangements with third party logistics providers and specialty pharmacies to distribute TARPEYO to customers and to provide related patient and administrative support services;
- enforce our intellectual property rights in and to TARPEYO and the global Nefecon franchise; and
- avoid third-party patent interference or intellectual property infringement claims.

If we do not achieve or maintain one or more of these factors, many of which are beyond our control, in a timely manner or at all, we may not be able to generate material and continuing revenue from sales of Nefecon, which may materially impact the success of our business.

If we are unable to successfully complete clinical development of, obtain regulatory approval for and successfully commercialize the global Nefecon franchise and our present or future product candidates or experience significant delays in doing so, our business will be materially harmed.

We have not completed the clinical development of any product candidates other than TARPEYO and Kinpeygo and we cannot guarantee that any present or future product candidates will ever become marketable drug products. We also must successfully complete clinical development of Nefecon in order to achieve full marketing approval in the EU and the UK.

To date, we have invested our efforts and financial resources primarily in the research and development of the global Nefecon franchise, and to building marketing, sales, market access and medical affairs functions in the United States. Nefecon was granted accelerated approval by the FDA in December 2021 and received full approval in December 2023. In July 2022, Nefecon was granted conditional marketing authorization by the EC. In February 2023, the UK Medicines and Healthcare Products Regulatory Agency, or MHRA, also granted conditional marketing authorization for Nefecon. Our partner STADA has submitted requests to the EMA in September 2023 for the EU and to the MHRA in October 2023 for the UK to convert the current conditional marketing authorization for these territories into a full marketing authorization. We reported the full data from the Phase 3 NefIgArd clinical trial in August 2023. The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant and clinically relevant benefit over placebo (p value < 0.0001) in eGFR over the two-year period of nine months of treatment with Nefecon or placebo and 15 months of follow-up off drug. The results indicate that Nefecon was generally well-tolerated, with the majority of treatment-emergent adverse events (TEAE) being mild or moderate, and with TEAEs leading to discontinuation of the study in less than 10% of patients. Although we believe that the data from the Phase 3 NefIgArd clinical trial supports our commercialization partners' regulatory filings for full approval in the EU and the UK, we cannot guarantee that Nefecon will receive full regulatory approvals on the timelines we expect or at all.

We are also developing setanaxib for the treatment of primary biliary cholangitis, or PBC, a fibrotic orphan disease, for the treatment of squamous cell carcinoma of the head and neck, or SCCHN, and for the treatment of Alport syndrome. Setanaxib has shown clinically relevant anti-fibrotic activity in a Phase 2 clinical trial in PBC, despite not achieving its primary endpoint. We are currently evaluating setanaxib in the TRANSFORM study, a Phase 2b clinical trial, in which we randomized the first patient in February 2022. Setanaxib will be administered to approximately 70-80 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA in a global trial conducted in 80-130 investigational centers in North America, the EU, Israel, Australia and New Zealand. The primary endpoint is alkaline phosphatase (ALP) reduction, with key secondary endpoints including change in liver stiffness and effect on fatigue and pruritus (itching). Following favorable safety data from a Phase 1 study, this trial will evaluate two dosing regimens of 1200mg/daily and 1600mg/daily. We expect to read out data in the third quarter of 2024, and this analysis will determine which dose of setanaxib will be used for a future potential Phase 3 study. Setanaxib was granted fast track designation by the FDA in August 2021.We are also currently conducting a Phase 2, proof-of-concept trial of setanaxib in patients with SCCHN, which is evaluating administration of setanaxib in conjunction with immunotherapy targeting cancer-associated fibroblasts. The first patient was randomized in this trial in the second quarter of 2022 and we reported interim data in July 2023. The analysis reflected encouraging early clinical progression-free survival (PFS) results and was supportive of the presumed anti fibrotic mode of action of setanaxib. We expect to report a full data readout from this trial in the second quarter of 2024. We are also currently conducting a Phase 2 clinical trial of setanaxib in Alport syndrome, which we initiated in November 2023. Finally, setanaxib is being evaluated in an investigator-led Phase 2 study in idiopathic pulmonary fibrosis, with topline data readout expected in the fourth quarter of 2024.

Our near-term prospects, including our ability to finance our operations and generate revenue, will depend substantially on the successful development and commercialization of the global Nefecon franchise and, to a lesser degree, setanaxib. The clinical and commercial success of Nefecon, setanaxib and any other present or future product candidates will depend on a number of factors, including:

- the timely completion of our planned and ongoing clinical trials;
- our ability to demonstrate Nefecon's and our present or future product candidates' safety and efficacy to the satisfaction of the FDA, the EC or comparable foreign regulatory authorities based on the endpoints that we are evaluating in our planned and ongoing clinical trials;
- our ability to comply with any requirements imposed by the FDA, the EC or comparable foreign regulatory authorities to conduct additional clinical trials in connection with approval to market Nefecon or our product candidates, including any additional testing following any accelerated approval or conditional authorization by such regulatory authorities;
- our ability to obtain and maintain marketing approvals in the US, the EU, the UK or other jurisdictions;
- our ability to obtain regulatory approval based on the data from the NefIgArd trial, to demonstrate safety and efficacy in our Phase 2b TRANSFORM trial evaluating setanaxib in PBC and to establish proof of concept in our Phase 2 trials of setanaxib in SCCHN and Alport syndrome;

- the prevalence and severity of adverse side effects of Nefecon and our present or future product candidates;
- our ability to successfully commercialize TARPEYO and our present or future product candidates, if and when approved for marketing and sale by the FDA, the EC or comparable foreign regulatory authorities, whether alone or in collaboration with others;
- our ability to develop, validate and maintain commercially viable manufacturing and testing processes and procedures that are compliant with current good manufacturing practices, or cGMP, and accepted by regulatory authorities;
- the ability of our third-party manufacturers to manufacture quantities of Nefecon and our present or future product candidates using commercially sufficient processes complying with applicable regulatory requirements and practices at a scale sufficient to meet anticipated demand;
- our success in educating physicians and patients about the benefits, risks, administration and use of Nefecon and our present or future product candidates;
- achieving and maintaining compliance with all regulatory requirements applicable to Nefecon and our present or future product candidates;
- acceptance of the Nefecon franchise and our present or future product candidates as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- our ability to obtain and sustain an adequate level of coverage and reimbursement for Nefecon and our present or future product candidates by third-party payors and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- the effectiveness of our own or any future strategic collaborators' marketing, sales and distribution strategy and operations;
- our ability to obtain, maintain, protect and enforce our intellectual property rights in and to Nefecon and our present or future product candidates;
- our ability to avoid and defend against third-party patent interference or patent infringement claims or other intellectual property related claims;
- a continued acceptable safety profile of Nefecon and our present or future product candidates following approval; and
- our ability to raise sufficient capital resources to fund the commercialization of our approved products.

Many of these factors are beyond our control. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize Nefecon or our present or future product candidates, which would materially harm our business. In addition, even if we were to obtain approval, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Third-party payors or insurers may also condition or limit reimbursement of our products. Any of the foregoing scenarios could materially harm the commercial prospects for Nefecon, setanaxib and any other product candidates we develop. If we are not successful in commercializing Nefecon or our present or future product candidates, or are significantly delayed in doing so, our business will be materially harmed.

The regulatory approval processes of the FDA, EC and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain acceptance for filing and regulatory approval for any of our products or present or future product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, EC and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, laws or regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, Nefecon has received full approval from the FDA (under the brand name TARPEYO) and conditional marketing authorization in the EU and the UK (under the brand name Kinpeygo). Although our partner STADA has submitted requests to both the EMA, in September 2023, for the EU and to the MHRA, in October 2023, for the UK to convert the current conditional marketing authorization for these territories into a full marketing authorization, it is possible that we and our licensees may not be able to obtain full marketing approval in these jurisdictions. Our partner Everest Medicines II Limited, or Everest, has received conditional approval for Nefecon in Macau in October 2023, in Singapore (under the brand name NEFEGAN) in March 2024, and in China, with us as the marketing authorization holder in November 2023. It is possible that we and our licensee may not be able to obtain approval for Nefecon in additional jurisdictions, or approval for setanaxib or other product candidates we may seek to develop in the future.

Any of our product candidates, including setanaxib and Nefecon, could fail to receive regulatory approval for many reasons, including the following:

- to the extent that we seek approval for any additional product candidates based on evaluation of a surrogate marker, including as we did for Nefecon, we may be unable to utilize the accelerated approval pathway under Subpart H of the FDA's New Drug Application, or NDA, regulations and comparable regulations promulgated in the EU or elsewhere if the appropriate regulatory authorities do not accept the proposed surrogate marker as the basis for an accelerated/conditional approval;

- the data collected from clinical trials of a product candidate may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the EU or elsewhere;

- the scientific advice and regulatory feedback provided by the FDA, the EMA, or comparable foreign regulatory authorities, as applicable, during the drug development phase is not legally binding, and the FDA, the EMA may depart from such advice and feedback on the basis of justified grounds during assessment of future marketing authorization applications;

- we may be unable to demonstrate to the satisfaction of the FDA, the EMA and the EC or comparable foreign regulatory authorities that a product candidate is safe or effective for its proposed indication;

- the results of clinical trials may not be sufficiently statistically significant or clinically meaningful as required by the FDA, the EMA, the EC or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that the product candidate's clinical and other benefits outweigh its safety risks;

- the FDA, the EMA, the EC or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials;

- the FDA, the EMA, the EC or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes, quality control procedures or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, the EC, or comparable foreign regulatory authorities or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy process towards approval as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, financial condition and results of operations. The FDA, EMA, EC and other comparable foreign regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EC or other comparable foreign regulatory authorities.

Additionally, disruptions at the FDA and other comparable foreign regulatory authorities and agencies may also lengthen the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, in 2018 and 2019, the US government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs in the future, our ability to obtain approval of our product candidates from the FDA and comparable foreign regulatory authorities may be adversely impacted.

Accelerated approval by the FDA, and conditional approval by the EC, even if pursued for any future product candidates, may not lead to a faster development process or regulatory review and does not increase the likelihood that our product candidates will receive marketing approval. If we are not successful with this process, the development or commercialization of such product candidates could be delayed, abandoned or become significantly more costly.

In certain circumstances, the FDA selectively allows the use of surrogate endpoints to permit a faster development and an accelerated approval path.

As a condition of approval, regulatory agencies may impose specific obligations, including the requirement to perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. The additional data generated through other post-marketing clinical trials may not confirm that the benefit-risk balance of a future product candidate is positive or the burden to further complete the post-approval obligations may become too high.

In the EU and UK, a conditional marketing authorization is valid for one year and must be renewed annually until all specific obligations have been fulfilled. Once all pending study results are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the obligations are not fulfilled within the timeframe set by the EC, the marketing authorization will cease to be renewed. Complying with the conditions of the marketing authorization may require financial resources and time. STADA, our commercialization partner, may not be able to comply with all required conditions and may need to withdraw the marketing authorization. Although our partner STADA has submitted requests to both the EMA, in September 2023, for the EU and to the MHRA, in October 2023, for the UK to convert the current conditional marketing authorization for these territories into a full marketing authorization the EC or the MHRA may decide not to grant this request. An analysis of reimbursement decisions by the competent authorities of the individual EU Member States for conditionally authorized medicines in the EU has shown some delays in the timeline for reaching a positive health technology recommendation. If this happens for Kinpeygo or any other present or future product candidate, it may delay the timing and success of the commercialization of such product.

The use of proteinuria as a surrogate endpoint to support initial approvals of Nefecon is a novel approach in nephrology.

There can be no assurances that regulatory authorities in countries where we seek regulatory approval of Nefecon will ultimately accept the outcome of the NefIgArd trial with regards to proteinuria and eGFR for the approval of Nefecon. Regulatory authorities may require us to provide additional data to support our regulatory applications, which may increase the complexity, uncertainty and length of the regulatory approval process for Nefecon. The EC and comparable foreign regulatory authorities may also withdraw any conditional approval granted for Nefecon if Part B, the post-approval confirmatory phase of the NefIgArd trial, is not considered to have confirmed the positive clinical benefit-risk balance of Nefecon in the approved indication and the EC for the EU and to the MHRA for the UK may refuse the request to convert the current conditional marketing authorization for these territories into a full marketing authorization.

Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future product candidates.

To obtain the requisite regulatory approvals to commercialize any present or future product candidates, we must demonstrate through extensive clinical trials that our product candidates are safe and effective in humans. Confirmatory clinical trials are required to maintain an accelerated approval in the US or a conditional authorization in the EU and the UK. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Successful completion of clinical trials is a prerequisite to submitting an NDA to the FDA, a Marketing Authorization Application, or MAA, to the EMA and similar marketing applications to comparable foreign regulatory authorities for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful.

Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Where a randomized, placebo-controlled clinical trial is designed to allow enrolled subjects to cross-over from the placebo cohort to the treatment cohort, there may be a risk of inadvertent unblinding of subjects prior to cross-over, which may limit the clinical meaningfulness of those data and may require the conduct of additional clinical trials.

In addition, we may experience delays in initiating or completing clinical trials. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- delays in or failure to obtain institutional review board, or IRB, or national competent authority approvals including positive ethics committee opinions for each site;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- failure to manufacture sufficient quantities of product candidate for use in clinical trials in a timely manner or shipping delays and interruptions;
- safety or tolerability concerns that could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- changes in regulatory requirements, policies and guidelines;

- failure of our third-party research contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- data which we have relied on produced previously by third parties turning out to be different than communicated, resulting in repositioning of the compound and the need for conducting additional trials and analysis;
- delays in establishing the appropriate dosage levels in clinical trials; and
- the quality or stability of the product candidate falling below acceptable standards.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, or by the FDA or other comparable foreign regulatory authorities, or recommended for suspension or termination by the Data Review Committee, or DRC, or Data Safety Monitoring Board, or DSMB, for such trial. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class to which our product candidates belong, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or if we terminate, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. From time to time, we may interact with regulatory agencies with the aim of facilitating the development of our product candidates by achieving alignment on an efficient trial design, a modest number of enrolled patients or a relatively expedient timeline. However, there can be no assurances that such alignment will be reached and, even if achieved, that we will realize the intended benefits from these interactions.

Moreover, if we make changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions, which could delay our clinical development plan or marketing approval for our product candidates. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates.

Any of these occurrences may harm our business, financial condition and results of operations significantly. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or result in the cessation of development of our product candidates.

In addition, the policies of the FDA, the competent authorities of the EU Member States, the EMA, the EC and other comparable regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation).

On January 17, 2022, the MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Our clinical trials may fail to adequately demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our products or present or future product candidates, we must demonstrate through lengthy, complex and expensive clinical trials that our products or product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and there is a high risk of failure and we may never succeed in developing marketable products.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our products or product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product or product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of current or future clinical trials are inconclusive with respect to the efficacy of our products or product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining, or fail to obtain, marketing approval.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, the EC, the EMA or other comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we can successfully submit our product candidates for approval. We cannot guarantee that the FDA, the EC, the EMA, or other comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA, the EC or other comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Some of our clinical trials for our product candidates have been conducted outside the United States, and we may in the future conduct clinical trials for our product candidates, outside the United States, and the FDA, EMA or comparable foreign regulatory authorities may not accept data from such trials.

Some of our clinical trials for our product candidates have been, and we may in the future choose to conduct one or more clinical trials, outside the United States, including in Europe. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA, EC, or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the US population and US medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice, or GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA, the EC, or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA, the EC, or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

The results of early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in a clinical trial may not be indicative of results obtained when these trials are completed or in later-stage trials.

Product candidates in later stages of clinical trials, including those with larger numbers of enrolled patients, may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier preclinical studies and clinical trials, and any such setbacks in our clinical development could have a material adverse effect on our business, financial condition and results of operations.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may be impacted as additional patient data become available and are subject to audit and verification procedures that could result in material changes in the conclusions based on the final analysis of the complete data set.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. For example, in July 2023, we announced interim data from our Phase 2 clinical trial of setanaxib in SCCHN and we expect to report the full data readout in the second quarter of 2024. Conclusions or assumptions based on preliminary and interim data from our clinical trials may change as more patient data become available and further analyses are performed. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes reported may materially change as patient enrollment continues, more patient data become available, and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final outcomes or conclusions being materially different from those based on the preliminary data we previously published. As a result, preliminary, topline and interim data should be viewed with caution until the final analysis of the complete data set is available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Our product candidates, including Nefecon, may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of one of our present or future product candidates or following approval we may need to abandon our development of such product candidate, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.

Undesirable side effects that may be caused by our product candidates, including Nefecon, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EC or other comparable foreign regulatory authorities. Budesonide, the active ingredient in Nefecon, is a corticosteroid, a class of drugs that is associated with high blood pressure, weight gain, diabetes, serious infections and osteoporosis. While budesonide has limited systemic availability due to high first pass metabolism and Nefecon is designed to leverage this inherent characteristic for local, rather than systemic effect, there can be no assurance we will avoid any or all of the side effects that may arise with corticosteroid treatment, whether local or systemic.

Although Nefecon has been generally well tolerated in previous clinical trials, the results from our ongoing or future trials may not replicate these observations. In our Phase 2b clinical trial of Nefecon, there were two drug-related serious adverse events, the first in a patient in the 16 mg treatment cohort who developed a deep venous thrombosis, which was classified by the investigator as possibly being treatment-related, and the second in a patient in the 8 mg treatment cohort who experienced aggravation of renal condition, which was classified by the investigator as possibly being treatment-related. In the placebo cohorts, three patients reported four serious adverse events (two events of proteinuria, sciatica and aggravated condition). Of these, two (proteinuria and aggravated condition) were classified by the investigator as possibly being treatment-related at the time when the safety results were blinded. We also observed adverse events that were generally consistent with those known to be associated with systemic corticosteroids like budesonide and a number of patient discontinuations due to mild to moderate adverse events, most frequently, acne and other transitory cosmetic side effects. In the full NefIgArd trial, we observed adverse events generally consistent with Part A; the most commonly reported TEAEs observed with an increased frequency compared to placebo were oedema peripheral, hypertension, muscle spasms and acne. The majority of TEAEs were of mild or moderate severity, and led to discontinuation of Nefecon in less than 10% of Nefecon-treated patients.

In completed studies of setanaxib (conducted in healthy volunteers or patients), the occurrence rates of TEAEs have been low and similar between setanaxib-treated and placebo-treated subjects. The most commonly reported TEAEs were headaches, upper respiratory tract infections, and common seasonal viral infections. These TEAEs occurred at similar rates in subjects treated with setanaxib in all dose groups and in subjects treated with placebo. The majority of TEAEs observed in subjects receiving setanaxib were mild or moderate in severity and transient. No treatment-related changes were observed in laboratory values, ECG evaluations, or vital signs. There have been no cases of allergy or hypersensitivity reactions.

There have been no fatal or life-threatening suspected unexpected serious adverse reactions (SUSARs) in the setanaxib clinical development program to date. The most commonly reported treatment-related serious adverse events (SAEs) were potential drug-induced liver injury (DILI) and hypothyroidism. It is important to note that these events have been reported from ongoing, blinded studies, so treatment attribution is not known. Hypothyroidism has only been reported in the ongoing study in head and neck cancer, and all five of the hypothyroidism events were considered to be related to pembrolizumab use (which all patients in the study receive). All four events of potential DILI have been reported in the ongoing study in PBC, where there is a potential confounding factor of the underlying disease, which may result in fluctuations in liver enzymes.

The results of any future clinical trials we conduct may show that our product candidates cause undesirable or unacceptable side effects. In such an event, our trials could be suspended, varied, or terminated and the FDA, the competent authorities of individual EU Member States, or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates or require postmarketing labeling changes for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and results of operations significantly.

Additionally, if Nefecon, setanaxib or any of our present or future product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, vary, or withdraw approvals of such product and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

We have and may in the future face challenges in enrollment of patients in our clinical trials given the relatively smaller patient population who have the diseases for which our product candidates are being developed. If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the competent authorities of individual EU Member States or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. There can be no assurance that we will not experience enrollment challenges in future trials, particularly those for indications with relatively small patient populations. In addition, because we are initially focused on developing product candidates for orphan indications, we may encounter similar challenges for patient enrollment if and when we commence clinical programs for additional product candidates in the future.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trial instead enroll in clinical trials of our competitors' product candidates. Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility and exclusion criteria for the trial in question;
- patients' and clinicians' perceived risks and benefits of the product candidate under study;
- competing clinical trials;

- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

Our inability to enroll a sufficient number of patients for our clinical trials may result in significant delays or may require us to abandon such trial altogether. Even though we were able to enroll the planned number of patients in the NefIgArd clinical trial, there can be no assurance that we will successfully enroll the necessary number of patients in the TRANSFORM clinical trial or any additional clinical trials we may conduct. Enrollment into the TRANSFORM clinical trial was significantly slower than initially anticipated potentially due to the requirement for patients to have both elevated liver stiffness and elevated liver enzymes at the baseline assessment. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Changes in methods of product candidate formulation, manufacturing or testing may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as formulation and manufacturing and testing methods, are altered along the way in an effort to optimize processes and results and comply with regulatory requirements or practices. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing or notification to or approval by the FDA, the competent authorities of individual EU Member States, or comparable regulatory authorities. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Product changes may also impact the scope of their intellectual property protection.

Nefecon and setanaxib have been granted orphan drug designation in a number of indications and we may seek orphan drug designation in other indications for future product candidates we develop. We may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Nefecon has been granted orphan drug designation by the FDA, EC and MHRA for the treatment of IgAN and setanaxib has been granted orphan drug designation by the FDA and EC for the treatment of PBC, idiopathic pulmonary fibrosis and Alport syndrome. We may seek orphan drug designations for other indications and future product candidates. There can be no assurances that we will be able to obtain such designations.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the EU, the EC grants orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the EC if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (2) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (3) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure.

Generally in the United States and the EU, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the EC, as applicable, from approving another marketing application for the same drug substance and indication in the United States or a similar drug for the same indication in the EU for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EU. This ten-year period may be extended by two years for medicinal products in relation to which the marketing authorization holder has complied with a related agreed pediatric investigation plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

In the EU, the period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product.

Orphan drug exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve another drug for the same condition if the FDA or comparable foreign regulatory authority concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA or comparable foreign regulatory authority later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In the EU, the period of market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application; (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for other indications for our current and any future product candidates, we may never receive such designations. Further, even with respect to the indications for which we have received orphan designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus, for example, approval of our product candidates could be blocked for seven years if another company previously obtained approval and orphan drug exclusivity in the United States for the same drug and same condition.

The target patient population of Nefecon for the treatment of IgAN is small and has not been definitively determined, and if the number of treatable patients for Nefecon or our present or future product candidates is lower than expected, our potential product sales revenues and our ability to achieve profitability would be compromised.

Our estimates of both the number of patients who have IgAN, as well as the subset of patients with this disease in a position to receive Nefecon, are based on our beliefs and estimates, and these estimates may prove to be incorrect. These estimates have been derived from a variety of sources, including scientific literature, input from physicians that treat patients with the diseases we are targeting, patient foundations and secondary market research databases. For example, our estimates of the prevalence of IgAN in certain geographies are based in part on the published prevalence of IgAN among patient populations in the United States split across ethnicities, and in part on our own analyses of prevalence in Europe, and on published disease incidence rates for certain geographies and estimated for the populations of such geographies. Further, new studies may change the estimated incidence or prevalence of IgAN, and any regulatory approvals that we may receive for Nefecon may include limitations for use or contraindications that decrease the addressable patient population. Accordingly, our target patient populations may turn out to be lower than expected, in which case the potential revenues from sales of Nefecon would be lower than expected.

We were not involved in the early development of setanaxib; therefore, we are dependent on third parties having properly conducted setanaxib's preclinical research, manufacturing control and clinical development.

We had no involvement in or control over the preclinical and clinical development or manufacturing of setanaxib, which we acquired upon completion of our acquisition of Genkyotex S.A. We are dependent on third parties having conducted setanaxib research and development in accordance with legal, regulatory and scientific standards and the applicable protocols; having accurately reported the mode of action and results of all setanaxib preclinical studies and clinical trials; and having correctly collected and interpreted the data from these studies and trials. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of setanaxib products, if pursued, could be adversely affected.

We face significant competition for our drug discovery, development and commercialization efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.

The market for biopharmaceutical products is highly competitive. Our competitors include many established pharmaceutical companies, biotechnology companies, universities and other research or commercial institutions, many of which have substantially greater financial, research and development resources than us. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the development of our product candidates. The fields in which we operate are characterized by rapid technological change and innovation. See "Item 4.B.—Business Overview—Competition."

We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our development and commercialization expenses. If we, our product candidates do not compete effectively, it may have a material adverse effect on our business, financial condition and results of operations.

Relevant regulatory exclusivities may not be granted or, if granted, may be limited.

The US, EU and UK provide opportunities for data and market exclusivity related to marketing authorizations. In the EU and UK, upon receiving a marketing authorization, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU and the UK from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU or UK until 10 years have elapsed from the initial marketing authorization of the reference product in the EU or UK. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU or UK regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the US, market exclusivity can delay the submission or approval of certain marketing applications. The Federal Food, Drug and Cosmetic Act, or FDCA, provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or accept for review an abbreviated new drug application, or ANDA, or a Section 505(b) (2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions of use for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from accepting ANDAs or Section 505(b) (2) NDAs for drugs referencing the approved application for review.

If we fail to develop and commercialize other product candidates in addition to Nefecon, such as setanaxib, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of Nefecon for IgAN is our primary focus, we are currently evaluating setanaxib for the treatment of PBC, Alport syndrome, SCCHN and, through an investigator-led study, idiopathic pulmonary fibrosis. We also intend to evaluate additional potential indications for setanaxib, and we may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from other diseases with significant unmet medical needs and limited treatment options, in particular orphan kidney and liver diseases.

Developing these other product candidates will require additional, time-consuming development efforts prior to commercial sale, including clinical trials and approval by the FDA, the EC and/or comparable foreign regulatory authorities. All present or future product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives. Our current strategy is to in-license or otherwise acquire product candidates for clinical development rather than discovering such candidates ourselves, and therefore our growth objectives are dependent on our ability to enter into in-licensing arrangements or acquisitions. For any such candidates for which we do not intend to conduct preclinical or early-stage clinical research, we may also become reliant on the research efforts of third parties. If we are unsuccessful in identifying and developing additional product candidates, our potential for growth and achieving our strategic objectives may be impaired.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on completing development and continuing our commercialization of Nefecon and developing setanaxib, and we may forego or delay pursuit of opportunities with other product candidates or for other indications for Nefecon or our product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may be unable to successfully integrate new products or businesses we may acquire.

We may in the future expand our product pipeline by pursuing acquisition of new development programs, technology or product candidates. If an acquisition is consummated, the integration of the acquired business, product or other assets into our company may also be complex and time-consuming and, if such businesses, products and assets are not successfully integrated, we may not achieve the anticipated benefits, cost-savings or growth opportunities. Potential difficulties that may be encountered in the integration process include the following:

- integrating personnel, operations and systems, while maintaining focus on developing and commercializing our existing product and product candidates;
- coordinating geographically dispersed organizations;
- distracting employees from operations; and
- managing inefficiencies associated with integrating the operations of the acquired company or product into our own operations.

Furthermore, these acquisitions and other arrangements, even if successfully integrated, may fail to further our business strategy as anticipated, expose us to increased competition or challenges with respect to our products or geographic markets, and expose us to additional liabilities associated with an acquired business, product, technology or other asset or arrangement. Any one of these challenges or risks could impair our ability to realize any benefit from our acquisitions or arrangements after we have expended resources on them.

Even if our approved products or any future product candidate of ours receives regulatory approval, it may fail to achieve the degree of market acceptance among physicians, patients, third-party payors and the medical community necessary for commercial success.

Nefecon, which has received full approval in the US (under the brand name TARPEYO) and which has been granted conditional marketing authorization in the EU and the UK (under the brand name Kinpeygo), is our only approved product to date, but we and our commercialization partners may have other approved products in the future. These products and product candidates, if approved, may not achieve an adequate level of acceptance by physicians, patients, third-party payors and the medical community for commercial success. Despite the studies we have done on the IgAN commercial market opportunity and other pre-commercial activities that we have undertaken, there can be no assurance that we or our commercialization partners will be successful in marketing TARPEYO in the United States, Kinpeygo in the EU or the UK or, if approved, in other jurisdictions. In addition, efforts to educate the medical community and third-party payors on the benefits of Nefecon or other approved products may require significant resources and may not be successful or insufficiently successful to generate significant revenues or becoming profitable. While we believe that the US IgAN market could be adequately covered by a specialized salesforce of approximately 70 field representatives, we may underestimate the number of field representatives that we will actually require. While we believe physicians, patients and other members of the medical community may more readily accept and use Nefecon and our product candidates, if approved, as compared to entirely new chemical entities, Nefecon and our product candidates may nonetheless fail to gain sufficient market acceptance by physicians, patients, other healthcare providers and third-party payors. Market acceptance of our future products by physicians, patients and third-party payors will depend on a number of factors, many of which are beyond our control, including, but not limited to:

- the clinical indications for which our existing or future product candidates are approved;
- physicians, hospitals, treatment centers, and patients considering our existing or future product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the EC or comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, the EC or comparable foreign regulatory authorities;
- the timing of market introduction of our product candidates in relation to other potentially competitive products;
- the cost of our product candidates in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage and adequate reimbursement from third-party payors and government; authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- the relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- the effectiveness of our sales and marketing efforts and distribution support; and
- the presence or perceived risk of potential product liability claims.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits and risks of our products, if approved, may require significant resources and may never be successful.

If our products fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

The successful commercialization of our products and present and future product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage and adequate reimbursement levels, as well as pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid in the US, comparable foreign programs, private health insurers and other third-party payors are essential for most patients to be able to afford Nefecon or any of our future product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for our other products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaboration partners to invest in the development of, our product candidates, if approved. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require patient out-of-pocket costs that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the US, the EU or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available or impose conditions or limitations on reimbursement, limiting the patient population that has access to the drugs. It is possible that a third-party payor may consider our products and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product, and may not be able to obtain a satisfactory financial return on products that we may develop.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the US, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. Some third-party payors may require pre-approval or various pre-authorization steps for coverage for new or innovative drug therapies before they will reimburse health care providers who use such therapies. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are seeking greater upfront discounts, additional rebates and other concessions to reduce the prices for therapeutics. If the price we are able to charge for any therapeutics we develop, the patient population we can successfully address, or the reimbursement provided for such therapeutics, is inadequate in light of our development and other costs, our return on investment could be adversely affected. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products exist among third-party payors in the US. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the US, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, and other jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the US, the reimbursement for our products may be reduced compared with the US and may be insufficient to generate commercially reasonable revenue and profits.

The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU Member States, have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Governments may support small scale pharmacy compounding (preparation of a drug in a pharmacy by a qualified pharmacist for an individual patient) of patented drugs as an alternative for expensive innovative drugs (forming a specific risk for orphan drugs with a small population) and may increasingly consider compulsory licensing of patented drugs to provide alternative options and control pharmaceutical prices. Coupled with EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

Moreover, increasing efforts by governmental and third-party payors in the US, the EU and other jurisdictions to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We may experience pricing pressures in connection with the sale of Nefecon or any of our product candidates that receive approval due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, and government policies and efforts to contain costs could decrease the price we may receive for our approved products.

In addition, patients' access to employer sponsored insurance coverage may be negatively impacted by economic factors that result in increased rates of unemployment. To the extent patients taking our current or future approved products become unemployed and experience a reduction to, or increased costs associated with, their insurance coverage, demand for our products could decline, which could have a material adverse effect on our sales and profitability, either as a result of decreased sales of our products and/or increased provision by us of free product to uninsured or commercially insured patients. The extent and duration of this potential impact on our business is currently unknown.

Recent federal legislation and actions by federal, state and local governments may permit reimportation of drugs from foreign countries into the US, including foreign countries where the drugs are sold at lower prices than in the US, which could materially adversely affect our operating results.

We may face competition in the US for our products and present or future product candidates, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products.

In the US, the Medicare Modernization Act, or MMA, contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to US importation laws will not take effect, unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On September 23, 2020, the Secretary of the US Department of Health and Human Services, or HHS, made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. The FDA also issued additional guidance providing pathways for states to build and submit importation plans for drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. On January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances, but Legislation, or regulation allowing the reimportation of drugs, if enacted, could decrease the price we receive for our products and adversely affect our future revenues and prospects for profitability.

We have only recently begun commercialization of the global Nefecon franchise and we have never previously commercialized a product. We may lack the necessary expertise, personnel and resources to successfully commercialize Nefecon or any other approved products on our own or together with suitable partners.

To achieve commercial success for any approved product, we must successfully develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into partnerships. While we have built a sales and marketing infrastructure to commercialize TARPEYO, we did not previously have a sales and marketing infrastructure and have no prior experience in the sale or marketing of biopharmaceutical products. We have begun to commercialize TARPEYO in the United States independently, and first reported commercial availability of TARPEYO in January 2022.

There are risks involved in establishing our own sales and marketing capabilities. We may fail to continue to launch or market our products effectively, including launching in new jurisdictions in which Nefecon receives approval, because we have limited experience in the sales and marketing of biopharmaceutical products. In addition, recruiting and training a sales force is expensive and time consuming. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to or effectively educate adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- reliance on third-party service providers for our field market access and reimbursement personnel and for the preparation of materials used in sales and market access materials;
- unforeseen costs and expenses associated with recruiting, training, and retaining a sales and marketing organization; and
- costs of marketing and promotion above those anticipated by us.

If we do not maintain sales and marketing capabilities successfully, we may not be successful in commercializing Nefecon and any other products that receive approval, which in turn would have a material adverse effect on our business, financial condition and results of operations.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the US and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell Nefecon and any product candidates for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect our business, financial condition and results of operations.

Among policy makers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the US pharmaceutical industry. The ACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the US Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent US Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services, ("CMS"), Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve the quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. In addition, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage bulk purchasing and importation from other countries, including Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug, which could have an adverse effect on customers for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

On April 26, 2023, the EC adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our products in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status. In addition, many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures In some EU Member States, including those representing the larger markets. The HTA process, which is currently governed by national laws in each EU Member State, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

On December 15, 2021, the Health Technology Regulation, or HTA Regulation, was adopted. The HTA Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. When it enters into application in 2025, the HTA Regulation will be intended to harmonize the clinical benefit assessment of HTA across the EU. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the US or any other jurisdiction. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from Nefecon and other product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

The terms of approvals of our products and present or future product candidates and ongoing regulation of our products may limit how we manufacture and market our products, which could impair our ability to generate revenue.

Once regulatory approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation.

We, and any future collaborators, must comply with requirements concerning advertising and promotion for Nefecon or any of our present or future product candidates, if approved. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product’s approved labeling. Thus, we and any future collaborators will not be able to promote Nefecon or any other products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA or comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other regulatory authorities, to monitor and ensure compliance with cGMPs. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be not in compliance with cGMP regulations, which may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products.

The marketing authorization holder is subject to extensive regulations in relation to the safety monitoring of its marketed products including good vigilance practices, or GVP, and will be subject to monitoring by the FDA, EMA, competent authorities of individual EU Member States, and other comparable foreign regulatory authorities involving inspections of pharmacovigilance systems. Non-compliance with GVP can result in inspection follow-up, actions on the marketing authorization (such as suspensions or restrictions), as well as administrative penalties and civil or criminal liabilities.

Failure to comply with US, EU, and other laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the US or any other jurisdiction.

Accordingly, assuming we, or any future collaborators, receive regulatory approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and any future collaborators, are not able to comply with post-approval regulatory requirements, we, and any future collaborators, could have the regulatory approvals for our products varied, suspended, or withdrawn by regulatory authorities and our, or any future collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Failure to comply with any related obligations may also result in civil and/or criminal penalties. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our current and future product candidates in other jurisdictions.

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, the fact that we have received full approval for TARPEYO in the United States does not guarantee that we or our commercialization partners will receive full approval in other jurisdictions such as in the EU and UK. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the US, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the US, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage; and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. The current and future use of our products or product candidates by us and our collaborators in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our products or product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

Although we believe we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We have expanded our insurance coverage to include our sale of our approved products. However, we may not be able to maintain insurance coverage at a reasonable cost and we may not obtain insurance coverage that will cover claims arising from the activities of our commercial partners or be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Off-label use or misuse of our products may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

We may only promote or market our approved products for their specifically approved indications. TARPEYO received full approval by the FDA to reduce the loss of kidney function in adults with primary IgAN. Kinpeygo currently has conditional approval by the EC and the MHRA only for the treatment of primary (IgAN in adults at risk of rapid disease progression with a UPCR ≥1.5 gram/gram. In China, Macao and Singapore, Nefecon (under the name NEFEGAN in Singapore) has conditional approval for the treatment of primary IgAN in adults at risk of rapid disease progression, generally with a UPCR ≥1.5 gram/gram. We have trained and will continue to train our marketing and sales force against promoting TARPEYO, or any product candidate approved in the future for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA, the EC or comparable foreign regulatory authorities may not effectively treat such conditions, and may increase the adverse events when compared to use for its approved indication. Any such off-label use could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur operating losses for the near future.

We are a commercial-stage pharmaceutical company with a limited operating history and only one recently approved product. Since our inception, we have incurred significant operating losses. We incurred total comprehensive losses of SEK 483.8 million and SEK 373.2 million for the years ended December 31, 2023 and December 31, 2022, respectively. As of December 31, 2023, we had an accumulated loss of SEK 2,305.6 million. Our losses resulted principally from costs incurred in clinical development of Nefecon and setanaxib, cost for sales and marketing activities in the US and from administrative costs associated with our operations. Any operating losses we incur, among other things, will cause our working capital and shareholders' equity to decrease. We anticipate that our expenses will increase if and as we:

- continue to develop and advance Nefecon, setanaxib and any other product candidates;
- initiate and continue clinical development for Nefecon and setanaxib for PBC, head and neck cancer, Alport syndrome and other potential indications;
- support our partners in pursuing regulatory approval for Nefecon in various jurisdictions;
- seek regulatory approval for setanaxib and any other present and future product candidates that successfully complete clinical trials;
- continue to build a sales, marketing and distribution infrastructure and scale-up external manufacturing to commercialize Nefecon and any other present or future product candidates that receive approval;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement or invalidity claims and enforcing patents against third parties;
- continue to add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts;
- seek to expand development pipeline, including through potential in-licensing opportunities and strategic acquisitions;
- expand our operations in the United States and Europe; and

- experience any delays or encounter any issues with regards to any of the above, including, but not limited to, failed studies, ambiguous trial results, safety issues or other regulatory challenges, including any unforeseen costs we may incur as a result of clinical trial or supply chain delays or other business interruptions due to health pandemics, geopolitical tensions or other world events.

To date, we have funded our operations through public and private placements of equity securities, proceeds from credit facilities, upfront and milestone payments and interest income from the investment of our cash and financial assets. We have also begun to fund our operations with the proceeds from sales of TARPEYO in the United States and royalties from the sales by our commercialization partners in the EU and China.

To become and remain profitable, we must succeed in developing and commercializing products and product candidates that generate significant revenue. This will require that we and our commercialization partners be successful in a range of challenging activities, including in-licensing and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, including full regulatory approval for Kinpeygo in the EU and UK and for Nefecon in various jurisdictions, establishing marketing capabilities and ultimately selling any products which are approved. We are only in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve or maintain profitability. We anticipate incurring significant costs associated with commercializing our approved products. Our expenses could increase beyond our current expectations if we are required by the FDA, the EMA or comparable foreign regulatory authorities to perform clinical trials or studies in addition to those that we currently anticipate, including as a result of any post-approval commitments or trial requirements. Even though we have begun to generate revenue from the sale of approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common shares and American Depositary Shares ("ADSs") and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our common shares or ADSs could also cause you to lose all or part of your investment.

We may need substantial additional funding in order to fund our operations. Failure to obtain this necessary capital at acceptable terms and when needed may force us to delay, limit or terminate certain or all of our operations and pursuit of our growth strategy.

Our operations have consumed substantial amounts of cash since inception. Unless and until we are able to successfully commercialize Nefecon and achieve significant revenue from sales, we will require substantial additional funding in the future to sufficiently finance our operations and advance the clinical development, seek regulatory approval for and potentially commercialize our approved products or product candidates, or potentially acquire or in-license additional product candidates.

As of December 31, 2023, we had SEK 973.7 million in cash. Based on our current operating plan, we expect that our existing cash will be sufficient to fund our planned operations and capital expenditure requirements until we become profitable, subject to continued revenue growth of the Nefecon franchise. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect and we may not achieve profitability on the timeline we expect or ever. Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of clinical trials for Nefecon, setanaxib and future product candidates;
- the number of potential new product candidates and indications we identify and decide to develop, if any;
- the time and costs involved in obtaining regulatory approval for Nefecon and any of our product candidates that successfully complete clinical development, and any delays we may encounter as a result of evolving regulatory requirements or adverse clinical trial results with respect to any of our product candidates;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the costs involved in growing our organization to the size needed to allow for the development and commercialization of Nefecon and any future approved products;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending against any invalidity or infringement claims raised by third parties;
- the costs related to our obligations under our existing collaboration and licensing agreements and the entry into new collaboration and licensing agreements;
- the cost and timing of future pre-commercialization activities and, with respect to any products that receive regulatory approval, post-commercialization activities, and costs involved in maintaining and, if necessary, expanding an effective sales and marketing organization;
- the revenue we receive either directly from commercial sales or in the form of royalty, upfront or milestone payments from future sales of Nefecon or future product candidates, if approved;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the effects of competing technological and market developments; and
- the costs of operating as a public company in both the United States and Sweden.

Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from pandemics, global armed conflicts, financial market disruption or other factors could also adversely impact our ability to access capital as necessary. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or some of our product candidates or research programs or we may be unable to take advantage of future business opportunities.

Raising additional capital may cause dilution to holders of our common shares or ADSs, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Other than our term loan facility (the "Credit Agreement") with Athyrium Capital Management, LP ("Athyrium"), we do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional external funding will be available on acceptable terms, or at all. Until we can generate substantial product revenues from sales of Nefecon or other approved products, if any, we expect to finance our operations predominantly through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements.

Under the Credit Agreement, Athyrium made available to us 92 million Euros, which we fully drew down. We used part of the proceeds from the Credit Agreement to repay in full outstanding obligations under our loan agreement with Kreos Capital VI (UK) Limited and Kreos Capital 2020 Opportunity (UK) Limited. The Credit Agreement contains financial covenants to maintain minimum unrestricted cash (including cash equivalents) and achieve minimum net revenue targets with respect to Nefecon. The Credit Agreement contains affirmative and negative covenants customary for a senior secured loan. The negative covenants under the Credit Agreement limit the ability of us and our subsidiaries to, among other things, dispose of assets, engage in certain mergers, acquisitions, and similar transactions, incur additional indebtedness, grant liens, make investments, pay dividends or make distributions or certain other restricted payments in respect of equity, prepay other indebtedness, enter into restrictive agreements, undertake fundamental changes or amend certain material contracts, in each case subject to certain exceptions. The Credit Agreement also contains certain customary events of default, including, but not limited to, a failure to comply with the covenants in the Credit Agreement. If an event of default has occurred and continues beyond any applicable cure period, the administrative agent or the required lenders may accelerate all outstanding obligations under the Credit Agreement and/or exercise any other remedies provided under the loan documents. See Item 5.B., Liquidity and Capital Resources, for more details on the Credit Agreement.

If we undertake additional financing arrangements in the future, the terms of any such financing may adversely affect the holdings or the rights of holders of our common shares or ADSs and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common shares or ADSs to decline. The sale of additional equity or convertible securities would dilute all of our existing shareholders and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ADSs. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, financial condition and results of operations. Further, any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize Nefecon and our product candidates.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our development programs or the commercialization of Nefecon or any of our product candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We have a limited operating history as a commercial company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We began operations in 2004. Prior to our commercialization of TARPEYO, with commercial availability which began in January 2022, we had not obtained marketing approvals for any product candidates, manufactured products on a commercial scale, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing products. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate activity or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable.

Given our limited operating history as a commercial company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors in achieving our business objectives. Our financial condition and operating results may continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We have transitioned from a company with solely a research and development focus to a company also capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations, or CROs, to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon, and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our clinical trials and to monitor and manage data for our clinical programs. We rely on these parties for execution of our clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EC, the EMA, or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard or not in conformity with our clinical trial protocols or GCP regulations, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

Although we are not currently conducting any clinical trials in Ukraine, the Russia-Ukraine military conflict could cause disruption in the region which could affect our CRO’s operations, which in turn could impact our own clinical trials.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative CROs or investigators or to do so on commercially reasonable terms. If CROs or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they cannot perform their contractual duties or obligations due to the impacts of the geopolitical tensions on their operations or at the sites they are overseeing, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs or investigators involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or a comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA or a comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidates or any future product candidates.

We are dependent on third parties to manufacture and distribute our products.

We have no manufacturing capabilities and rely on third-party manufacturers who are sole source suppliers for manufacturing of Nefecon. If our third-party manufacturers are unable to meet our demand, our ability to commercialize our products will be adversely impacted and could affect our ability to gain market acceptance for our products and negatively impact our revenues. Our dependence on third parties for the manufacture of our products may harm our profit margin on the sale of Nefecon and our ability to deliver Nefecon on a timely and competitive basis. Because we are ultimately responsible for ensuring supply of Nefecon to the market, it is critical that we maintain effective management practices and oversight with respect to our third-party manufacturers, including supply chain management.

We currently have no in-house distribution channels for Nefecon and we are dependent on third-party distributors to distribute such products. The outsourcing of our distribution function is complex, and we may experience difficulties that could reduce, delay or stop shipments of such products. If we encounter such distribution problems, and we are unable to quickly enter into a similar agreement with another distributor on substantially similar terms, distribution of Nefecon could become disrupted, resulting in lost revenues, provider dissatisfaction, and/or patient dissatisfaction.

Use of third parties to manufacture our products and product candidates may increase the risk that we will not have sufficient quantities of our product and product candidates or such quantities at an acceptable cost, and clinical development and commercialization of our product and product candidates could be delayed, prevented or impaired.

We do not own or operate manufacturing facilities for clinical or commercial production of our products or product candidates. We have limited personnel with experience in drug manufacturing and we lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We outsource all manufacturing and packaging of our nonclinical, clinical, and commercial products to third parties. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production and in maintaining required quality control. These problems include difficulties with production costs and yields and quality control, including stability of the product candidate.

We intend to rely on third-party manufacturers for the long-term commercial supply of Nefecon and for our development stage product candidates. We have a single CMO for each of Nefecon and setanaxib. We face risks inherent in relying on a single CMO, as any disruption, such as a fire, natural hazards, pandemic, epidemic, or outbreak of an infectious disease or vandalism at the CMO could significantly interrupt our manufacturing capability. We currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as we build or locate replacement facilities and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. Also, operating any new facilities may be more expensive than operating our current facility. Further, business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of the manufacturing facility could have drastic consequences, including placing our financial stability at risk.

Reliance on third-party manufacturers entails risks to which we may not be subject if we manufactured our product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;

- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- less control over cost increases resulting from inflationary pressures affecting raw materials and other supply chain components;
- impact on our reputation in the marketplace if manufacturers of our products fail to meet the demands of our customers;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

The failure of any of our contract manufacturers to maintain high manufacturing standards could result in injury or death of clinical trial participants or patients using our products. Such failure could also result in product liability claims, product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability.

Our contract manufacturers are required to adhere to FDA regulations setting forth cGMP and comparable foreign regulatory authority requirements. These regulations cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our product candidates and any products that we may commercialize. Our manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our manufacturers are subject to unannounced inspections by the FDA, state regulators and similar regulators outside the United States to monitor and ensure compliance with cGMP. We are ultimately responsible for ensuring that our API and finished products are manufactured in accordance with cGMP regulations and similar regulatory requirements outside the United States, and it is therefore critical that we maintain effective management practices and oversight with respect to our third-party manufacturers, including routine auditing. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our product candidates.

Our product and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. A health epidemic or pandemic and associated vaccine or treatment development and manufacturing efforts may increase demand for the services supplied by many third-party manufacturers, including some of those that we utilize for our products and product candidates, which may result in decreased availability of manufacturing slots at many such facilities. If the third parties that we engage to manufacture products for our developmental or commercial products should halt or cease to continue to do so for any reason, we likely would experience interruptions in cash flows and/or delays in advancing our clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. Later relocation to another manufacturer will also require notification, review and other regulatory approvals from the FDA and other regulators and will subject our production to further cost and instability in the availability of our product candidates. In addition, if we are not able to obtain adequate supplies of our products and product candidates, or the drug substances used to manufacture them, it will be more difficult for us to sell our products and to develop our product candidates. This could greatly reduce our competitiveness and negatively affect our results of operations.

Our current and anticipated future dependence upon others for the manufacture of our products and product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize our marketed products and any other products that may obtain regulatory approval on a timely and competitive basis.

Materials necessary to manufacture our products and product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our products and product candidates.

We rely on the manufacturers of our products and product candidates to purchase from third-party suppliers the materials necessary to produce the compounds for our nonclinical and clinical studies and rely on these other manufacturers for commercial distribution if we obtain marketing approval for any of our product candidates. Suppliers may not sell these materials to our manufacturers at the time we need them or on commercially reasonable terms and all such prices are susceptible to fluctuations in price and availability due to transportation costs, government regulations, price controls, and changes in economic climate or other foreseen circumstances. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. In addition, inflation and global supply chain disruptions, as well as past disruptions related to COVID-19 and potential future disruptions related to a future health epidemic or pandemic, wars, armed conflicts, and global geopolitical tension, including between the U.S. and China, have had and may continue to have a negative impact on our manufacturers' ability to acquire the materials necessary for our business. Moreover, we currently do not have any agreements for the commercial production of these materials. If our manufacturers are unable to obtain these materials for our nonclinical and clinical studies, product testing and potential regulatory approval of our product candidates would be delayed, significantly impacting our ability to develop our product candidates. If our manufacturers or we are unable to purchase these materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would materially affect our ability to generate revenues from the sale of our product candidates.

We have entered into agreements with third parties to develop and commercialize Nefecon in jurisdictions outside the United States, if approved in such jurisdictions, and we plan to enter into additional agreements in the future with respect to any of our present or future product candidates that receive approval. If we are unable to establish and maintain such collaborations, we may not be successful in our commercialization efforts. If our commercialization partners do not to satisfy their obligations or are unsuccessful, we could be adversely affected.

We have arrangements with third parties to commercialize our products in territories outside of the US and may enter into additional agreements in the future. As a result, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell the products that we develop ourselves. Such collaborative arrangements may result in the commercialization of our products being out of our control and would subject us to a number of risks including that we may not be able to control such as the amount or timing of resources that our commercialization partner devotes to our products and that our partner's willingness or ability to optimally commercialize our products may be adversely affected by business combinations or significant changes in our collaborator's business strategy. In addition, we may not be successful in entering into arrangements with additional third parties to sell and market our products or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to sell and market our products effectively.

Outside of the US, we intend to commercialize Nefecon through either regional partnerships or on a country-by-country basis. In Europe, we have entered into a commercialization agreement with STADA to commercialize Nefecon (approved under the name Kinpeygo) in the EU and the UK. STADA will also commercialize Nefecon in Switzerland, if approved in that jurisdiction. We have transferred the conditional marketing authorizations received from the EC and the MHRA to STADA. STADA has submitted requests to both the EMA and to the MHRA to convert the current conditional marketing authorizations for these territories into full marketing authorizations. In 2019, we granted a license to Everest, to develop and commercialize Nefecon for the treatment of IgAN and other potential indications in Greater China and Singapore and in March 2022, we expanded the territory covered by the agreement to include the Republic of Korea. We have also entered into a commercialization agreement with Viatris Pharmaceuticals Japan Inc., a subsidiary of Viatris Inc., or Viatris, to commercialize Nefecon for the treatment of IgAN in Japan.

Our existing collaborations and any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, including, for example, that the collaborators may not: adequately perform their obligations under the collaboration agreement; devote sufficient resources to the collaboration to ensure success; or agree with us on the strategy or tactical aspects of the collaboration.

To the extent that we depend on collaborators for sales and marketing activities, any revenues we receive will depend upon the success of those collaborators' sales and marketing teams and the collaborators' prioritization of our product and compliance with applicable regulatory requirements, and there can be no assurance that the collaborators' efforts will be successful or that their compliance systems will be effective. If any existing or future collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, the development of our product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to our product development, regulatory activities and commercialization apply to the activities of our existing and future collaborators.

If we are unable to enter into a collaboration for the commercialization of product candidates we develop, if approved, we may be forced to delay the commercialization of our product candidates or reduce the scope of our sales or marketing activities in such jurisdictions, which would have an adverse effect on our business, operating results and prospects.

In foreign countries, the pricing of drugs is generally subject to governmental control and other market regulations which could put pressure on the pricing and usage of our products and present or future product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our products and product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures. We will be dependent on the abilities and efforts of our commercialization partners to obtain optimal pricing and reimbursement status for our products and product candidates and, should our commercialization partners fail to do so, the amounts paid to us by commercialization partners and the value of our products could be adversely impacted.

Jurisdictions outside of the United States generally also have laws, regulations, or industry or professional codes of conduct concerning the provision of benefits or advantages to health care providers to prevent inducement or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products, anti-bribery laws, laws requiring the disclosure of benefits provided to healthcare professionals, healthcare organizations or patient organizations, or laws requiring prior notification and approval by the a health care provider's employer, his or her competent professional organization and/or regulatory authorities. Should our commercialization partners fail to comply with these requirements, they could be subject to reputational risk, public reprimands, administrative penalties, fines or imprisonment, and the amounts paid to us by our commercialization partners and the value of products could be adversely impacted.

If our third-party providers, including our CMOs and CROs, fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

Our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of hazardous materials and wastes. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations.

Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Risks Related to Intellectual Property

We rely on patents and other intellectual property rights to protect Nefecon, setanaxib and our other product candidates, the enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for Nefecon, setanaxib and our other present and future product candidates, methods used to manufacture those products and the methods for treating patients using those products, or on licensing in such rights. Patent law relating to the scope of claims in the fields in which we operate is complex and uncertain, and we cannot make any assurances that we will be able to obtain or maintain patent or other intellectual property rights, or that the patent and other intellectual property rights we may obtain will be valuable, provide an effective barrier to competitors or otherwise provide competitive advantages. For example, although we co-own a single patent family relating to the formulation of Nefecon, which expires in 2029, such rights may not provide adequate protection against competitors. In January 2024, the United States Patent and Trademark Office, or USPTO, issued a new patent to us relating to the method of treating IgA nephropathy which expires in 2043; such rights may not provide adequate protection against competitors. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and product candidates. Patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology at issue. We cannot be certain that patents will be issued or granted with respect to future patent applications, or that issued or granted patents will not later be found to be invalid or unenforceable, or that they will provide effective commercial protection to our products. The patent position of pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations.

The standards applied by the USPTO, the European Patent Office or EPO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from future patent applications and the claim scope achieved may vary across territories.

The patent prosecution process is expensive and time-consuming, and we and our future licensors, licensees or collaboration partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future licensors, licensees or collaboration partners will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaboration partners' patent rights are highly uncertain. Our future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaboration partners. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaboration partners fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaboration partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. The patent examination process may require us or our licensors, licensees or collaboration partners to narrow the scope of the claims of our or our licensors', licensees' or collaboration partners' future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application.

Even if patents do successfully issue, third parties may initiate an opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. For example, opposition proceedings at the EPO are increasingly common, and are costly and time consuming to defend. Furthermore, it is possible that we will need to defend other patents outside the EPO from challenges by others from time to time. It is possible that one or more of our US patents may be challenged by parties who file a request for post-grant review or inter partes review or ex parte reexamination.

Our patent rights may not be sufficient to provide us with a proprietary position in or competitive advantages in respect of our products or product candidates. We have been, and may in the future become, involved in post-grant proceedings in the US which are increasingly common and are costly to defend or prosecute. We may seek to modify or supplement relevant patent claims through reissuance proceedings, for example to submit prior art references not submitted during the prosecution of the US patent or to pursue additional claims within the scope of the originally issued claims but more tailored to our products or product candidates, in the course of which their patentability would be re-assessed, the legal scope of our patent protection may be limited or our application for a reissued patent may be refused. There can be no assurance that any or all of the originally issued claims will be reissued or that any or all of the additional claims that may be included in a petition will be granted in any such proceeding. In addition, we will be unable to enforce any such U.S. patent unless and until it is reissued. There can be no assurance that any such reissued US patent will not be challenged, invalidated or circumvented. Furthermore, even if the outcome of any reissuance proceeding is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

Issued patents covering Nefecon, setanaxib or our present or future product candidates could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of our or our licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors' or collaboration partners' efforts, we or our licensors or collaboration partners may not have sufficient resources or ability to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States and Europe. We may fail in enforcing our rights, in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our product candidates, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party who we considered to be infringing a patent covering one of our products, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. A claim for unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or the EPO or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Such a loss of patent protection could have a material adverse impact on our business. Further, litigation could result in substantial costs and diversion of management resources, regardless of the outcome, and this could harm our business and financial results. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell Nefecon, setanaxib and our present or future product candidates without being sued for infringement of the intellectual property and other proprietary rights of third parties. However, our development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Third parties may have US and non-US issued patents and pending patent applications relating to compounds, methods of manufacturing compounds and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product and products candidates, including patent infringement lawsuits in Europe, United States or abroad, as well as interference, derivation, inter partes review, and post-grant proceedings before the USPTO and opposition or other proceedings before the EPO and other foreign patent offices. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our products and product candidates. We cannot guarantee that any of our patent searches or analyses including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States, Europe and other jurisdictions that is relevant to or necessary for the commercialization of our products and product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products and product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources, and we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product. If we were required to obtain a license to continue to manufacture or market the affected product, we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, be certain that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Furthermore, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively, or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Our former, present and future employees may have had prior employment at universities or at other biotechnology or pharmaceutical companies. Some of these employees may have executed proprietary rights, non-disclosure, non-competition or other similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed third-party intellectual property, including trade secrets or other proprietary information. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may sustain damages or lose key personnel, valuable intellectual property rights or the personnel's work product, which could hamper or prevent commercialization of our technology, which could materially affect our commercial development efforts. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We may become involved in lawsuits to protect or enforce our patent or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patent, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patent could limit our ability to assert those patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the trademarks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Additionally, for certain of our existing and future in-licensed patent rights, we may not have the right to bring suit for infringement and may have to rely on third parties to enforce these rights for us. If we cannot or choose not to take action against those we believe infringe our intellectual property rights, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

Our ability to compete may be adversely affected if we are unsuccessful in defending against any claims by competitors or others that we are infringing upon their intellectual property rights.

The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, biopharmaceutical companies have employed intellectual property litigation as a means to gain an advantage over their competitors. As a result, we may be required to defend against claims of intellectual property infringement that may be asserted by our competitors against us and, if the outcome of any such litigation is adverse to us, it may affect our ability to compete effectively.

Our involvement in litigation, and in any interference, derivation, reexamination, inter partes review opposition or post-grant proceedings or other intellectual property proceedings inside and outside of the United States or Europe may divert management time from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, incorporating, manufacturing, or using our products in the US, Europe or other jurisdictions that use the subject intellectual property;

- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;

- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or

- pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, we could have a substantial adverse effect on our share price. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We license intellectual property from third parties for Nefecon and may do so for certain of our present or future product candidates, and termination of any of these licenses could result in the loss of significant rights, which would substantially harm our business.

We have in-license rights with respect to a formulation patent for Nefecon and we may in-license additional intellectual property rights with respect to our present or future product candidates. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to our ability to develop and commercialize any product or product candidate subject to such licenses.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;

- our right to sublicense patent and other rights to third parties under collaborative development relationships;

- our diligence obligations with respect to the use of licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations; and

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we own, as we are for intellectual property that we license, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could materially suffer.

We may not be successful in obtaining or maintaining necessary rights to our products or present or future product candidates through acquisitions and in-licenses.

Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire or in-license such proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product or product candidate or program and our business and financial condition could suffer.

If our trademarks and various brand elements are not adequately protected, then our business may be adversely affected in our markets of interest.

Our registered and unregistered trademarks, trade dress, get-up and trade names (collectively, brand elements) may be challenged, infringed, invalidated, declared generic or determined to be infringing on other registered or unregistered trademarks, unless adequate steps are taken to clear them before use, register them and then enforce them. It is vital that we are able to build brand recognition in these brand elements, to maximize the value to potential partners or customers in our markets of interest. Over the long term, if we are unable to establish brand recognition based on our various brand elements, then we may not be able to compete effectively, or indeed at all, and our business may be adversely affected.

If other entities use trademarks similar or identical to ours in different jurisdictions, or have senior rights to ours, we could be prevented from using our brand elements in certain jurisdictions, which may of course interfere with our use of our current trademarks throughout the world.

We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain jurisdictions, which may diminish the value of intellectual property rights in those jurisdictions.

We often file our first patent application (i.e., priority filing) with the USPTO, the EPO, or more typically, in the national office of a European country (e.g., in the UK or Sweden). International applications under the Patent Cooperation Treaty, or PCT, are filed within twelve months after the priority filing, with equivalent applications being filed simultaneously in territories not bound by the PCT, if any such territories are of sufficient commercial interest. From the PCT filing, we have the option to file national and regional patent applications in any of the 155 jurisdictions party to the PCT where we believe protection of our product candidates may be commercially valuable. We have filed for patent protection in territories that are of current commercial interest to us and have achieved grant in at least some of these territories. However, our commercial interests may extend beyond these territories meaning we may enter into markets in the future where we do not have patent protection or pending patent applications. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or product candidate or technology.

Competitors may use our and our licensors' or collaboration partners' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors or collaboration partners have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products or product candidates, and our and our licensors' or collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and Europe, and companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

Proceedings to enforce our and our licensors' or collaboration partners' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaboration partners' efforts and attention from other aspects of our business, could put our and our licensors' or collaboration partners' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaboration partners' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaboration partners. We or our licensors or collaboration partners may not prevail in any lawsuits that we or our licensors or collaboration partners initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make product candidates that are similar, but not identical, to our products or product candidates with workarounds such that the product is not covered by the claims of the patents that we own or have licensed;
- the claims of our patents may not adequately cover our product, meaning others may be able to manufacture the same product and not infringe the claims of the patents that we own or have licensed;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain aspects of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license; and
- we may not develop additional technologies that are patentable.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, has been enacted in the United States, resulting in significant changes to the US patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our US patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in US federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, the US Supreme Court and the Court of Appeals for the Federal Circuit have ruled on patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the US Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets, confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and confidential know-how are difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors, and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Failure to obtain or maintain trade secrets or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets or confidential know-how.

Under certain circumstances, we may also decide to publish some know-how to attempt to prevent others from obtaining patent rights covering such know-how.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, the EPO and national patent offices in several stages over the lifetime of the patent. The USPTO, the EPO and various foreign governmental patent offices require compliance with a number of procedural, documentaries, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or collaboration partners fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Risks Related to Our Employee Matters, Managing Our Growth and Other Risks Relating to Our Operations

Our business and operations may be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events or other macroeconomic conditions, which could negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability. The US Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly or more dilutive or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Our available cash and cash equivalents are held in accounts managed by third party financial institutions in the United States and in Europe and consist of cash in our operating accounts. At any point in time, the funds in our operating accounts at US financial institutions may exceed the Federal Deposit Insurance Corporation insurance limits. While we monitor the cash balances in our operating accounts and adjust the cash balances as appropriate, these cash balances could be impacted if the underlying financial institutions fail. We can provide no assurances that access to our operating cash or invested cash and cash equivalents will not be impacted by adverse conditions in the financial markets.

Terrorist attacks and international hostilities and instability in any region could adversely affect our business.

Terrorist attacks, the outbreak of war, or the existence of international hostilities could damage the world economy, adversely affect the global supply chain and adversely affect both our ability to sell our products to certain regions or purchase supplies from such regions. In particular, the warfare and political turmoil in Ukraine could adversely impact our financial condition, result of operations and cash flows. In February 2022, Russian troops invaded Ukraine. Although the severity and duration of the ongoing military action are highly unpredictable, the Russia-Ukraine military conflict could materially disrupt our operations in Europe and/or increase their costs. In addition, Russia's prior annexation of Crimea, recent recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine and subsequent military interventions in Ukraine have led to sanctions being levied by the United States and other countries against Russia, Belarus and the two separatist republics in the Donetsk and Luhansk regions, with additional potential sanctions threatened and/or proposed. Russia's military incursion and the resulting sanctions could adversely affect the global economy and financial markets and thus could affect our business, operations, operating results and financial condition as well as, potentially, the price of our common shares and ADSs.

We also work with a global network of collaborators, suppliers, CROs and commercial partners, any of which may be directly or indirectly negatively impacted by the war in Ukraine and unrest in the region. Such negative impacts could indirectly affect our own business and operations. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions caused by Russian military action or resulting sanctions may magnify the impact of other risks described in this annual report.

Our business depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific and technical personnel, who have been instrumental for us and have substantial experience with Nefecon and our other product candidates. The loss of key managers and senior scientists could delay our development activities, and we do not carry key person insurance. In addition, our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified management, scientific and medical personnel. Many other biotechnology and pharmaceutical companies and academic institutions that we compete with for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Therefore, we might not be able to attract new qualified personnel or retain our key persons on conditions that are economically acceptable. Furthermore, we will need to recruit new managers and qualified scientific personnel to develop our business if we expand into fields that will require additional skills. Our inability to attract qualified personnel and retain our key persons could prevent us from achieving our objectives and implementing our business strategy, which could have a material adverse effect on our business and prospects. Given the stage of our programs and our plans to expand operations, our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior personnel across our organization.

We expect to continue to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company incorporated and based in Sweden, our business is subject to risks associated with conducting business in Sweden, the US and internationally. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-US economies and markets;
- developments in the ongoing Russia-Ukraine military conflict;
- differing regulatory requirements for product candidate approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-US regulations and customs, tariffs and trade barriers;

- changes in non-US currency exchange rates of the Swedish Krona, US dollar, Swiss franc and Euro and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain international markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad, including, for example, the variable tax treatment in different jurisdictions of stock options granted under our employee stock plan or equity incentive plan;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- an outbreak of a contagious disease, such as coronavirus, which may cause us or our distributors, third party vendors and manufacturers and/or customers to temporarily suspend our or their respective operations in the affected city or country;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

The UK's withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common shares.

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator for medicinal products and medical devices. Great Britain (England, Scotland and Wales) is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules for now.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland currently remains within the scope of EU authorizations in relation to centrally authorized medicinal products. Accordingly, until the Windsor Framework is implemented in Northern Ireland on January 1, 2025, products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may also rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in Great Britain, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in Great Britain.

Since a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU Directives and Regulations, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU, now that UK legislation has the potential to diverge from EU legislation. It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any marketing approvals for our product candidates, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are affected by fluctuations in the exchange rates of several currencies, particularly the Swedish Krona, the US dollar, the Swiss franc and the Euro. The functional currency of Calliditas Therapeutics AB and our consolidated subsidiaries is the Swedish Krona and a significant portion of our operating expenses are paid in US dollars, Swedish Krona and Swiss francs. The operating currency of our French and Swiss subsidiaries are the Euro and the Swiss franc, respectively.

Additionally, although we are based primarily in Sweden, we may receive payments from our business partners in US dollars and Euros, and we regularly acquire services, consumables and materials in US dollars and Euros. Further, potential future revenue may be derived from the United States, countries within the Euro zone and various other countries around the world. These future revenues may also be affected by fluctuations in foreign exchange rates which may, in turn, have a significant impact on our results of operations and cash flows from period to period. As a result, to the extent we continue our expansion on a global basis, we expect that increasing portions of our revenue, cost of revenue, assets and liabilities will be affected by fluctuations in currency valuations. We may, therefore, experience economic loss and a negative impact on earnings or net assets solely as a result of currency exchange rate fluctuations.

If our information technology systems, or those of third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, loss of customers or sales, and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information).

Cyberattacks, malicious internet-based activity, and online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. For example, we have operations and third parties upon which we rely to support our business located in unstable regions and regions experiencing (or expected to experience) geopolitical or other conflicts.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, and telecommunications failures, attacks enhanced or facilitated by AI, and other similar threats.

In particular, severe ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Our partially remote workforce poses increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, quality assurance, medical affairs and pharmaceutical promotion compliance tools and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of the third parties upon whom we rely) to provide our products. interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also have a material adverse effect on our business. To the extent that any security incident or interruption were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We are subject to stringent and evolving US and foreign laws, regulations, rules, contractual obligations, industry standards, and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation (including class claims) and mass arbitration demands, fines and penalties, a disruption of our business operation, reputational harm, loss of revenue or profits, loss of customers or sales and other adverse business consequences.

In the ordinary course of our business, we process personal data and other sensitive information Our data processing activities subject us, and any potential collaborators, numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws and regulations, including health information privacy laws, data breach notification laws, personal data privacy laws, and consumer protection laws, including Section 5 of the Federal Trade Commission Act could apply to our operations or the operations of our collaborators. For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH. To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of protected health information, mandates the adoption of standards relating to the privacy and security of protected health information, and requires the reporting of certain security breaches to healthcare provider customers with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we violate HIPAA.

In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 or CPRA, (collectively, "CCPA") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely, and our customers.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the EU's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law or PIPL impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions, fines of up to €20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of a company's global annual revenues, whichever is greater, or private litigation related to processing of personal data brought by classes of data subjects, or consumer protection organizations authorized at law to represent their interests. There has been limited enforcement of the GDPR to date, particularly in pharmaceutical development, so we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdiction have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area or EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we may face significant adverse consequences, including limiting our ability to conduct clinical trial activities in Europe and elsewhere, limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws, the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial penalties and fines, the inability to transfer data and work with partners, vendors, and other third parties, and injunctions against processing or transferring personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to or other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Compliance with US and international data privacy and security obligations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal data, as well as the providers who share this data with us, may limit our ability to collect, use and disclose the data. Claims that we have violated individuals' privacy rights, failed to comply with data privacy and security laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations.

If we or our third-party processors on which we rely fail, or are perceived to have failed. to address or to comply with applicable data privacy and security obligations, we could face significant consequences, including but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

As a European public company with a registered office in Sweden, we will likely be subject to the sustainability disclosure requirements set out in the EU Corporate Sustainability Reporting Directive.

A growing number of investors, regulators, self-regulatory organizations and other stakeholders have expressed an interest in Environmental, Social and Corporate Governance ("ESG") matters, and are requiring more robust ESG disclosures. The related legislative landscape in the EU has been evolving accordingly. For example, EU Directive No 2464/2022 on Corporate Sustainability Reporting ("CSRD") was adopted and entered into force on January 5, 2023, amending the current EU Accounting Directive No 2013/34. The CSRD introduces new mandatory reporting obligations that will require the publication of audited sustainability information. The CSRD is supplemented by EU Delegated Regulation No 2023/2772 which establishes the first set of European Sustainability Reporting Standards ("ESRS"), which are applicable to in-scope EU entities. Further reporting standards are due to be adopted by June 2026, including for in-scope non-EU entities.

The CSRD and ESRS require certain mandatory disclosures, as well as disclosures of certain "material" sustainability matters in the company's own operations, those of their subsidiaries and those of their value chain. The identification of material sustainability matters requires a "double materiality" assessment. This means that in-scope entities will have to assess both financial materiality (i.e., sustainability matters which generate risks or opportunities that affect, or could reasonably be expected to affect, the company's financial position, financial performance, cash flows, access to finance or cost of capital over the short, medium or long term) and impact materiality (i.e., the company's material actual or potential, positive or negative impacts on people or the environment over the short-, medium- and long-term.). Sustainability matters are material if they satisfy one or both of these materiality tests.

The CSRD applies to entities with securities admitted to trading on an EU regulated market, as well as large EU companies, EU parents of a "large group", and to listed EU small or medium-sized enterprises, amongst others. It will also apply to non-EU companies that have a certain threshold of EU-generated turnover and an in-scope EU subsidiary or EU branch meeting the turnover thresholds. Companies subject to the CSRD are required to fulfil their reporting obligations in accordance with a staggered timeline depending on the category of company. The first reports are expected in 2025 for the 2024 financial year, predominantly for entities with securities admitted to trading on an EU regulated market, and in 2026 for the 2025 financial year for many other EU companies (including EU subsidiaries of non-EU parents) that are not listed on an EU regulated market but meet the relevant size thresholds.

In response to new ESG initiatives and regulations we may voluntarily elect, or be required, to adopt strategies, policies, or procedures related to ESG matters and report on these. Reporting on ESG goals and objectives may cause us to expend significant capital and human resources, and could divert management's attention from central operational matters. Reports could also lead to the disclosure of information that which may have a negative impact on our operations and reputation which may lead to additional exposure. Failure to accurately comply with any ESG reporting obligations may result in enforcement actions, sanctions, reputational harm or private litigation.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend, in so far as is permitted by applicable laws, to utilize appropriate social media in connection with our commercialization efforts following approval of our product candidates, if any. Social media practices in the biotechnology and pharmaceutical industry continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators, including equivalent foreign regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding our company, management, product candidates or products. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to US federal and state, EU or foreign jurisdictions' healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our current and future operations may be directly, or indirectly through our relationships with investigators, health care professionals, customers and third-party payors, subject to various US federal and state healthcare laws and regulations, including, without limitation, the US federal Anti-Kickback Statute. Healthcare providers, including physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws impact, among other things, our sales, marketing and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and others who recommend, purchase, or provide our approved products, and other parties through which we research as well as market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the US federal government and the states in which we conduct our business. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the US federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under US federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act, or FCA. The definition of the "remuneration" under the federal Anti-Kickback Statute has been interpreted to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. For example, manufacturers have been prosecuted for causing false claims to be submitted because of off-label promotion purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, and business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs;

- the US federal legislation commonly referred to as Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians (as defined by such law) and their immediate family members;

- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the US federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral source, state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- the national laws of individual EU Member States and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers. Outside the United States, interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid or comparable foreign healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. Prohibitions or restrictions on sales or withdrawal of marketed products could materially affect business in an adverse way. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA, the EC and comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

We are subject to the UK Bribery Act 2010, the US Foreign Corrupt Practices Act of 1977, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the UK Bribery Act 2010, or the Bribery Act, US Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the US domestic bribery statute contained in 18 U.S.C. §201, the US Travel Act, the Swedish Penal Code, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, a financial or other advantage, or anything of value, to government officials or other persons to induce them to improperly perform a relevant function or activity (or reward them for such behavior), or for any other improper purpose.

Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We, along with those acting on our behalf and our commercial partners, operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

Compliance with the Bribery Act, FCPA and these other anti-corruption laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, anti-corruption laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered government officials.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the UK, Sweden, Norway and the US, and authorities in the EU, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. Exports and imports of our products must be made in compliance with these laws and regulations. Trade Control laws may also restrict or prohibit altogether the provision or supply of certain of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions, unless there are license exceptions that apply or specific licenses are obtained. In addition, as a result of the Russia-Ukraine military conflict, the US, EU, UK, and other jurisdictions adopted a series of financial and trade sanctions in relation to Russia, Belarus, and certain Russian and Belarussian citizens and entities. Further sanctions against Russia and Belarus may be imposed by the UK, US and other jurisdictions as the Russia-Ukraine military conflict continues. Any changes in Trade Control laws, shift in the enforcement or scope of existing Trade Control laws, or change in the countries, governments, persons, or technologies targeted by such laws and regulations, could result in the decreased ability to export our products internationally.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses. Such liabilities could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, FCPA, other anti-corruption laws or Trade Control laws could also have an adverse impact on our reputation, business, results of operations and financial condition. Further, the failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or our development operations, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. Disaster recovery and business continuity plans may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management approach, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to the Ownership of our Securities

The price of our equity securities may be volatile and may fluctuate due to factors beyond our control.

The market price of the ADSs and our common shares has fluctuated significantly, and may continue to fluctuate significantly due to a variety of factors, including:

- the commencement, enrollment or results of our planned and future clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, strategic partners or competitors;

- the amount of revenue from sales of TARPEYO in the United States, Kinpeygo in the EEA and UK, and Nefecon in other jurisdictions, if approved;
- delays in entering into strategic relationships with respect to development or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes or developments in laws or regulations applicable to our product candidates;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- the loss of any of our key scientific or management personnel;
- announcements concerning our competitors or the biopharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the biopharmaceutical industry or in the economy as a whole, including pandemics, bank failures, global armed conflicts, and related global economic uncertainty;
- the trading volume or our ADSs on The Nasdaq Global Select Market or our common shares on Nasdaq Stockholm;
- sales of our ADSs or common shares by us, members of our senior management and directors or our shareholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or Sweden;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

The stock market in general, and The Nasdaq Global Select Market and pharmaceutical companies like ours in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may therefore be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs at or above the price paid for the ADSs and may otherwise negatively affect the liquidity of the ADSs. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

We will continue to incur increased costs as a result of operating as a US-listed public company, and our board of directors will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a US-listed public company we will continue to incur significant legal, accounting and other expenses that we did not incur as a public company listed on Nasdaq Stockholm. The Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market, or Nasdaq, and other applicable securities rules and regulations impose various requirements on non-US reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report on our internal control over financial reporting. In addition, we are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

We have no present intention to pay dividends on our common shares in the foreseeable future and, consequently, your only opportunity to achieve a return on your investment during that time is if the price of the ADSs or common shares, as applicable, appreciates.

We have no present intention to pay dividends in the foreseeable future. Any recommendation by our board of directors to pay dividends will depend on many factors, including our financial condition (including losses carried-forward), results of operations, legal requirements, and other factors. Furthermore, pursuant to Swedish law, the calculation of amounts available for distribution to shareholders, as dividends or otherwise, must be determined on the basis of our non-consolidated statutory accounts prepared in accordance with Swedish accounting rules. If the price of the ADSs or the common shares declines before we pay dividends, you will incur a loss on your investment, without the likelihood that this loss will be offset in part or at all by potential future cash dividends.

We have identified material weaknesses in our internal control over financial reporting. If our remediation of these material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.

In connection with our preparation and the audits of our financial statements as of and for the years ended December 31, 2022 and 2023, we identified material weaknesses as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States) in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's financial statements will not be prevented or detected on a timely basis. All of these material weaknesses are described in detail in Item 15.B, "Management's Annual Report on Internal Control over Financial Reporting."

We initially identified some of these material weaknesses in our preparation and the audits of our financial statements as of and for the year ended December 31, 2022 and initiated a remediation plan, as further described in Item 15.B, to remediate the material weaknesses and to enhance our overall control environment. In fiscal 2023, we were able to complete remediation of the prior material weakness related to Entity-level control environment, IT Processes, and Payroll, and we continue to take action to remediate the remaining material weaknesses, including steps to increase dedicated resources, improve reporting processes and enhance related supporting technology. We will continue to enhance documentation of our risks-related controls and related assertions to facilitate tracking and analyzing internal control deficiency trends to support timely remediation. We will continue to leverage an outsourced team to perform independent testing of our internal controls throughout the year. We are committed to strengthen and further improve our internal control environment and implementing measures designed to help ensure that control deficiencies contributing to the material weakness are remediated as soon as possible, as further described below.

Although we intend to complete the remediation process as promptly as possible, we cannot at this time estimate how long it will take to remediate these material weaknesses, and our remediation plan may not prove to be successful. In addition, we may discover additional material weaknesses that require additional time and resources to remediate. Our failure to correct these material weaknesses or our failure to discover and address any other control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and make related regulatory filings on a timely basis. As a result, our business, financial condition, results of operations and prospects, as well as the trading price and listing of our ADSs may be materially and adversely affected. We cannot assure you that all of our existing material weaknesses have been identified, or that we will not identify additional material weaknesses in the future.

We are subject to reporting obligations under US securities laws and the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires that we include a report from management on the effectiveness of our internal control over financial reporting in this annual report. As a result of the material weaknesses identified above, our management has concluded that our internal control over financial reporting was not effective as of December 31, 2023. This conclusion could adversely impact the market price of our ADSs due to a loss of investor confidence in the reliability of our reporting processes.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of the ADSs.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of the ADSs. For example, we have identified material weaknesses in our internal control over financial reporting related to our financial statement closing process. For example, we did not adequately design or execute controls that address the relevant financial statement assertions over the Financial Statement Close and Reporting Process. Specifically, we did not adequately design or execute internal controls over certain aspects of management review procedures, certain aspects of journal entry approvals and processing, general ledger master data maintenance, share-based payments and income taxes.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to perform system and process evaluation and testing of our internal control over financial reporting to allow our management to report on the effectiveness of our internal control over financial reporting and we are also required, as of this annual report, to have our independent registered public accounting firm issue an opinion on the effectiveness of our internal control over financial reporting on an annual basis. Based upon our evaluation, as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures, in accordance with the Exchange Act Rule 13a-15(e), as a result of the material weaknesses in our internal control over financial reporting, as discussed in Item 15 of this report, were not effective. We may in the future discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Moreover, our internal controls over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. Moreover, we are aware that the remote working arrangements which is a function of specific roles potentially present new areas of risk, and we are carefully monitoring any impact to our internal controls and procedures.

If we continue to be unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, the market price of our common shares could decline and we could be subject to sanctions or investigations by The Nasdaq Global Market, the SEC or other regulatory authorities.

Concentration of ownership of our common shares (including common shares in the form of ADSs) among our existing executive officers, directors and principal shareholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors, greater than five percent shareholders and their affiliates beneficially own approximately 28.4% of our outstanding common shares (including common shares in the form of ADSs) as of February 29, 2024. Depending on the level of attendance at our general meetings of shareholders, these shareholders either alone or voting together as a group may be in a position to determine or significantly influence the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the share capital present and voting at our general meetings of shareholders may control any shareholder resolution requiring a simple majority, including the appointment of board members, certain decisions relating to our capital structure, and the approval of certain significant corporate transactions. Among other consequences, this concentration of ownership may prevent or discourage unsolicited acquisition proposals that you may believe are in your best interest as one of our shareholders. Some of these persons or entities may have interests different than yours. For example, to the extent certain shareholders purchased their shares or ADSs at prices below those at which other shareholders purchased theirs and have held their common shares for a longer period, they may be more interested in selling our company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other shareholders.

Currently, we are not aware that any of our existing shareholders have entered or will enter into a shareholders' agreement with respect to the exercise of their voting rights. Nevertheless, depending on the level of attendance at our general meetings of shareholders, or the General Meeting, these significant shareholders could, alone or together, have the ability to determine the outcome of decisions taken at any such General Meeting. Any such voting by these shareholders may not be in accordance with our interests or those of our shareholders. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of the ADSs.

Fluctuations in exchange rates may increase the risk of holding ADSs and common shares.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the Swedish Krona, US dollar, Swiss franc and Euro. Our functional currency is the Swedish Krona, and some of our operating expenses are paid in Swedish Krona, but we also receive payments and pay expenses in US dollars and Euro. The operational currency of our French and Swiss subsidiaries is the Swiss franc. Further, potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the price of the ADSs and common shares on The Nasdaq Global Select Market and Nasdaq Stockholm, respectively, may be affected by fluctuations in foreign exchange rates between these currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period.

Moreover, because our common shares currently trade on Nasdaq Stockholm in Swedish Krona, and the ADSs trade on The Nasdaq Global Select Market in US dollars, fluctuations in the exchange rate between the US dollar and the Swedish Krona may result in temporary differences between the value of the ADSs and the value of our common shares, which may result in heavy trading by investors seeking to exploit such differences.

Holders of ADSs are not treated as holders of our common shares.

Holders of ADSs are not treated as holders of our common shares unless they withdraw the common shares underlying their ADSs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the common shares underlying the ADSs. Holders of ADSs therefore do not have any rights as holders of our common shares, other than the rights that they have pursuant to the deposit agreement. See "Item 12.D.—American Depositary Shares."

Holders of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying common shares.

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or a governmental body, or under any provision of the deposit agreement, or for any other reason, subject to the right of ADS holders to cancel their ADSs and withdraw the underlying common shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying common shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of common shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our common shares. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying common shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of common shares or other deposited securities. See "Item 12.D.—American Depositary Shares."

Holders of ADSs will not have the same voting rights as the holders of our common shares and may not receive voting materials in time to be able to exercise your right to vote.

Except as described in this annual report and the deposit agreement, which was filed as an exhibit to the registration statement filed in connection with the initial public offering of our ADSs, holders of the ADSs will not be able to exercise voting rights attaching to the common shares represented by the ADSs. Under the terms of the deposit agreement, holders of the ADSs may instruct the depositary to vote the common shares underlying their ADSs. Otherwise, holders of ADSs will not be able to exercise their right to vote unless they withdraw the common shares underlying their ADSs to vote them in person or by proxy in accordance with applicable laws and regulations and our articles of association. Even so, ADS holders may not know about a meeting far enough in advance to withdraw those common shares. If we ask for the instructions of holders of the ADSs, the depositary, upon timely notice from us, will notify ADS holders of the upcoming vote and arrange to deliver our voting materials to them. Upon our request, the depositary will mail to holders a shareholder meeting notice that contains, among other things, a statement as to the manner in which voting instructions may be given. We cannot guarantee that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote the common shares underlying their ADSs. A shareholder is only entitled to participate in, and vote at, the meeting of shareholders, provided that it holds our common shares as of the record date set for such meeting and otherwise complies with our articles of association. In addition, the depositary's liability to ADS holders for failing to execute voting instructions or for the manner of executing voting instructions is limited by the deposit agreement. As a result, holders of ADSs may not be able to exercise their right to give voting instructions or to vote in person or by proxy and they may not have any recourse against the depositary or us if their common shares are not voted as they have requested or if their shares cannot be voted.

Claims of US civil liabilities may not be enforceable against us.

We are incorporated under Swedish law. Certain members of our board of directors and senior management are non-residents of the US, and all or a substantial portion of our assets and the assets of such persons are located outside the US. As a result, it may not be possible to serve process on such persons or us in the US or to enforce judgments obtained in US courts against them or us based on civil liability provisions of the securities laws of the US. As a result, it may not be possible for investors to effect service of process within the US upon such persons or to enforce judgments obtained in US courts against them or us, including judgments predicated upon the civil liability provisions of the US federal securities laws.

The US and Sweden do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon US securities laws, would not automatically be recognized or enforceable in Sweden. In addition, uncertainty exists as to whether the courts in Sweden would entertain original actions brought in Sweden against us or our directors or senior management predicated upon the securities laws of the US or any state in the US. Any final and conclusive monetary judgment for a definite sum obtained against us in US courts would not be automatically recognized. Instead, new proceedings would need to be initiated before the competent court in Sweden. However, a judgment obtained in the US may still have a strong evidentiary weight in the Swedish proceedings, depending on the circumstances and the assessment of the court. If a Swedish court gives judgment for the sum payable under a US judgment, the Swedish judgment will be enforceable by methods generally available for this purpose. As a result, US investors may not be able to enforce against us or certain of our directors any judgments obtained in US courts in civil and commercial matters, including judgments under the US federal securities laws.

We qualify as a foreign private issuer and, as a result, we are not subject to US proxy rules and are subject to reporting obligations under the Securities Exchange Act of 1934, as amended, that, to some extent, permit less detailed and frequent reporting than that of a US domestic public company.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-US company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to US domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (iii) the rules under the Exchange Act requiring the filing with the Securities and Exchange Commission, or SEC, of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while US domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are entitled to, and do, rely on a provision in Nasdaq's corporate governance rules that allows us to follow Swedish law with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to US companies listed on Nasdaq. For example, we are exempt from Nasdaq regulations that require a listed US company and follow home country practice with respect to (i) the minimum quorum requirement for a meeting of shareholders, (ii) the requirement that non-management directors to meet on a regular basis without management present and (iii) the composition of the nominating and corporate governance committee.

In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act. Because we are a foreign private issuer, however, our audit committee is not subject to additional Nasdaq requirements applicable to listed US companies, including an affirmative determination that all members of the audit committee are "independent" using more stringent criteria than those applicable to us as a foreign private issuer. Furthermore, Nasdaq's corporate governance rules require listed US companies to, among other things, seek shareholder approval for the implementation of certain equity compensation plans and issuances of common shares, which we are not required to follow, and do not intend to follow, as a foreign private issuer. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to US domestic issuers.

We may in the future lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to US domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the US or (b) (i) a majority of our executive officers or directors may not be US citizens or residents, (ii) more than 50 percent of our assets cannot be located in the US and (iii) our business must be administered principally outside the US. We are required to evaluate our foreign private issuer status as of June 30 of each year. If we lose foreign private issuer status, we would be required to comply with the Exchange Act reporting and other requirements applicable to US domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under US securities laws if we are required to comply with the reporting requirements applicable to a US domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to US domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our management team.

If securities or industry analysts cease coverage of us, or publish inaccurate or unfavorable research about our business, the price of the ADSs and our trading volume could decline.

The trading market for the ADSs will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. Securities or industry analysts may elect not to provide research coverage of our ADSs, and such lack of research coverage may negatively impact the market price of our ADSs. If one or more of the analysts who cover us downgrade the ADSs or publish inaccurate or unfavorable research about our business, the price of the ADSs would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for the ADSs could decrease, which might cause the price of the ADSs and trading volume to decline.

Holders of ADSs may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiffs in any such action.

The deposit agreement governing the ADSs representing our common shares provides that, to the fullest extent permitted by applicable law, ADSs holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the US federal securities laws. The waiver to right to a jury trial of the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of ADSs of our or the depositary's compliance with the US federal securities laws and the rules and regulations promulgated thereunder.

If we or the depositary oppose a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. The enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the US Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before investing in the ADSs.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcome than a trial by jury would have had, including results that could be less favorable to the plaintiffs in any such action.

Nevertheless, if this jury trial waiver is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or our ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of the US federal securities laws and the rules and regulations promulgated thereunder.

If we were to be classified as a "passive foreign investment company," or a PFIC, there could be adverse US tax consequences to certain US holders.

Based on our analysis of our income, assets, activities and market capitalization for our taxable year ending December 31, 2023, we do not believe that we were a PFIC for our taxable year ending December 31, 2023. Because PFIC status is a fact specific determination that generally cannot be made until the close of the taxable year in question, the calculation of the value of our non-cash assets may be based in part on the value of our common shares or ADSs, the value of which may fluctuate considerably, and we hold a substantial amount of cash and cash equivalents, our PFIC status may change from year to year, it is difficult to predict whether we will be a PFIC for the current taxable year or any future year, and no assurance can be given that we will not be a PFIC for our current taxable year or any future year. Therefore, we have not yet made any determination as to our expected PFIC status for the current year. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the Internal Revenue Service, or IRS, will agree with our conclusion. Furthermore, because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge our classification of certain income and assets as non-passive or our valuation of our tangible and intangible assets, each of which may result in us being treated as a PFIC. Our US counsel expresses no opinion with respect to our PFIC status for any prior, the current, or any future taxable year.

Under the Internal Revenue Code of 1986, as amended, we will be a PFIC for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average percentage of our gross assets (determined under applicable Treasury Regulations) consists of assets that produce, or are held for the production of, passive income. If we are a PFIC for any taxable year during which a US Holder (as defined below in "Item 10.E—Taxation—Certain United States Federal Income Tax Consequences") holds our common shares, or ADSs, the US Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred and additional reporting requirements. Each US Holder is strongly urged to consult its tax advisor regarding these issues. For further discussion of the adverse US federal income tax consequences in the event we are classified as a PFIC, see "Item 10.E—Taxation—Certain United States Federal Income Tax Consequences."

If a United States person is treated as owning at least 10% of our common shares or ADSs, such holder may be subject to adverse US federal income tax consequences.

If a US Holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our common shares or ADSs, such US Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our corporate group, if any. A controlled foreign corporation is any foreign corporation in which more than 50% of the total combined voting power of classes of voting stock or the total value of the corporation is owned (or treated as owned) by United States shareholders. Because our corporate group currently includes one or more US subsidiaries, our non-US subsidiaries will be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its US taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in US property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a US corporation.

Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder's US federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist our investors in determining whether any of our non-US subsidiaries are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations described in this risk factor. US Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares or ADSs.

Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

Our tax treatment is subject to changes in tax laws, regulations and treaties, or, in each case, the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organization for Economic Co-Operation and Development's (OECD), Base Erosion and Profit Shifting, Project (including "BEPS 2.0"), the EC's state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid. In addition, on October 8, 2021, the OECD announced an agreement by members of the Inclusive Framework delineating an implementation plan, and on December 20, 2021, the OECD released model rules for the domestic implementation of a 15% global minimum tax. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, a tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

The rights of our shareholders may differ from the rights typically offered to shareholders of a US corporation.

Under Swedish corporate law, except in certain limited circumstances, which require at a minimum that a proposal for special review of accounts or a review of a specific item/topic as defined by shareholders requesting such review, has been supported by a minimum of 10% of the shareholders voting and being present at a general meeting, our shareholders may not ask for an inspection of our corporate records, while under Delaware corporate law any shareholder, irrespective of the size of such shareholder's shareholdings, may do so. Shareholders of a Swedish limited company are also unable to initiate a derivative action, a remedy typically available to shareholders of US companies, in order to enforce a right of our company, in case we fail to enforce such right ourselves, other than in certain cases of board member/management liability under limited circumstances. In addition, a majority of our shareholders may release a member of our board of directors or our executive management from any claim of liability we may have, including if such board member or manager has acted in bad faith or has breached his or her duty of loyalty. However, a shareholder may bring a derivative action on behalf of our company against, among other persons, a member of our board of directors or our executive management, provided that the circumstances of the act or omission giving rise to the claim of liability were not known to the shareholders at the time of such shareholder resolution, or if shareholders representing at least 10% of the share capital represented at the relevant general meeting has opposed such shareholder resolution. In contrast, most US federal and state laws prohibit a company or its shareholders from releasing a board member from liability altogether if such board member has acted in bad faith or has breached such board member's duty of loyalty to our company. Additionally, distribution of dividends from Swedish companies to foreign companies and individuals can be subject to non-refundable withholding tax, and not all receiving countries allow for deduction. See "Item 10.E.—Taxation—Material Swedish Tax Considerations" for a more detailed description of the withholding tax. Also, the rights as a creditor may not be as strong under Swedish insolvency law as under US law or other insolvency law, and consequently creditors may recover less in the event our company is subject to insolvency compared to a similar case including a US debtor. In addition, the use of the tax asset consisting of the accumulated tax losses requires that we are able to generate positive taxable income and the use of tax losses carried forward to offset against future income is subject to certain restrictions and can be restricted further by future amendments to Swedish tax law. Finally, Swedish corporate law may not provide appraisal rights in the case of a business combination equivalent to those generally afforded a shareholder of a US company under applicable US laws. As a result of these differences between Swedish corporate law and our articles of association, on the one hand, and US federal and state laws, on the other hand, in certain instances, you could receive less protection as an equity holder of our company than you would as a shareholder of a US company.

Holders of the ADSs will not be able to exercise the pre-emptive subscription rights related to the shares that they represent and may suffer dilution of their equity holding in the event of future issuances of our shares.

Under the Swedish Companies Act, our shareholders benefit from a pre-emptive subscription right on the issuance of shares for cash consideration only and not in the event of issuance of shares against non-cash contribution or debt conversion. Shareholders' pre-emptive subscription rights, in the event of issuances of shares against cash payment, may be disapplied by a resolution of the shareholders at a general meeting of our shareholders and/or the shares may be issued on the basis of an authorization granted to the board of directors pursuant to which the board may disapply the shareholders' pre-emptive subscription rights. The absence or waiver of pre-emptive rights for existing equity holders may cause dilution to such holders.

Furthermore, the ADS holders would not be entitled, even if such rights accrued to our shareholders in any given instance, to receive such pre-emptive subscription rights related to the shares that they represent. Rather, the depositary is required to endeavor to sell any such subscription rights that may accrue to the shares underlying the ADSs and to remit the net proceeds therefrom to the ADS holders pro rata. In addition, if the depositary is unable to sell rights, the depositary will allow the rights to lapse, in which case you will receive no value for these rights. Further, if we offer holders of our shares the option to receive dividends in either cash or shares, under the deposit agreement, ADS holders will not be permitted to elect to receive dividends in shares or cash, but will receive whichever option we provide as a default to shareholders who fail to make such an election.

We are a Swedish company with limited liability. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of US jurisdictions.

We are a Swedish company with limited liability. Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in Sweden. The rights of shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and boards of directors in companies governed by the laws of US jurisdictions. In the performance of its duties, our board is required by Swedish law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, the interests of our shareholders.

Our articles of association designate specific courts in the US as the exclusive forum for certain US litigation that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us.

Our articles of association provide that, unless we consent in writing to the selection of an alternative forum and without any infringement on Swedish forum provisions and without applying Chapter 7, Section 54 of the Swedish Companies Act (2005:551), the US District Court for the Southern District of New York shall be the sole and exclusive forum for resolving any complaint filed in the US asserting a cause of action arising under the Securities Act, or the Federal Forum Provision.

We recognize that the proposed Federal Forum Provision may impose additional litigation costs on shareholders in pursuing any such claims, particularly if the shareholders do not reside in or near the State of New York. Additionally, proposed Federal Forum Provision may limit our shareholders' ability to bring a claim in a US judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our shareholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other US or Swedish courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The US District Court for the Southern District of New York may also reach different judgments or results than would other courts, including courts where a shareholder considering a US-based action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

The dual listing of our common shares and the ADSs may adversely affect the liquidity and value of the ADSs.

Our ADSs are listed on The Nasdaq Global Select Market and our common shares are listed on Nasdaq Stockholm. Trading of the ADSs or common shares, as applicable, in these markets will take place in different currencies (US dollars on Nasdaq and Swedish Kronor on Nasdaq Stockholm), and at different times (resulting from different time zones, different trading days and different public holidays in the US and Sweden). The trading prices of our common shares or ADSs, as applicable, on these two markets may differ due to these and other factors. Any decrease in the price of our common shares on Nasdaq Stockholm could cause a decrease in the trading price of the ADSs on Nasdaq. Investors could seek to sell or buy our common shares or ADSs to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both the trading prices on one exchange and the common shares or Ads available for trading on the other exchange. In addition, holders of ADSs will not be immediately able to surrender their ADSs and withdraw the underlying common shares for trading on the other market without effecting necessary procedures with the depositary. This could result in time delays and additional cost for holders of ADSs. We cannot predict the effect of this dual listing on the value of our common shares and the ADSs. However, the dual listing of our common shares and the ADSs may reduce the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the US.

We could be subject to securities class action litigation or other litigation matters.

From time to time we may become involved in certain litigation matters. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant securities price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Although we intend to vigorously defend our interests in any litigation matters, there is no guarantee that we will be successful and we may have to pay damages awards or otherwise may enter into settlement arrangements in connection with such matters.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our ADSs. Even if we are successful in defending our interests in each matter, litigation with respect to such matters could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition

ITEM 4. INFORMATION ON THE COMPANY

A. HISTORY AND DEVELOPMENT OF THE COMPANY

We were formed in 2004 in order to develop and commercialize Nefecon, which we acquired from Nefecon's inventors, Professors Bengt Fellström and Roger Hällgren at Uppsala University, Sweden. We are led by an experienced and dedicated management team with more than 15 years of prior experience on average in the pharmaceutical industry, including at leading pharmaceutical companies such as GlaxoSmithKline, Novo Nordisk, Astra Zeneca, Pfizer and UCB. Our board of directors includes highly qualified researchers, pharmaceutical sector executives and experts in the fields of drug development, corporate development and pharmaceutical commercialization. We are supported by a highly regarded network of leading experts within the field of IgAN, including prominent IgAN specialists throughout the world that serve as external advisors and investigators on clinical trials of Nefecon.

The legal and commercial name of the company is Calliditas Therapeutics AB. We were founded as a public limited company under the laws of Sweden on February 20, 2004 under the name Pharmalink AB and were registered with the Swedish Companies Registration Office on April 15, 2004. On September 19, 2017, we changed our name to Calliditas Therapeutics AB.

In June 2018, we completed an initial public offering of our common shares on Nasdaq Stockholm, pursuant to which we raised gross proceeds of SEK 738.7 million. Our common shares trade on Nasdaq Stockholm under the ticker "CALTX."

In July 2019, we completed a private placement of our common shares, pursuant to which we raised gross proceeds of SEK 210.3 million.

In June 2020, we completed an initial public offering of our American Depositary Shares, or ADSs, on The Nasdaq Global Select Market in the United States and sold 924,000 common shares in Europe and countries outside of the United States in a concurrent private placement to qualified investors for gross proceeds of approximately $90 million (approximately SEK 828 million) before deduction of issuance costs, underwriting commissions and expenses. In July 2020, the underwriters exercised a portion of their over-allotment option, whereby we received additional gross proceeds of approximately $6.9 million (approximately SEK 63 million) before deduction of issuance costs, underwriting commissions and expenses. We refer to this transaction as our US IPO. Our ADSs trade on The Nasdaq Global Select Market under the ticker "CALT."

In August 2021, we completed a private placement of our common shares, pursuant to which we raised gross proceeds of SEK 324.0 million.

Our registered office is located at Kungsbron 1, D5, SE-111 22, Stockholm, Sweden, and our telephone number is +46 (0) 8 411 3005. Our website address is www.calliditas.se. The information contained on our website is not a part of this annual report.

We have five wholly owned subsidiaries, listed below:

Company	Country of incorporation
Calliditas Therapeutics US Inc.	United States
Calliditas NA Enterprises Inc.	United States
Nefecon AB	Sweden
Calliditas Therapeutics France SAS	France
Calliditas Therapeutics Suisse S.A.	Switzerland

In November 2020, we acquired a controlling interest in Genkyotex S.A., or Genkyotex, a biopharmaceutical company specializing in NOX therapies with offices in France and Switzerland. In March 2021, we participated in a rights issue in Genkyotex, and increased our ownership percentage to 90.2% of the share capital of Genkyotex and in October 2021, we completed the purchase of the remaining share capital of Genkyotex, resulting in our ownership of 100% of the current share capital and the delisting of Genkyotex's securities from the Euronext stock exchange. In April 2022, Genkyotex S.A. was renamed Calliditas Therapeutics France SAS and Genkyotex Suisse S.A. was renamed Calliditas Therapeutics Suisse S.A.

The SEC maintains an Internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

B. BUSINESS OVERVIEW

Overview

We are a commercial-stage specialty pharmaceutical company with the first product approved in the US and in EU for patients with the renal disease immunoglobulin A nephropathy, Nefecon, and a portfolio of innovative product candidates.

Nefecon is a proprietary, novel oral, delayed release formulation of budesonide designed to specifically target the presumed origin of the disease and provide a potentially disease modifying treatment of immunoglobin A nephropathy, or IgAN, for which there is a high unmet medical need. Budesonide is a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism, resulting in limited systemic exposure. IgAN is a progressive, chronic disease that over time results in deterioration of kidney function in patients, many of whom are at risk of developing end-stage renal disease, or ESRD, with the need for dialysis or kidney transplant. Nefecon is designed to target the origin of the disease presumed to be located in the ileum, the distal region of the small intestine, which has the highest concentration of the Peyer's patches, which are responsible for the production of pathogenic secretory immunoglobulin A, or IgA, antibodies.

The US Food and Drug Administration, or FDA, approved Nefecon under the brand name TARPEYO under accelerated approval on December 15, 2021 and we reported commercial availability in the United States in January 2022. Under accelerated approval, the indication for TARPEYO (budesonide) delayed release capsules (4mg) is reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio, or UPCR, ≥1.5gram/gram. In June 2023, we submitted a supplemental New Drug Application, or sNDA, to the FDA seeking to convert the accelerated approval to full approval for TARPEYO. On December 20, 2023, the FDA granted full approval to TARPEYO for a new indication to reduce the loss of kidney function in adults with IgAN who are at risk for disease progression. The European Commission, or EC, granted conditional marketing authorization for Nefecon under the name Kinpeygo (budesonide) capsules for the treatment of primary IgAN in adults at risk of rapid disease progression with a UPCR ≥1.5 gram/gram on July 15, 2022 and our licensee STADA Arzneimittel AG, or STADA, announced commercial availability in Germany in September 2022, and in Greece under a Special Import License since June 2023. On February 1, 2023, the Medicines and Healthcare products Regulatory Agency, or MHRA, of the UK granted Conditional Marketing Authorization for Kinpeygo for the same indication as the EC. STADA submitted requests to both the EMA, in September 2023, for the EU and to the MHRA, in October 2023, for the UK to convert the current conditional marketing authorization for these territories into a full marketing authorization. A decision is expected from the EMA during the first half of 2024. Nefecon received conditional approval from China's National Medical Products Administration on November 24, 2023 for the reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR, ≥1.5gram/gram and approval from the Pharmaceutical Administration Bureau of the Macau Special Administrative Region on October 27, 2023 for the same indication. Nefecon received approval from Singapore's Health Science Agency for the reduction of proteinuria in adults with IgAN at risk of rapid disease progression, generally a UPCR ≥1.5 g/g on March 19, 2024.

TARPEYO was the first treatment ever approved for the US market indicated for patients with IgAN. The FDA approved TARPEYO under the accelerated approval pathway based on the reduction in proteinuria and supportive data on the estimated Glomerular Filtration Rate, or eGFR, a measure of kidney function, shown in Part A of our pivotal NefIgArd trial. We reported topline results from the full NefIgArd clinical trial in March 2023. The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in eGFR over the two-year period of nine months of treatment with Nefecon or placebo and 15 months of follow-up off drug. The results indicate that Nefecon was generally well-tolerated and the safety profile was consistent with that observed in Part A of the trial. These results were the basis for the June 2023 sNDA submission to the FDA to convert the accelerated approval to full approval for TARPEYO.

Nefecon as TARPEYO was granted seven years orphan drug exclusivity in the United States, expiry December 15, 2028, based on the initial indication based on proteinuria. Following the full approval in December of 2023, a new orphan drug exclusivity period of 7 years was granted for the new indication, expiring in December 2030. Kinpeygo, was granted ten years orphan market exclusivity by the EC, expiry July 15, 2032, and by the MHRA, expiring February 1, 2033.

We retain worldwide rights to Nefecon other than in territories where we have established strategic collaborations. In 2019, we entered into an agreement pursuant to which we granted Everest Medicines II Limited, or Everest, an exclusive license to develop and commercialize Nefecon for the treatment of IgAN in Greater China and Singapore, and in March 2022, we expanded the territory covered by the agreement to include the Republic of Korea. In July 2021, we entered into a license agreement with STADA to commercialize Nefecon for the treatment of IgAN in the EEA, the UK, and, if approved, in Switzerland. In December 2022, we entered into an exclusive license agreement with Viatris Pharmaceuticals Japan Inc., a subsidiary of Viatris Inc., or Viatris, to register and commercialize Nefecon for the treatment of IgAN in Japan.

We are also developing a novel platform of nicotinamide adenine dinucleotide phosphate, or NADPH, oxidase, or NOX, inhibitors, which we intend to primarily develop for orphan diseases with fibrotic pathology, with a main focus on kidney and liver diseases. From this platform, we are developing setanaxib, a NOX inhibitor, for the treatment of primary biliary cholangitis, or PBC. We are currently evaluating setanaxib in the TRANSFORM study, a Phase 2b clinical trial, in which we randomized the first patient in February 2022. Setanaxib will be administered to approximately 70-80 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA in a global trial conducted in 80-130 investigational centers in North America, Europe, Israel, Australia and New Zealand. The primary endpoint is alkaline phosphatase (ALP) reduction, with key secondary endpoints including change in liver stiffness and effect on fatigue and pruritus (itching). Following favorable safety data from a Phase 1 study, this trial will evaluate two dosing regimens of 1200mg/daily and 1600mg/daily. We expect data to read out data in the third quarter of 2024, and this analysis will determine which dose of setanaxib will be used for a future potential Phase 3 study. Setanaxib was granted fast track designation by the FDA in August 2021. We are also conducting a proof of concept, Phase 2 clinical trial of setanaxib administered in conjunction with pembrolizumab, a check point inhibitor, in squamous cell carcinoma of the head and neck, or SCCHN, in order to explore setanaxib's use as a treatment approach in cancers with high levels of tumors associated fibroblasts, or CAFs. We are also currently conducting a Phase 2 clinical trial of setanaxib in Alport syndrome, which we initiated in November 2023.

Our Pipeline

The following table summarizes the development stage and status of our portfolio of key product candidates:

* Approved in the US under the tradename TARPEYO® to reduce the loss of kidney function in adults with primary IgAN at risk for disease progression, and granted condi[1]tional marketing authorization in the EEA and UK under the tradename Kinpeygo® for the treatment of primary IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram, granted conditional approval in China and approval in Macao under the tradename Nefecon® for the treatment of primary IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram, granted conditional approval in Singapore under the tradename NEFEGAN® for the treatment of primary IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram.

Our Strategy

We aim to apply our interdisciplinary expertise in pharmaceutical product development to identify, develop and commercialize novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. To achieve this objective, we intend to pursue the following strategies:

- **Support our partners in pursing regulatory approval for TARPEYO and Kinpeygo**. We reported positive topline results from the full NefIgArd Phase 3 clinical trial in March 2023. Based on the topline results from the NefIgArd trial, our partner STADA has submitted requests to both the EMA, in September 2023, for the EU and to the MHRA, in October 2023, for the UK to convert the current conditional marketing authorization for these territories into a full marketing authorization. We expect a decision from EMA in the first half of 2024. Full approval for TARPEYO in the US was received in December of 2023. We are also supporting our partners Everest and Viatris in pursuing regulatory approvals of Nefecon in various jurisdictions in Asia.

- **Maximize the potential of Nefecon, where approved, through commercialization independently and through collaborations with third parties**. Since the approval of TARPEYO in the United States in December 2021, we have been commercializing TARPEYO independently in the United States through a targeted commercial sales infrastructure. We launched TARPEYO in the United States in January 2022. Based on third party research we commissioned to assess the US nephrologist IgAN market, we believe this market can be served by a targeted and dedicated number of marketing and medical sales specialists to efficiently cover the approximately 4-5,000 nephrologists focused on our target patient population in the United States. In 2019, we granted a license to Everest to develop and commercialize Nefecon for IgAN and other potential indications in Greater China and Singapore. In March 2022, we expanded the territory covered by the agreement to include the Republic of Korea. In July 2021, we entered into a license agreement with STADA to commercialize Nefecon for the treatment of IgAN in the EEA, the UK and, if approved, in Switzerland. In December 2022, we entered into an exclusive license agreement with Viatris to register and commercialize Nefecon for the treatment of IgAN in Japan. We retain worldwide rights to Nefecon other than in Greater China, Singapore, the Republic of Korea, Europe and Japan and have entered into a Managed Access Program Distribution Agreement with TannerGAP, Inc. and Tanner Pharma UK Limited, or Tanner, under which Tanner agrees to act as the exclusive distributor for Calliditas to provide pre-approval access to the TARPEYO in response to requests by physicians, hospitals, pharmacies, distributors, ministries of health or other parties on behalf of specific or named patients, when the TARPEYO is not approved or licensed for use in the named patient's home country.

- **Efficiently advance our first-in-class NOX platform candidate setanaxib through clinical trials**. We believe that our leading product candidate, setanaxib, has potential to meaningfully impact fibrosis and inflammation, and hence provide significant benefit in orphan diseases, including in PBC. Setanaxib is the first clinical product candidate within the newly created "-naxib" international nonproprietary name stem designated by the World Health Organization. We are currently conducting a Phase 2/3 clinical trial in patients with PBC who have more advanced signs of liver fibrosis, as measured by Fibroscan. We are also conducting a proof of concept, Phase 2 clinical trial in SCCHN with setanaxib, administered in conjunction with pembrolizumab, a checkpoint inhibitor, in order to explore setanaxib's use as a treatment approach in cancers with high levels of CAFs. In preclinical studies setanaxib has been shown to significantly reduce levels of CAFs in relevant mouse models of head and neck cancer, which in conjunction with administration of immunotherapies have resulted in tumor size reduction and overall survival benefits. Based on supportive pre-clinical data generated during 2022, we initiated a Phase 2a study with setanaxib in about 20 patients with Alport syndrome in November 2023.

- **Complement our existing pipeline by selective acquisitions or in-licensing of product candidates focused on nephrology, hepatic or orphan diseases**. We actively seek to complement our existing pipeline by selectively acquiring or in-licensing additional product candidates that present a strong strategic and commercial fit. We believe that our team is well-positioned to identify attractive assets and accelerate their development. In particular, we seek to expand our pipeline with product candidates with an attractive risk/reward profile, such as those that have demonstrated proof-of-concept in patients, are in late-stage clinical development or can be rapidly advanced to market approval. We currently focus on, and we expect to continue to focus on, nephrology, hepatic and orphan diseases for our business development efforts.

Our Company and Management Team

We were formed in 2004 and we acquired Nefecon from Professors Bengt Fellström and Roger Hällgren at Uppsala University, Sweden. We are led by an experienced and dedicated management team with significant pharmaceutical industry experience, including at leading pharmaceutical companies such as GlaxoSmithKline, Novo Nordisk, Astra Zeneca, Pfizer and UCB. Our board of directors includes highly qualified researchers, pharmaceutical sector executives and experts in the fields of drug development, corporate development and pharmaceutical commercialization. We are supported by a highly regarded network of leading renal and hepatic experts, including prominent IgAN specialists throughout the world that serve as external advisors and investigators on clinical trials of Nefecon.

Our Commercial Product: TARPEYO for the treatment of IgAN

Overview

In November 2020, we reported positive topline data from Part A of our global, pivotal Phase 3 clinical trial, which we refer to as NefIgArd. In this trial of 200 patients, treatment with Nefecon was associated with a statistically significant and clinically meaningful reduction of protein in the urine, or proteinuria, and stabilization of kidney function. The primary endpoint analysis showed a 31% mean reduction in the treatment arm versus baseline, with placebo showing a 5% mean reduction versus baseline, resulting in a 27% mean reduction at nine months of the treatment arm versus placebo (p=0.0005). The key secondary endpoint, eGFR, showed a treatment benefit of 7% versus placebo at nine months, reflecting stabilization in the treatment arm and a 7% decline of eGFR in the placebo arm (p=0.0029). This reflected an absolute decline of 4.04 ml/min/1.73m^2 in the placebo group over nine months compared to a 0.17 ml/min/1.73m^2 decline in the treatment arm. Patients who had reached 12 months at the time of the data cut-off recorded a proteinuria reduction of 52% from baseline in the treatment arm, versus 7% in the placebo arm. In addition, the trial showed that Nefecon was generally well-tolerated.

We reported topline results from the Phase 3 NefIgArd clinical trial in March 2023. The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in eGFR over the two-year period of nine months of treatment with Nefecon or placebo and 15 months of follow-up off drug. The eGFR benefit was observed across the entire study population, irrespective of UPCR baseline. UPCR reductions observed were durable, reflecting a long-lasting treatment effect during the 15 month follow-up period off treatment. The results indicate that Nefecon was generally well-tolerated and the safety profile was consistent with that observed in Part A of the trial. The NefIgArd trial was completed in June 2023 when the final 29 patients in China (not required for global submission purposes) completed nine months of treatment and 15 months of observation.

The FDA has approved TARPEYO (developed under the name of Nefecon) under the accelerated approval pathway based on the reduction in proteinuria. TARPEYO was the first ever approved treatment on the US market indicated for patients with IgAN. Based on the topline results from the Phase 3 NefIgArd clinical trial, in June 2023, we submitted an sNDA to the FDA seeking to convert the accelerated approval to full approval for TARPEYO. On December 20, 2023, the FDA granted full approval to TARPEYO for a new indication to reduce the loss of kidney function in adults with IgAN who are at risk for disease progression.

The EC has granted conditional marketing authorization for Nefecon under the name Kinpeygo (budesonide) capsules for the treatment of IgAN in adults at risk of rapid disease progression with a UPCR ≥1.5 gram/gram. On February 1, 2023, the MHRA granted conditional marketing authorization for Kinpeygo for the same indication as the EC. Our partner STADA has submitted requests to both the EMA, in September 2023, for the EU and to the MHRA, in October 2023, for the UK to convert the current conditional marketing authorization for these territories into a full marketing authorization.

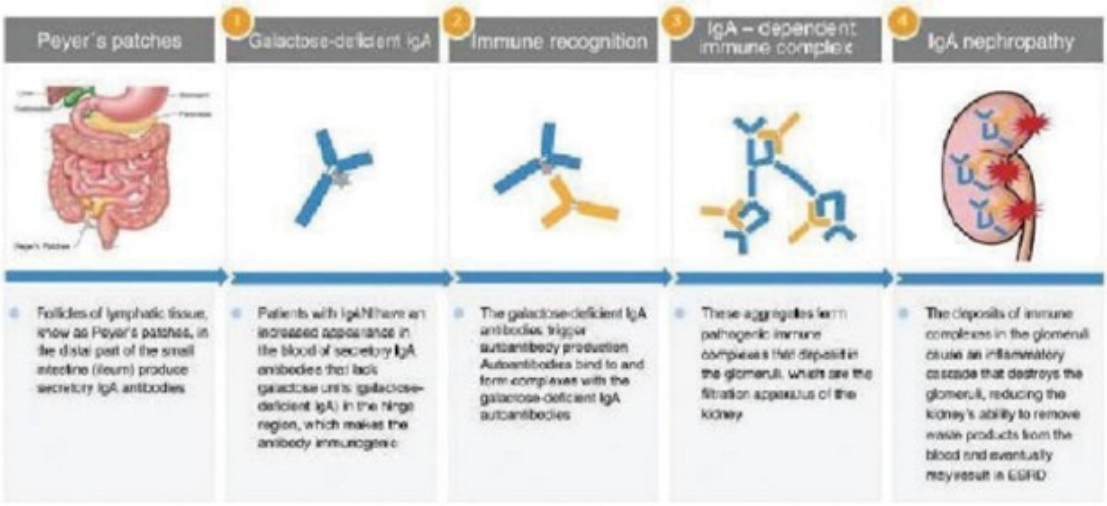
TARPEYO was granted seven years orphan drug exclusivity in the United States, expiring December 15, 2028, for the accelerated approval indication, and was recently awarded orphan exclusivity through December 20, 2030 for that portion of the full approval indication not covered by the accelerated approval indication. Kinpeygo was granted ten years orphan market exclusivity by the EC, expiring in July 15, 2032, and by the MHRA, expiring February 1, 2033. Since the approval of TARPEYO in the United States in December 2021, we have been commercializing TARPEYO independently in the United States through a targeted commercial sales infrastructure. We launched TARPEYO in the United States in January 2022. In 2019, we granted a license to Everest to develop and commercialize Nefecon for IgAN and other potential indications in Greater China and Singapore. In March 2022, we expanded the territory covered by the agreement to include the Republic of Korea. In July 2021, we entered into a license agreement with STADA to commercialize Nefecon for the treatment of IgAN in the EEA, the UK and, if approved, in Switzerland. In December 2022, we entered into an exclusive license agreement with Viatris to register and commercialize Nefecon for the treatment of IgAN in Japan. We retain worldwide rights to Nefecon other than in Greater China, Singapore, the Republic of Korea, the EEA, Switzerland, the UK and Japan and have entered into a Managed Access Program Distribution Agreement with Tanner, under which Tanner agrees to act as the exclusive distributor for Calliditas to provide pre-approval access to the TARPEYO in response to requests by physicians, hospitals, pharmacies, distributors, ministries of health or other parties on behalf of specific or named patients, when the TARPEYO is not approved or licensed for use in the named patient's home country.

IgAN Disease Background

IgAN, sometimes referred to as Berger's disease, is a serious progressive disease of the kidney, in which up to 50% of patients are at risk of developing ESRD within ten to twenty years. The standard of care for ESRD is dialysis or kidney transplant, which represents a significant health economic burden as well as a material impact on patients' quality of life. IgAN is an orphan disease that we estimate affects approximately 130,000 to 150,000 people in the United States and approximately 200,000 people in Europe. A significantly higher prevalence of IgAN has been observed in Asia, including in Greater China, where it has historically been a leading cause of ESRD. We estimate that IgAN affects approximately five million people in Greater China.

Although IgAN manifests in the kidney, there is now a consensus supporting a pivotal role of the mucosal immune system in the pathogenesis of the condition and that the origins of the disease reside in the mucosal tissue of the gastrointestinal tract. The intestine represents the largest component of the immune system in the body, and is a site of continuous exposure to antigens and pathogens. Masses of lymphatic tissue, known as Peyer's patches, are concentrated in the ileum where they produce secretory IgA antibodies. IgA antibodies play a key role in the immune system by protecting the body from foreign substances such as food-derived factors, bacteria and viruses. Patients with IgAN have elevated levels of a subclass of IgA antibodies produced in the gut that lack units of galactose, a type of sugar, at their hinge region. The hinge region is a flexible amino acid stretch in the central part of the heavy chains of the IgA antibody. In IgAN patients, a combination of genetic predisposition, environmental, bacterial or dietary factors are presumed to lead to an increased production of these galactose-deficient IgA antibodies, potentially in combination with increased intestinal permeability, which leads to these antibodies appearing in the blood. The galactose-deficient IgA antibodies are immunogenic when found in the circulation, which triggers autoantibodies, or antibodies created by the body in response to a constituent of its own tissue. This in turn leads to the formation of pathogenic immune complexes, or clusters of antibodies, which deposit in the glomeruli, the kidney's filtration apparatus. These trapped immune complexes initiate an inflammatory cascade that damages the glomeruli, resulting in protein and blood leaking into the urine. Ultimately the glomeruli are destroyed, reducing the kidney's ability to remove waste products from the blood. As the disease progresses, waste products that are normally removed from the blood accumulate leading to potentially life-threatening complications that in many patients result in the need for dialysis or kidney transplant. Commercial patients on hemodialysis (in the US) average 145 sessions per year with costs that frequently exceed $250,000 per year. The average cost of a kidney transplant is approximately $415,000 with a total estimated annual cost in the US of $7.0 billion. The graphic below illustrates the pathogenesis of IgAN.

IgA production in the Peyer's patches in the ileum is believed to cause IgAN in the kidney.



Treatment Landscape for IgAN Patients

Until the approval of TARPEYO and Kinpeygo (developed under the project name of Nefecon), there were no approved treatment options for IgAN. Physicians have attempted to control disease progression with a variety of off-label treatments. KDIGO (kidney disease improving global outcomes) Guidelines, a standard clinical assessment classification system used to predict risk for progression of kidney disease, were last updated in 2020, prior to the accelerated approval of TARPEYO. It recommends the use of blood pressure-lowering agents that inhibit or block the renin-angiotensin system, or RAS, using either inhibitors of angiotensin converting enzyme, or ACE inhibitors, or angiotensin receptor blockers, or ARBs. RAS inhibition reduces pressure in the kidney glomeruli, thereby lowering leakage and protein excretion in urine. Treatment via RAS inhibition is primarily symptomatic and does not address the underlying cause of IgAN. Over time, a significant proportion of patients experience continued deterioration of kidney function.

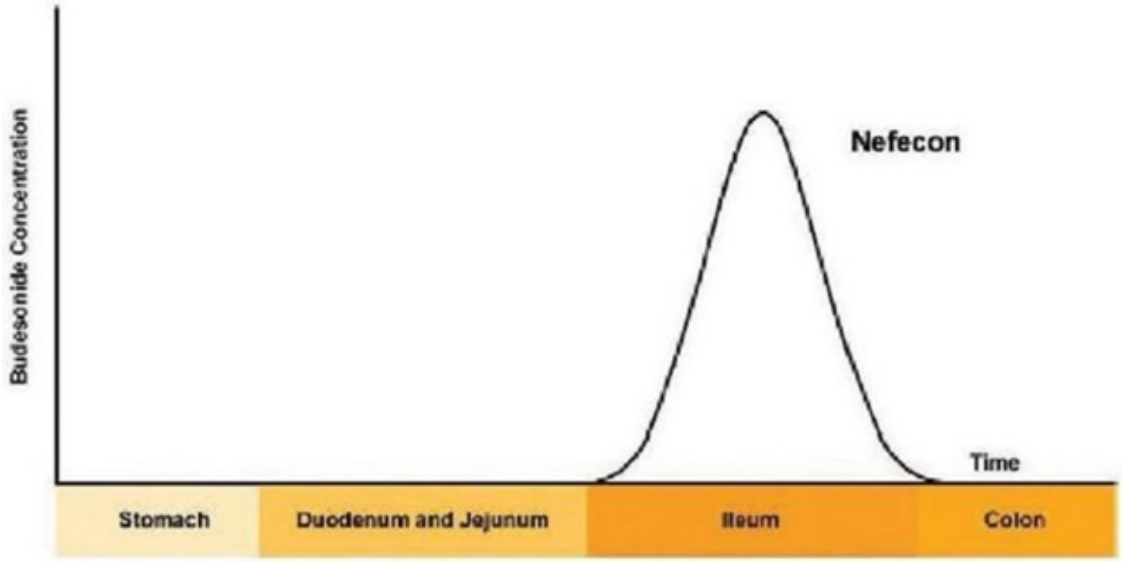
For IgAN patients whose disease has progressed, clinicians may treat patients with systemic immunosuppressive agents, primarily consisting of high doses of systemic corticosteroids, such as prednisone, prednisolone and methylprednisolone. While some published reports indicate that these agents may reduce proteinuria, the use of systemic corticosteroids is also associated with a wide range of adverse events, including high blood pressure, weight gain, diabetes, serious infections and osteoporosis.

The seriousness of these adverse events in patients with IgAN has been documented in two independent clinical trials investigating the safety and efficacy of systemic corticosteroids monotherapy and in combination with immunosuppressives. In the Therapeutic Evaluation of Steroids in IgA Nephropathy Global, or TESTING, clinical trial that was started in 2012 and conducted by The George Institute for Global Health based in Sydney, Australia, 262 patients who had progressive IgAN despite treatment with RAS blockade agents were randomized to receive oral corticosteroid methylprednisolone or placebo. A significantly higher rate of serious infections and two infection-related deaths were observed in patients receiving oral methylprednisolone, leading to temporary suspension of the trial in 2015 and a restart again in 2017 with a lower dose of methylprednisolone. Recently published results suggest this risk may be somewhat mitigated by reducing the dose of methylprednisolone and by administering prophylactic antibiotic treatment. In the open-label Supportive Versus Immunosuppressive Therapy for the Treatment of Progressive IgA Nephropathy, or STOP-IgAN, trial conducted by Rheinisch Westfälische Technische Hochschule of Aachen University in 162 patients, there was also an increase in the rate of serious infections including one infection related death in the 82 patients who received immunosuppressive therapy (systemic corticosteroids monotherapy or in combination with cyclophosphamide and azathioprine) in addition to supportive care. In this trial, immunosuppressives were not observed to have a lasting effect on proteinuria and there was no significant difference in the decline in eGFR. The STOP-IgAN trial concluded that the addition of immunosuppressive therapies, including systemic corticosteroids, to comprehensive supportive care was not beneficial in IgAN. We are expecting that the KDIGO Guidelines will be updated during 2024 and that these will include TARPEYO.

Our Solution: Nefecon

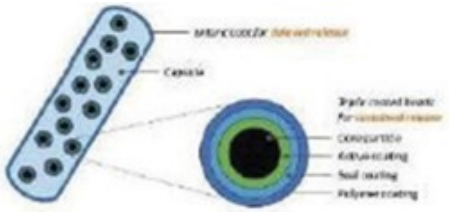
Nefecon is a proprietary, novel, oral formulation of budesonide, designed to deliver budesonide to the ileum of the small intestine, where the Peyer’s patches are concentrated. Budesonide is a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism, resulting in limited systemic exposure. Nefecon was designed as a 4 mg delayed release capsule with an enteric coating so that it remains intact until it reaches the ileum. Each capsule contains beads coated with various polymers and budesonide designed to target the area with the highest concentration of Peyer’s patches, with the intention of having a disease-modifying effect.

Nefecon is designed to release budesonide in the ileum to provide peak drug concentrations to immune cells in the Peyer's patches.



As illustrated below, Nefecon has an enteric coating layer that delivers the capsule intact to the ileum of the small intestine, where the Peyer's patches are concentrated. The capsule contains triple coated beads that help control the rate of release of the active ingredient, budesonide. Nefecon is thought to reduce the levels of circulating galactose deficient IgA and subsequently the production of IgA or IgG antibodies that bind to galactose deficient IgA to form immune complexes that accumulate in the kidneys causing renal injury.

Nefecon has two components: an enteric-coated layer that delivers the capsule intact to the ileum and triple coated beads that control the release of the active ingredient.



Budesonide is an established corticosteroid that is generally well tolerated compared to other corticosteroids like prednisone. This active ingredient was selected because of its high first pass metabolism in the liver with minimal systemic absorption. Only a small portion of the orally administered active ingredient reaches the systemic circulation and therefore mitigates the risk of serious side effects that are typically associated with systemic corticosteroids that are used to treat IgAN.

Nefecon is differentiated in its indications, properties, profile and mechanism of action as compared to other marketed products that deliver budesonide to the intestine and is the only formulation of budesonide that is indicated for the treatment of IgAN. Uceris is formulated as a 9 mg extended release tablet administering budesonide specifically to the colon for the treatment of ulcerative colitis. Entocort is formulated as a 3 mg delayed release capsule used at a maximum dose of 9 mg throughout the entire approximately eight meters of the intestine in a continuous release for the treatment of Crohn's disease. Unlike Nefecon, neither of these two formulations are designed to, or are in their approved dosages capable of, delivering the dose of budesonide to the ileum that was found to be efficacious for the treatment of IgAN in our clinical trials. Neither have been tested in randomized, controlled clinical trials in IgAN patients. We believe that any attempts to use these drugs to address IgAN would either be ineffective or would require dosing patients at levels several times higher than the doses approved, with unknown consequences for patient safety.

We have combined our proprietary formulation technology with know-how developed internally to create Nefecon. We believe this proprietary formulation will constitute a barrier to entry that would require significant time, focus and investment for a competitor to overcome. TARPEYO was initially granted seven years orphan drug exclusivity in the United States which was to expire on December 15, 2028, and was recently extended to December 2030 based on receiving full approval of TARPEYO. Kinpeygo was granted orphan drug market exclusivity in the EU and the UK, which will provide marketing exclusivity until July 15, 2032 and February 1, 2033, respectively.

Nefecon Phase 3 Clinical Trial (NefIgArd Trial)

We completed our global pivotal Phase 3 clinical trial in IgAN, which we refer to as NefIgArd. NefIgArd was a double-blind, placebo-controlled, two-part phase 3 clinical trial comparing nine months of Nefecon 16 mg once daily to placebo in IgAN patients on a stable recommended or maximum tolerated dose of RAS inhibitor therapy for control of blood pressure. We randomized our first patient in NefIgArd in November 2018, the results of the first part of the trial were published in a peer reviewed journal in October 2022, topline data from the full study were reported in March 2023, and full results from the trial were published in a peer reviewed journal in August 2023.

Trial Design

The first part of NefIgArd, which we refer to as Part A, was designed to evaluate reduction of the surrogate marker proteinuria, measured by the urine protein to creatinine ratio, or UPCR as its primary endpoint, which is the same endpoint used in our previously completed NEFIGAN clinical trial. In addition, a key secondary endpoint of Part A was the difference in kidney function between treated and placebo patients as measured by eGFR. This key secondary endpoint in Part A, measured over a nine-month period, provided information relevant to the primary endpoint of Part B.

The second part, which we refer to as Part B, was the post-approval confirmatory part of the trial designed to provide evidence of long-term renal benefit. Completion of enrollment of the additional 160 patients required for Part B took place in January 2021. The total number of 360 patients was required to sufficiently power the trial to assess the difference in kidney function between Nefecon-treated and placebo patients as measured by eGFR over a two-year period from the start of dosing of each patient. We reported positive topline results of Part B in March 2023. Across both parts of the study, NefIgArd enrolled a total of 366 patients in the global study.

NeflgArd Interim Results

We reported interim topline results in November 2020. The complete interim results from NeflgArd were published in a peer reviewed journal, Kidney International, in October 2022. The analysis set included 199 patients diagnosed with IgAN and who were on a background of optimized and stable renin-angiotensin system, or RAS inhibitor therapy. The patients were randomized in a 1:1 ratio into one of two arms-Nefecon 16 mg/day or placebo-and treated orally for nine months daily.

- **UPCR (Proteinuria) Data**: Analysis of the primary UPCR endpoint showed that after nine months of treatment, patients treated with Nefecon showed a 31% reduction in UPCR compared to a 5% reduction in patients treated with placebo (p=0.0001). UPCR at nine months was reduced from baseline by 34% in patients treated with Nefecon compared with 5% in placebo-treated patients when applying an ITT (intention to treat) approach. The treatment effect for the UPCR endpoint at nine months was consistent across key subgroups, including key demographic (such as age, sex, race) and baseline disease (such as baseline proteinuria) characteristics. Based on the patients who had reached 12 months at the time of the data cut-off, proteinuria reduction was 52% from baseline compared to 7% for placebo treated patients.

- **eGFR Data**: The key secondary endpoint, eGFR, showed a mean treatment benefit of 7% versus placebo at nine months, reflecting stabilization in the treatment arm and a 7% decline of eGFR in the placebo arm (p=0.0029). This corresponds to an absolute decline of 4.04 ml/min/1.73 m2 in the placebo arm over nine months compared to a 0.17 ml/min/1.73 m2 decline in the treatment arm.

- **Safety Profile**: The results indicate that Nefecon was generally well-tolerated, with adverse events similar to those observed in the Phase 2b trial, and overall consistent with the known safety profile of Nefecon's active ingredient, budesonide. The majority of adverse events were mild or moderate in severity. The withdrawal rate in this trial was less than 10%, hence significantly less than what was seen in the Phase 2b NEFIGAN trial.

NeflgArd Full Results

We reported topline results for the full study in March 2023. The analysis included 364 patients diagnosed with primary IgAN and who were on a background of optimized and stable renin-angiotensin system (RAS) inhibitor therapy. The patients were randomized in a 1:1 ratio into one of two treatment groups – Nefecon 16 mg/day orally or placebo – and treated for nine months daily, and then monitored for 15 months off-drug.

- **eGFR Data**: The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in eGFR over the two-year period of nine months of treatment with Nefecon or placebo and 15 months of follow-up off drug. On average, eGFR over 2 years was 5.05 mL/min/1.73 m^2 higher with Nefecon compared to placebo (p<0.0001). Mean change in eGFR over the 2-year period was -2.47 mL/min/1.73 m^2 for Nefecon 16 mg versus -7.52 mL/min/1.73 m^2 for placebo. Supportive 2-year total slope analyses were statistically significant and clinically meaningful reflecting a sustained treatment benefit. The eGFR benefit was observed across the entire study population, irrespective of UPCR baseline.

- **UPCR (Proteinuria) Data**: UPCR reductions observed were durable, reflecting a long-lasting treatment effect during the 15 month follow-up period off treatment.

- **Safety Profile:** The results indicate that Nefecon was generally well-tolerated and the safety profile was consistent with that observed in Part A of the trial.

All patients enrolled into the NefIgArd trial have completed the 9-month treatment period and 15 months of observational follow-up. The last patient in China completed the study in June 2023 so the study has therefore concluded.

Open-Label Extension Trial

An open-label extension trial, or the OLE trial, for eligible patients who have completed treatment in Part A and Part B of NefIgArd is ongoing. The OLE trial commenced when the first patient completed both Part A and Part B of NefIgArd, which occurred in the fourth quarter of 2020, and we reported dosing of the first patient in February 2021. We expect the OLE trial to complete in first half of 2024.

Regulatory Approval and Plans

The FDA granted accelerated approval to TARPEYO on December 15, 2021 and we reported commercial availability of TARPEYO in the United States in January 2022. The FDA granted full approval to TARPEYO in December 2023 for a new indication to reduce the loss of kidney function in adults with IgAN who are at risk for disease progression.

The EC granted conditional marketing authorization for Kinpeygo on July 15, 2022 and our licensee STADA announced commercial availability in Germany in September 2022 and in Greece under a Special Import License since June 2023. On February 1, 2023, the MHRA granted conditional marketing authorization for Kinpeygo. Our partner STADA has submitted requests to both the EMA, in September 2023, for the EU and to the MHRA, in October 2023, for the UK to convert the current conditional marketing authorizations for these territories into a full marketing authorizations. We expect a decision from EMA in the first half of 2024.

TARPEYO was initially granted seven years orphan drug exclusivity in the United States which was to expire on December 15, 2028, and was recently extended to December 2030 based on receiving full approval of TARPEYO. Kinpeygo was granted ten years orphan market exclusivity by the EC, expiry July 15, 2032, and by the MHRA, expiring February 1, 2033.

Commercialization

We estimate the prevalence of IgA nephropathy in the United States to be between 130,000 and 150,000, with over 50% of patients potentially progressing to ESRD. Nephrologists, in syndicated research conducted and published in 2023 by Spherix Global Insights, anticipate 66% of their IgA nephropathy patients will progress to ESRD.

Following FDA approval, we began commercializing TARPEYO in the United States. Our targeted commercial sales infrastructure now consists of approximately 70 experienced rare disease account managers, focused on the approximate 4-5,000 nephrologists who we believe treat the vast majority of IgAN patients in the United States. TARPEYO sales began in late January 2022 and our US organization remains focused on disease and product education, so that physicians can identify appropriate patients for TARPEYO. In addition, we work with advocacy organizations and have developed a comprehensive patient services program to assist with access to TARPEYO.

In 2019, we granted a license to Everest to develop and commercialize Nefecon for IgAN and other potential indications in Greater China and Singapore. In March 2022, we expanded the territory covered by the agreement to include the Republic of Korea. In November 2022, we announced that Everest's New Drug Application for Nefecon was accepted for review by the Chinese National Medical Products Administration. The Chinese National Medical Products Administration granted approval for Nefecon in November 2023 for the reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5gram/gram and approval from the Pharmaceutical Administration Bureau of the Macau Special Administrative Region on October 27, 2023 for the same indication. Nefecon was launched in Macau in December 2023. Approval was granted by Singapore's Health Science Agency for Nefecon (for the reduction of proteinuria in adults with IgAN at risk of rapid disease progression, generally a UPCR ≥1.5 gram/gram to on March 19, 2024 for Nefecon.

In July 2021, we entered into a license agreement with STADA to commercialize Nefecon for the treatment of IgAN in the EEA, the UK and, if approved, in Switzerland. STADA is commercializing the product under the brand name Kinpeygo. STADA announced commercial availability of Kinpeygo in Germany in September 2022 and in certain other EU countries during 2023, including in Greece under a Special Import License since June 2023.

In December 2022, we entered into an exclusive license agreement with Viatris, to register and commercialize Nefecon for the treatment of IgAN in Japan.

We retain worldwide rights to Nefecon other than in Greater China, Singapore, the Republic of Korea, Europe, and Japan and have entered into a Managed Access Program Distribution Agreement with Tanner, under which Tanner agrees to act as the exclusive distributor for Calliditas to provide pre-approval access to the TARPEYO in response to requests by physicians, hospitals, pharmacies, distributors, ministries of health or other parties on behalf of specific or named patients, when the TARPEYO is not approved or licensed for use in the named patient's home country.

Our pipeline: First-in-class NOX inhibitor platform with a lead product candidate: setanaxib

Introduction to NOX inhibitors

Nicotinamide adenine dinucleotide phosphate, or NADPH, oxidases, otherwise known as NOX enzymes, are the only known enzymes that are solely dedicated to producing reactive oxygen species, or ROS. They are transmembrane enzymes that transfer electrons from NADPH in the cytoplasm across the cell membrane, which results in the formation of ROS. There are seven NOX members, each differing in composition, modes of activation and the ROS type they produce. NOX1, NOX2, NOX3, and NOX5 transfer electrons from NADPH to molecular oxygen, producing superoxide anion (O2 −). NOX4, DUOX1 and DUOX2, meanwhile, mainly produce hydrogen peroxide (H_2O_2).

At appropriate concentrations, ROS have essential functions in cellular signaling processes, helping to regulate cell proliferation, differentiation and migration, as well as modulating the innate immune response, inflammation and fibrosis. However, disruption of redox homeostasis has been implicated in multiple disease pathways. Oxidative stress, caused by an excess of ROS, is a likely common underlying mechanism for many disorders, including cardiovascular diseases, neurodegenerative disorders, and cancer disease pathways. We believe our lead product candidate setanaxib impacts inflammation and fibrosis pathways, which also was seen in the transcriptomics analysis carried out in relation to the interim analysis of our Phase 2 SCCHN trial.

Setanaxib for the Treatment of PBC

Setanaxib has shown clinically relevant biochemical and anti-fibrotic activity in a Phase 2 clinical trial in PBC, an orphan liver disease in which fibrosis in an important part of the underlying pathology, despite not achieving its primary endpoint. Setanaxib is the first clinical product candidate within the newly created "-naxib" international nonproprietary name stem designated by the World Health Organization. Based on available Phase 2 clinical data and recent Phase 1 data, combined with interactions with the FDA related to setanaxib, we initiated a Phase 2b trial in this indication, with the first patient randomized in February 2022. We believe that setanaxib is differentiated from other approved or late-stage development candidates in PBC, due to its effect on fibrosis, inflammation, and potentially significant impact on fatigue, as seen in the Phase 2 trial. We have received orphan drug designation for the treatment of PBC by the FDA. Orphan designation was also granted in the EU prior to our acquisition of the product.

PBC Disease Background

PBC is a progressive and chronic autoimmune disease of the liver that causes a cycle of immune injury to biliary epithelial cells, resulting in cholestasis and fibrosis. The origin of the autoimmune response is believed to be the production of cytotoxic T-cells and B-cell derived autoantibodies directed towards the epithelial cells of the small bile ducts in the liver, resulting in inflammation and damage to the duct cells and eventually destroying the bile ducts. This destruction results in the accumulation of bile acids in the liver, a condition known as cholestasis, to levels that are toxic to the liver cells, resulting in destruction of liver cells and fibrosis. PBC can culminate in liver failure, necessitating the need for a liver transplant. PBC is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 140,000 patients in the United States. The annual incidence for PBC ranges from 0.3 to 5.8 cases per 100,000 in the United States.

Early symptoms include fatigue, itchy skin, dry eyes and mouth dryness. As the disease progresses, there is pain in the upper right abdomen, musculoskeletal pain, edema, jaundice, osteoporosis, elevated cholesterol and hypothyroidism. If untreated, the active liver tissue is destroyed and replaced by fibrous tissue, leading to cirrhosis liver failure and the need for a liver transplant. Individuals with PBC are also at a greater risk than the general population of developing hepatocellular carcinoma.

Current Treatments for PBC

Ursodeoxycholic acid, a generic drug also known as ursodiol, or UDCA, and obeticholic acid, marketed as Ocaliva by Intercept Pharmaceuticals, are the only FDA-approved treatments for PBC. Both of these agents are bile acid analogs whose mechanisms of action aim to protect the liver from damage caused by endogenous bile acids and inhibition of bile acid synthesis. These drugs are primarily anticholestatic. Neither of these drugs specifically addresses the autoimmune response that is believed to drive PBC or the inflammatory consequences of the autoimmune response. Approximately one-third of PBC patients do not respond adequately to UDCA and are at risk of requiring liver transplant. Despite showing improvements in liver enzymes in the blood, there is no clinical information currently available to show whether patients treated with OCALIVA live longer or if their symptoms improve. Although systemic corticosteroids have been shown to alleviate PBC symptoms, their adverse event profile limits their treatment potential.

Setanaxib Clinical Development

Based on earlier Phase 2 data and recent positive Phase 1 data, we initiated a Phase 2b trial in PBC. We believe that setanaxib is differentiated from other approved or late-stage development candidates in PBC, due to its effect on fibrosis, inflammation and potentially significant impact on fatigue, as seen in the Phase 2 trial. Setanaxib was developed initially by the Genkyotex group of companies, now our wholly-owned subsidiaries.

In a Phase 2 trial conducted by Genkyotex and concluded in 2019, setanaxib did not reach its selected primary endpoint of change in GGT (Gamma-glutamyl Transferase); however, it showed an effect on the secondary endpoint of ALP (Alkaline Phosphatase) and an effect on fibrosis as measured by a variety of biomarkers as well as Fibroscan. It also resulted in a statistically significant impact on fatigue, the most commonly reported symptom of PBC, and is the only drug candidate, to our knowledge, to achieve this to date in this patient population.

In January 2021, Genkyotex reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib. The Phase 1 trial assessed the safety and pharmacokinetics of oral setanaxib at selected doses in 46 healthy adult male and female subjects. The trial consisted of a single ascending dose, or SAD, part and a multiple ascending dose, or MAD, part with dosing up to 1600 mg/day. The trial demonstrated that setanaxib was generally well tolerated at the doses tested, with no safety concerns or dose-limiting toxicity being identified.

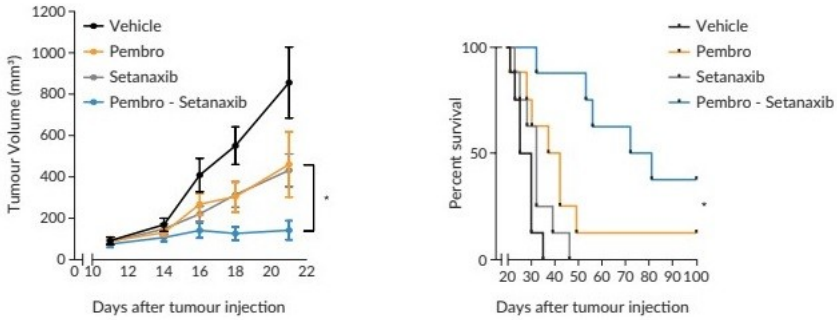
In August 2021, we received FDA Fast Track Designation for setanaxib in PBC. Based on the positive data from the Phase 1 trial of setanaxib doses up to 1600 mg/day, we have initiated a 24-week, randomized, placebo-controlled, double-blind Phase 2b trial in PBC, incorporating higher doses than previously used in the Phase 2 trial and using the change in ALP as the primary endpoint. The first patient was randomized in this trial in February 2022. Setanaxib will be administered to approximately 70-80 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to UDCA in a global trial conducted in 80 to 130 investigational centers in North America, Europe, Israel, Australia and New Zealand. The primary endpoint is ALP reduction, with key secondary endpoints including change in liver stiffness and effect on fatigue and pruritus (itching). The trial will evaluate two dosing regimens of 800mg AM + 400mg PM, and 800mg twice daily.

Setanaxib – SCCHN

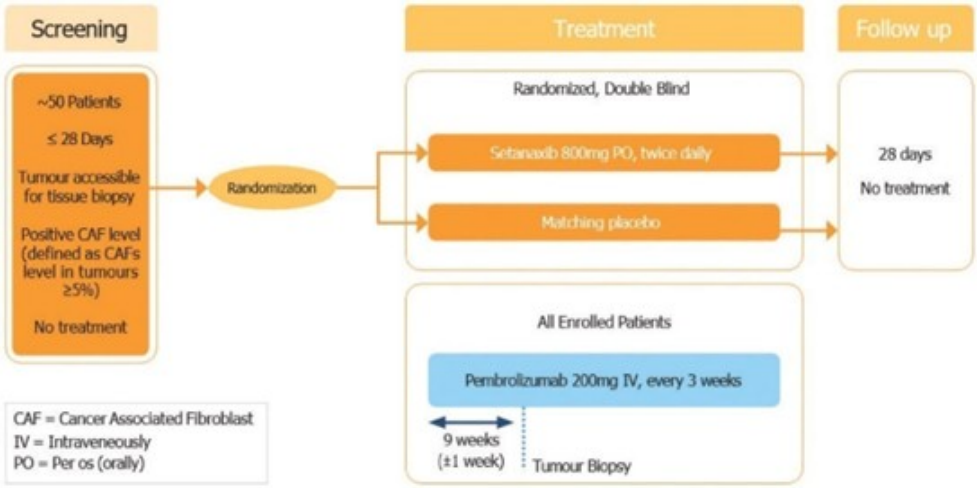
We are also evaluating setanaxib in head and neck cancer, building on promising *in vivo* preclinical data that suggests that setanaxib could function as an adjunct therapy to immune-oncology therapies. The response to immuno-oncology therapies can be affected by the tumor microenvironment, in particular by the numbers of tumor-infiltrating lymphocytes, or TILs, and cancer-associated fibroblasts, or CAFs, in the tumor. A relationship between CAFs and prognosis in squamous cell carcinoma of the head and neck, or SCCHN, has been established.

NOX4 is highly over-expressed in CAFs and drives myofibroblastic activation within tumors, shielding them from CD8+ TILs. Targeting CAFs with setanaxib could improve patients' responses to immunotherapies, and function as an adjunct therapy. There is increasing use of pembrolizumab as first-line monotherapy in patients with relapsed or metastatic SCCHN, although response rates are low (ORR approx. 20%).

Using a CAF-rich tumor model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in improved penetration of TILs into the center of the tumor and slowing of tumor growth and improved survival.



We are conducting a Phase 2 proof-of-concept study in patients with head and neck cancer, which will investigate administration of setanaxib in conjunction with immunotherapy targeting CAFs. The graphic below depicts the trial design.



The study will enroll approximately 50 patients. The first patient was randomized in the second quarter of 2022 and enrolment completed in the fourth quarter of 2023. The final analysis of the study is expected in the second quarter of 2024. An interim assessment of biomarker data (not subject to formal statistical analysis) conducted in mid-2023 provided evidence supporting that setanaxib may modulate gene expression associated with fibrosis pathways that have potential relevance for the tumor microenvironment.

Setanaxib – Other Indications

Alport syndrome is a genetic disease of collagen including mutations in COL4A3, COL4A4 and/or COL4A5. Prevalence is approximately 1 in 50,000 live births with a prevalence estimated to 30 – 60,000 persons in the US. It accounts for an estimated 3% of chronic kidney disease in children and 0.2% of adults with end-stage kidney disease in the United States. It is the second most common monogenic cause of chronic kidney disease after autosomal dominant polycystic kidney disease. Patients have a family history of kidney disease, urine abnormalities (haematuria, proteinuria) hearing impairment (sensorineural hearing loss), visual impairment (lens and retinal abnormalities). There are no approved treatments today, with RAS inhibitors used as supportive care.

Based on supportive pre-clinical data generated during 2022, we initiated a Phase 2a study with setanaxib in patients with Alport syndrome in November 2023; we plan to enroll 18 patients into the study. The study treatment period will be 24 weeks with the primary objective to investigate safety and tolerability, with secondary endpoints related to reduction of UPCR.

Setanaxib is also being evaluated in two Phase 2 investigator led trials. One is being conducted in type 1 diabetic kidney disease, or DKD. In addition, a grant from the United States National Institutes of Health, or NIH, of $8.9 million was awarded to the University of Alabama at Birmingham to fund a multi-year research program evaluating the role of NOX enzymes in idiopathic pulmonary fibrosis, or IPF, a chronic fibrosing lung disease. The core component of this program is a randomized, placebo-controlled Phase 2 trial with setanaxib in patients suffering from IPF, with topline data readout expected in the fourth quarter of 2024.

We believe this platform also has several other potential applications across orphan indications, focusing on anti-fibrotic and anti-inflammatory applications. Subject to positive data from ongoing trials, we could also see setanaxib as an important potential drug candidate for larger indications in oncology and NASH. Setanaxib is the lead compound, complemented by a research effort focused on developing follow up compounds.

Collaborations and License Agreements

License Agreement with Everest

In 2019, we entered into a license agreement with Everest, pursuant to which we granted Everest an exclusive, royalty-bearing, non-transferable (other than in connection with a change of control transaction) license to develop, manufacture and commercialize Nefecon for IgAN, which Everest may exercise its option to develop Nefecon in other potential indications, if and when we initiate a registrational clinical study in such indications, which we collectively refer to as the Licensed Product. The territories covered by the Everest license are Greater China, including mainland China, Taiwan, Hong Kong and Macau, and Singapore which we collectively refer to as the Territories. In March 2022, we expanded the territory covered by the agreement to include the Republic of Korea.

Pursuant to the terms of the Everest license, Everest must use commercially reasonable efforts to develop the Licensed Product and to obtain, support and maintain approval of the Licensed Product in the Territories. Everest is also entitled to sublicense the rights granted under the Everest license to its affiliates and to other third-parties with our prior consent.

As initial consideration for the license, Everest paid us an upfront payment of $15.0 million and in March 2022, in connection with the expansion of the agreement, Everest paid us an additional upfront payment of $3.0 million. Additionally, as of December 2023, Everest has paid us an aggregate of $21.0 million in regulatory milestones and is required to pay us additional milestone payments of up to $85.0 million upon the achievement of specified regulatory and commercial milestones. Everest is also required to pay tiered royalties of a high single digit to mid-teens percentage on annual net sales of the Licensed Product, subject to customary reductions.

Unless earlier terminated, the Everest license will expire upon the expiration of the last-to-expire royalty term for the Licensed Product in the Territory. The royalty term will terminate on a country-by-country basis on the later of (i) twelve years from the first commercial sale of the Licensed Product in such country, (ii) the expiration of the last to expire valid claim of the licensed patents and any patents covering licensed intellectual property in such country or region, or (iii) the expiration of all regulatory exclusivity for such Licensed Product in such country or region. Upon expiration of the Everest license, the licenses granted to Everest will be considered fully paid-up, perpetual and irrevocable. Either party may terminate the Everest license upon a material breach by the other party and failure to cure such breach within a specified period. The Everest license is also terminable in the event of bankruptcy, insolvency, dissolution or winding up of the other party. Everest has the right to terminate the license agreement for convenience by providing 12 months written notice to us. We have the right to terminate the license agreement in full upon 30 days prior written notice to Everest in the event that Everest, their affiliates or sublicensees directly challenge the patentability, enforceability or validity of any licensed patents.

License Agreement with STADA

On July 21, 2021, we entered into a license agreement with STADA, to register and commercialize Nefecon for IgAN in the EEA, Switzerland and the UK. Under the terms of the agreement, Calliditas is entitled receive an initial upfront payment of €20 million upon signing and up to an additional €77.5 million in future payments linked to pre-defined regulatory and commercialization milestones, for a total value of €97.5 million, plus royalties. Of these amounts, as of December 31, 2023, STADA has paid the initial upfront payment of €20 million and two milestones totaling €12.5 million. STADA is obligated to pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

License Agreement with Viatris

In December 2022, we entered into a license agreement with Viatris, pursuant to which we granted Viatris an exclusive, royalty-bearing, non-transferable license to develop, manufacture and commercialize Nefecon for IgAN in Japan. Under the terms of the agreement, we received an initial upfront payment of $20 million upon signing the agreement, and we are eligible to receive future payments upon the satisfaction of specific development and commercial milestones of up to an additional $80 million. As of December 31, 2023, we have received the initial upfront payment of $20 million. Viatris is also required to pay typical mid-teens percentage royalties on net sales.

Manufacturing

We rely on third parties to manufacture Nefecon. We have agreements with a third-party vendors to produce drug substance and drug product for Nefecon for our commercial needs and ongoing and planned clinical trials.

In December 2020, we entered into a Manufacturing Services Agreement ("MSA") with Patheon Pharmaceutics Inc. ("Patheon"), a wholly-owned subsidiary of Thermo Fisher Scientific Inc., for certain manufacturing and quality control services. The MSA governs the general terms under which Patheon, or one of its affiliates, will provide non-exclusive manufacturing services for products specified by us from time to time. Each project under the MSA will be governed by a specific project agreement. Upon the entry of the MSA, the parties entered into a project agreement that provides for the manufacturing of Nefecon, pursuant to which Patheon will manufacture commercial supply of Nefecon from active pharmaceutical ingredient that we supply. The MSA and the Nefecon product agreement each have an initial term that expires on December 31, 2026, subject to renewal terms, as applicable. The MSA has customary termination and cancellation terms.

We require all of our contract manufacturing organizations, or CMOs, to conduct manufacturing activities in compliance with current good manufacturing practice, or cGMP, requirements. We currently rely solely on these CMOs for scale-up and process development work and to produce sufficient quantities of our commercial product and product candidates for use in clinical trials. We anticipate that these CMOs will have the capacity to support both clinical supply and commercial-scale production. We may also elect to enter into agreements with other CMOs to manufacture supplies of drug substance and finished drug product.

Competition

The pharmaceutical industry is characterized by rapid evolution of technologies and intense competition. While we believe that our products, product candidates, technology, knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

Smaller or earlier-stage companies, may also prove to be significant competitors, particularly through collaborative arrangements with large established companies. These companies may also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, enrolling patients in clinical trials and acquiring technologies complementary to, or necessary for, our programs.

A competitor may obtain FDA or other foreign regulatory approvals for their products more rapidly than we may obtain approvals for our product candidates, which could result in such competitor establishing a strong market position before we are able to commercialize our product candidates. In addition, the availability of reimbursement from government and private payors will also significantly impact the pricing and competitiveness of our products.

Nefecon, along with any other product candidates that we successfully develop and commercialize, competes with other approved treatment options, including off-label therapies, and new therapies that may become available in the future. Key considerations that impact our ability to effectively compete with other therapies include the efficacy, safety, method of administration, cost, level of promotional activity, regulatory market exclusivity and intellectual property protection of our products. Many of the companies against which we may compete have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products.

On December 20, 2023 the FDA has approved TARPEYO (budesonide) delayed release capsules to reduce the loss of kidney function in adults with IgAN at risk for disease progression. TARPEYO was first approved in December 2021 under accelerated approval, based on the surrogate marker of proteinuria.

In February 2023, the FDA conditionally approved FILSPARI (sparsentan), an orally-administered small molecule indicated to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5 gram/gram. FILSPARI was developed and is commercialized by Travere Therapeutics, Inc. (previously Retrophin Inc.). This approval was granted based on positive proteinuria results from the Phase 3 trial with no supportive eGFR being presented. Due to risks of liver injury and birth defects, FILSPARI was approved with a boxed warning concerning hepatotoxicity and embryo-fetal toxicity and is only available through a restricted distribution program called the FILSPARI Risk Evaluation and Mitigation Strategies (REMS), requiring liver enzyme testing before initiation of treatment, monthly for the first year of treatment, and every three months thereafter and, for female patients, pregnancy testing before initiation of treatment and monthly thereafter. Prior to initiating treatment with FILSPARI, physicians are advised to discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs) or aliskiren. In September 2023, Travere Therapeutics announced that the Phase 3 Protect Study of FILSPARI missed its primary eGFR total slope endpoint vs. active control. In March 2024, Travere Therapeutics filed an sNDA seeking full approval of FILSPARI in the US.

In the fourth quarter of 2023, Novartis announced Phase 3 data from their IgAN studies with iptacopan (Factor B complement inhibitor) and atrasentan (endothelin receptor antagonist), and we anticipate that Novartis will file with the FDA for accelerated approval in 2024. Additionally, Novartis has also announced the commencement of a Phase 3 IgAN study with zigakibart (an anti-APRIL monoclonal antibody (mAb)). Both atrasentan and zigakibart were obtained by Novartis via the acquisition of Chinook Therapeutics in 2023.

We are aware of three additional Phase 3 IgAN programs that are ongoing and/or enrolling in the United States and Europe. Roche initiated their Phase 3 study with (licensed via Ionis Pharmaceuticals) IONIS-FB-L_{Rx}, Factor B complement inhibitor), Vera Therapeutics with atacicept (BAFF / APRIL inhibitor), Otsuka Corporation with sibeprenlimab (anti-APRIL mAb).

According to publicly available sources, several companies are developing product candidates for IgAN, including Alpine Immune Sciences Inc., BioCryst, Arrowhead Pharmaceuticals, Takeda, Alnylam Pharmaceuticals, AstraZeneca (with its subsidiary Alexion Pharmaceuticals), DiaMedica Therapeutics, MorphoSys, and Kira Pharma.

With respect to PBC, UDCA, a generic drug, and obeticholic acid, marketed as Ocaliva by Intercept Pharmaceuticals, Inc., are the only FDA-approved treatments for PBC. Additionally, we are aware that other companies are developing product candidates with pharmacologies distinct from setanaxib for this indication, the most advanced being peroxisome proliferator-activating receptor, or PPAR, agonists developed by Cymabay Therapeutics Inc, and Ipsen together with GENFIT SA which both have filed their INDs with the FDA during the fourth quarter of 2023 seeking approval for the treatment of PBC. Zydus Pharmaceuticals (USA) Inc. is also exploring a PPAR agonist in a Phase 2b/3 study. GlaxoSmithKline plc is conducting Phase 3 development of linerixibat, a sodium-bile acid cotransport inhibitor, for managing the pruritus symptoms of PBC. Additional compounds are in earlier phases of development.

Additionally, systemic corticosteroids, like prednisone, have been shown to alleviate symptoms associated with PBC but are associated with increased rates of osteoporosis.

There are currently no approved therapies for the treatment of AIH in the United States and there are few product candidates in development for this indication. We are aware of an injectable immunosuppressive monoclonal antibody in Phase 2/3 clinical development by Novartis AG and Kezar Life Sciences has initiated a Phase 2 study with zetomipzomib. The standard of care for the treatment of AIH includes immunosuppressive systemic corticosteroids, typically prednisone, alone or in combination with azathioprine.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the technologies incorporated into, or used to produce, our product candidates, including compositions of matter of our product candidates and their methods of use, as well as other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that we do not consider appropriate for patent protection, including certain aspects of our technology and drug product manufacturing. Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

Patents

The patent positions for biotechnology companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our technologies and product candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the inventions and patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

With regard to Nefecon, we co-own one patent family with Kyowa Kirin Services Ltd., f/k/a Archimedes Development Ltd., to which we have a sole and exclusive global license, even in relation to the other co-owner, in any field of use. This patent family protects a formulation for the oral delivery of budesonide and the medicinal use thereof. The patents in this patent family expire in 2029 provided all renewal fees are paid within the prescribed period, which we intend to do. The patents in this family include a United States patent, a patent in each of China, Hong Kong and Japan and a European patent that has been validated in 15 countries (Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, the UK, Italy, the Netherlands, Norway, Poland, Sweden and Turkey). The patents in this family are not eligible for extension in the United States because the active ingredient is used in existing approved drugs. In Europe, extension of the patents is not likely subject to the recent judgement of litigation in the EU, CJEU C-443/17, related to the degree to which it is possible to obtain a Supplementary Protection Certificate for a previously authorized active ingredient. In January 2024, the USPTO issued a new patent to us relating to the method of treating IgA nephropathy which expires in 2043.

With regard to the NOX estate, there are four patent families covering various aspects of the setanaxib asset derived from four PCT applications. The composition of matter and certain methods of therapy are covered in two of these patent families. The third covers the use of setanaxib in certain oncology indications, including head and neck cancer. The fourth covers the use of setanaxib in the prevention and/or treatment of an osteoclastogenesis dysfunction related with increased bone turnover or bone resorption of secondary cause and/or osteoporosis. There is one additional patent family that covers other NOX inhibitors and their use. As our NOX inhibitor patents and applications cover new chemical entities, the territorial coverage is generally quite wide, and as the compounds do not yet form part of an approved drug product, patent life may potentially be extended in countries where legislation provides for patent term extension. The two families covering setanaxib's composition of matter have projected expiry dates in 2028 and 2029, excluding potential extensions.

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, we believe we have gained significant know-how related to the composition, manufacturing process and the drug release performance of Nefecon through our extensive product development work. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. These agreements generally provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These agreements also generally provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Government Regulation

Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the EC following a positive opinion provided by the EMA through the marketing authorization application process for a drug falling within the scope of the centralized procedure or by a national Competent Authority through other marketing authorization application processes (national procedure, mutual recognition or decentralized procedure) before they may be legally marketed in the EU. Medicines with orphan designation fall within the mandatory scope of the centralized procedure. Our product candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable US requirements at any time during the drug development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including imposition of a clinical hold, refusal by the FDA to approve applications, withdrawal of an approval, import/export delays, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are governed by extensive regulation by governmental authorities in the United States and other countries. The steps required by the FDA before a drug may be approved for marketing in the United States generally include:

- completion of extensive preclinical, laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- the submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials commence;
- approval by an IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials, in accordance with applicable IND and GCP requirements, to establish the safety and efficacy of the drug for each proposed indication;
- preparation and submission to the FDA of an NDA;
- FDA acceptance, review and approval of the NDA, which might include an advisory committee review;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the drug, or components thereof, are made to assess compliance with current good manufacturing practices, or cGMPs; and
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data; and agreement for compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and any post-approval studies required by the FDA.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain. The FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Preclinical and Human Clinical Trials in Support of an NDA

Preclinical studies include laboratory evaluations of the product candidate, as well as in vitro and animal studies to assess the potential safety and efficacy of the product candidate. The conduct of preclinical studies is subject to federal regulations and requirements including GLP regulations. The results of the preclinical studies, together with manufacturing information and analytical data, among other things, are submitted to the FDA as part of the IND, which must become effective before human clinical trials may commence. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time and places a clinical hold on the IND. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. The FDA may nevertheless initiate a clinical hold after the 30 days if, for example, significant public health risks arise.

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, subject selection and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Each clinical trial must be reviewed and approved by an IRB at or servicing each of the sites at which the trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completion.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap or be combined. These phases generally include the following:

Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.

Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks.

Phase 3. If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 clinical trials, the clinical trial program will be expanded to Phase 3 clinical trials to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites.

In some cases, the FDA may approve an NDA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in enforcement action or withdrawal of approval. Companies that conduct certain clinical trials also are required to register them and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Progress reports detailing the results of clinical trials, among other information, must be submitted at least annually to the FDA. Within 15 calendar days after the sponsor determines that the information qualifies for reporting, written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk to humans exposed to the drug and any clinically important increase in the rate of a serious adverse reaction over that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must have in place methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and testing and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Submission and FDA Review of an NDA

The results of preclinical studies and clinical trials, together with detailed information on the drug's manufacture, composition, quality, controls and proposed labeling, among other things, are submitted to the FDA in the form of an NDA, requesting approval to market the drug for one or more indications. The application must be accompanied by a significant user fee payment, which typically increases annually, although waivers may be granted in limited cases. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The FDA has substantial discretion in the approval process and may refuse to file or approve any application or decide that the data are insufficient for approval and require additional preclinical, clinical or other studies.

Once an NDA has been accepted for filing, the FDA sets a user fee goal date that informs the applicant of the specific date by which the FDA intends to complete its review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 10 months from the receipt of an NDA for a non-new molecular entity in which to complete its initial review of a standard NDA and respond to the applicant. The review process can be extended by FDA requests for additional information or clarification. The FDA reviews NDAs to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMPs to assure and preserve the drug's identity, strength, quality and purity. Before approving an NDA, the FDA typically will inspect the facilities at which the drug is manufactured and will not approve the drug unless the manufacturing facilities comply with cGMPs. Additionally, the FDA will typically inspect one or more clinical trial sites for compliance with GCP and integrity of the data supporting safety and efficacy.

During the approval process, the FDA also will determine whether a REMS is necessary to assure the safe use of the drug. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS, and the FDA will not approve the application without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information.

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities and clinical trial sites, the FDA will issue either an approval of the NDA or a Complete Response Letter, detailing the deficiencies in the submission and the additional testing or information required for reconsideration of the application. FDA may also issue a Complete Response Letter or defer action on an application if the agency has determined that a pre-approval inspection of an applicant's manufacturing facilities is necessary and the agency is unable to complete such an inspection due to the COVID-19 pandemic. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application or request a hearing. Even with submission of this additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a new drug, it may limit the approved indications for use of the drug. It may also require that contraindications, warnings or precautions be included in the drug labeling, such as a special warning, known as a boxed warning, to highlight a particular safety risk. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the drug's safety after approval. The agency may also require testing and surveillance programs to monitor the drug after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the drug outweigh the potential risks. The FDA may prevent or limit further marketing of a drug based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved drug, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track and Breakthrough Designations and Priority Review

The FDA is authorized to designate certain drugs for expedited programs, including fast track designation, breakthrough therapy designation, and priority review, if they demonstrate the potential to address an unmet medical need and are intended for the treatment of a serious or life-threatening disease or condition. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

The FDA may designate a drug for fast track designation if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. For fast track designated drugs, sponsors may have a higher number of interactions with the FDA during preclinical and clinical development. In addition, the FDA may review sections of the NDA for a fast track designated drug on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product is eligible for priority review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

The FDA may designate a drug for breakthrough designation if the drug, alone or in combination with one or more other drugs, is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. The feature of this program allows the same advantages of the fast track designation, but also intensive FDA guidance to promote efficient development and FDA organizational commitment.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the drug has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. The benefit of accelerated approval derives from the potential to receive approval based on surrogate endpoints sooner than possible for trials with clinical or survival endpoints, rather than deriving from any explicit shortening of the FDA approval timeline, as is the case with priority review.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the drug.

All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Requirements

In additional to the post-approval requirements specific to an accelerated approval pathway, there are other post-approval requirements whatever the registration pathway.

Approved drugs that are manufactured or distributed in the United States pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, drug sampling and distribution, advertising and promotion and reporting of adverse experiences with the drug. After approval, most changes to the approved drug, such as adding new indications or other labeling claims and some manufacturing and supplier changes are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for marketed drugs, as well as new application fees for certain supplemental applications.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance programs to further assess and monitor the drug's safety and effectiveness after commercialization. The FDA may also require a REMS, which could involve requirements for, among other things, medication guides, special trainings for prescribers and dispensers, patient registries, and elements to assure safe use.

In addition, entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA has promulgated specific requirements for drug cGMPs. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market. Corrective action could delay drug distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug, suspension of the approval, complete withdrawal of the drug from the market or product recalls;

- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of drugs that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different product for the same disease or condition, or the same product for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the application user fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than or different from the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

FDA Marketing Exclusivity Provisions for Drugs

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, as amended, certain NDAs or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the drug for use in adults, or full or partial waivers from the pediatric data requirements if certain criteria are met.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent marketing and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the drug to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of FDA-requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

EU Regulation for Drug Development and Registration

Preclinical and Clinical Development

In the EU, our product candidates are also subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20, or CTD, and related national legislation of EU Member States. The CTR has been fully applicable to all clinical trials commenced from January 31, 2023.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increasing their transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. For clinical trials in relation to which application for approval was made on the basis of the CTD before January 31, 2022, the CTD will continue to apply on a transitional basis for three years. These clinical trials will be governed by the CTD until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the clinical trial has already transitioned to the CTR framework.

European Drug Review and Approval

To obtain a marketing authorization, or MA, for a product in the EEA (which is comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein), an applicant must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the EC that is valid for all EU Member States and plus Norway, Iceland and Liechtenstein. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients authorization through, the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (CHMP) is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application process is the same as the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralized Procedures – Human (CMDh) for review. The subsequent related decision of the EC is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has an initial validity of five years in principle. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The EC or the competent authorities of the EU Member States may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the US PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

Within this framework, manufacturers may seek approval of medicinal products under the hybrid application pathway in accordance with Article 10(3) of Directive 2001/83/EC. Hybrid MAAs rely, in part, on information and data from a reference product and new data from appropriate pre-clinical tests and clinical trials. In accordance with Article 10(3) of Directive 2001/83/EC, hybrid applications are relevant in cases where the medicinal product does not fall within the definition of a generic medicinal product, where bioequivalence cannot be demonstrated through bioavailability studies, or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic product compared to the reference medicinal product. In such cases the results of tests and trials must be consistent with the data content standards required in the Annex to Directive 2001/83/EC. Hybrid MAAs have automatic access to the centralized procedure when the reference product was authorized for marketing via that procedure. Where the reference product was authorized through the national, mutual recognition or decentralized procedure, a hybrid application may be accepted for consideration under the centralized procedure if the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation, or that grant of a centralized authorization for the medicinal product is in the interest of patients at the EU level.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The EC may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the EC, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU and national EU Member State laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU and national EU Member State laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States. MA holders and/or manufacturing and import authorization, or MIA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Orphan Drugs

In the EU, Regulation (EC) No 141/2000, as amended, provides that a drug will be designated as an orphan drug if its sponsor can establish:

- that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition and either (i) such condition affects not more than five in ten thousand persons in the EU when the application is made, or (ii) without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment in its development; and

- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, that the drug will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a drug as an orphan drug. An application for the designation of a drug as an orphan drug must be submitted at any stage of development of the drug but before filing of a MA application. A MA for an orphan drug may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate MA has to be sought.

If a centralized MA in respect of an orphan drug is granted pursuant to Regulation (EC) No 726/2004, regulatory authorities will not, for a period of usually 10 years, accept another application for a MA, or grant a MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a "similar medicinal product". A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity.

The exclusivity period may increase to 12 years if the MA application includes the results of studies from an agreed pediatric investigation plan. Notwithstanding the foregoing, a MA may be granted, for the same therapeutic indication, to a similar medicinal product if:

- the holder of the MA for the original orphan drug has given its consent to the second applicant;

- the holder of the MA for the original orphan drug is unable to supply sufficient quantities of the drug; or

- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

The EC is currently looking into the experience gathered with the orphan and pediatric regulations and may propose changes to the incentives and rewards as they exist today. The EC submitted its proposal in March 2023.

Regulation (EC) No 847/2000 lays down definitions of the concepts ‘similar drug’ and ‘clinical superiority’. Other incentives available to orphan drugs in the EU include financial incentives such as a reduction of fees or fee waivers and protocol assistance. Orphan drug designation in itself does not shorten the duration of the regulatory review and approval process but an applicant’s request for an accelerated review may be granted in case the medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation.

Data and marketing exclusivity

The EEA also provides opportunities for market exclusivity. Upon receiving a marketing authorization in the EEA, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator’s pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization during a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator’s data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies.

Regulatory Requirements after Marketing Authorization

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

Advertising Regulation

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States’ laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product’s Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Coverage, Pricing, and Reimbursement

Significant uncertainty exists in the United States as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. Sales of our products will depend, in part, on the extent to which our products, once approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Adequate coverage and reimbursement from third party payors are critical to new product acceptance. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the US Department of Health and Human Services, or HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third party payors. Third-party payors decide which therapeutics they will pay for and establish reimbursement levels. These third-party payors are increasingly reducing reimbursement levels for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

To secure coverage and reimbursement for any product candidate approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. Third-party reimbursement may not be sufficient to enable us to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The United States federal government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, utilization management and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for Nefecon or any of our product candidates, if approved, or a decision by a third-party payor to not cover such products could reduce physician usage of the product and could have a material adverse effect on our sales, results of operations and financial condition.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, in the EU Member States can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and they can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Approaches between Member States are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if third party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

On December 15, 2021, the Health Technology Regulation, or HTA Regulation, was adopted. The HTA Regulation is intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. When it enters into application in 2025, the HTA Regulation will be intended to harmonize the clinical benefit assessment of HTA across the European Union.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, ACA, enacted in the United States in March 2010, has already had, and is expected to continue to have, a significant impact on the healthcare industry. The ACA has expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA: (i) created an annual, nondeductible fee on entities that manufacture or import certain branded pharmaceutical products; (ii) expanded and increased industry rebates for drugs covered under Medicaid programs; and (iii) made changes to the coverage requirements under the Medicare Part D program, including a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. Specifically, the Joint Select Committee on Deficit Reduction was created to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013 and which, due to subsequent legislative amendments will stay in effect through 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Further, on January 2, 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA. The ATRA, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent US Congressional inquiries, Presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services, ("CMS"), Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve the quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

Brexit and the Regulatory Framework in the UK

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has changed the regulatory relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator for medicinal products and medical devices. Great Britain (England, Scotland and Wales) is now a third country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules for now.

Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is now considered a "third country," a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland will continue to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods.

Marketing authorizations in the UK are now governed by the Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for the EU centralized procedure marketing authorization can no longer be established in the UK. As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorization to market products in the UK. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. Northern Ireland currently remains within the scope of EU authorizations in relation to centrally authorized medicinal products. Accordingly, until the Windsor Framework is implemented in Northern Ireland on January 1, 2025, products falling within the scope of the EU centralized procedure can only be authorized through UK national authorization procedures in Great Britain.

The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may also rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in Great Britain, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in Great Britain.

The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, it is currently unclear to what extent the UK will seek to align its regulations with the EU following entry into application of the Clinical Trials Regulation on January 31, 2022.

It is currently unclear what the UK regulatory arrangements will be in the future. The MHRA have taken steps to build relationships and partnerships with other global regulators such as joining the ACCESS group (Canada, Australia, Switzerland and Singapore) and taking part in Project Orbis, which is an FDA-led project. The future regulatory system and these partnerships may provide alternative routes to market in the UK and beyond.

Other US Healthcare Laws and Compliance Requirements

Our business operations in the United States and our arrangements with clinical investigators, healthcare providers, consultants, third-party payors and patients expose us to broadly applicable federal and state fraud and abuse and other healthcare laws. These laws may impact, among other things, our research, sales, marketing and education programs. The laws that may affect our ability to operate include, among others:

- the US federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA;

- federal civil and criminal false claims laws, including the FCA, which can be enforced by private individuals through civil whistleblower or qui tam actions, and civil monetary penalty laws, which prohibit individuals and entities from, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willingly falsifying, concealing or covering up a material fact or making materially false statements, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items, or services. A person or entity does not have to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes certain requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their business associates, which are individuals and entities that perform functions or activities on behalf of covered entities that involve protected health information as well as their covered subcontractors, relating to the privacy, security and transmission of protected health information; HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of drugs for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians (as defined by such law), other healthcare professionals (such as physicians assistants and nurse practitioners) and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members; and

- state and foreign equivalents of each of the above federal laws and regulations, such as: state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require the reporting of information related to drug pricing; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require the registration of pharmaceutical sales representatives; and state and/or foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

The ACA broadened the reach of the federal fraud and abuse laws by, among other things, amending the intent requirement of the US federal Anti-Kickback Statute and certain federal criminal healthcare fraud statutes. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the US federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA or the civil monetary penalties laws.

In the ordinary course of our business, we may process personal or sensitive data. We may be subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, HIPAA, as amended by HITECH, and their implementing regulations, the California Consumer Privacy Act of 2018 ("CCPA"), the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"), and the ePrivacy Directive. Several states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data. The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance.

We may develop products that, once approved, may be administered by a physician. Under currently applicable US law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors.

In order to distribute any approved products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws involves substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to, for example, significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to administrative, civil, and/or criminal sanctions, including exclusions from government funded healthcare programs.

Employees and Human Capital Resources

As of December 31, 2023, we had 217 full-time employee equivalents. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. Other objectives include diversity and inclusion, employee development, training and safety. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

None of our personnel are covered by a collective bargaining agreement. Collective bargaining agreements, or CBAs, can be entered into in Swedish law at the national, industry, or company levels. These CBAs are binding on both employers and employees. We have no trade union representation or CBAs at the company level, but CBAs may, however, change the employment conditions of our employees in the future and hence adversely affect our employment relationships.

Facilities

Our principal office is located at Kungsbron 1, D5, SE-111 22 Stockholm, Sweden. We lease approximately 1,552 square meters of office space at this location, under one lease agreement, and our lease for this location extends through December 31, 2026. We hold an option to extend our leases for three additional years. We believe that suitable additional or substitute space will be available as needed to accommodate any future expansion of our operations.

C. ORGANIZATIONAL STRUCTURE

As of December 31, 2023, we had five subsidiaries. The following table sets out for each of our principal subsidiaries, the country of incorporation, and percentage ownership and voting interest held by us (directly or indirectly through subsidiaries) as of December 31, 2023:

Company	Country of incorporation	Percentage ownership and voting interest	Main activity
Calliditas Therapeutics US Inc.	United States	100%	Biopharmaceutical company
Calliditas NA Enterprises Inc.	United States	100%	Biopharmaceutical company
Nefecon AB	Sweden	100%	Administrative company
Calliditas Therapeutics France SAS	France	100%	Biopharmaceutical company
Calliditas Therapeutics Suisse S.A.	Switzerland	100%	Biopharmaceutical company

D. PROPERTY, PLANTS AND EQUIPMENT

We lease our operational office, which consists of approximately 1,552 square meters located in Stockholm, Sweden. The lease for this facility expires in December 2026.

We have a total of five facilities worldwide owned or leased as of December 31, 2023, as set forth in the following table:

Facility location	Use	Approx. size (m^2)	Lease expiry
Sweden	Principal office	1,552	December 2026
France	Laboratory	155	July 2029
Switzerland	Office	526	August 2027
US	Office	502	October 2026
US	Office	169	July 2026

(i) Environment, Health and Safety

Our research and development activities take place in our facilities in Stockholm, Sweden, Geneva, Switzerland and Archamps, France. For these activities we have obtained the necessary environmental and biohazard permits from the responsible governments.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following "Operating and Financial Review and Prospects" should be read together with the information in our financial statements and related notes included elsewhere in this annual report. The following discussion is based on our financial information prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including US GAAP. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described in "Risk Factors" and elsewhere in this annual report. Please also see "Special Note Regarding Forward-Looking Statements."

A. OPERATING RESULTS

Overview

We are a commercial-stage pharmaceutical company with the first ever product approved in the US and in the EU for adult patients with the renal disease immunoglobulin A nephropathy, or IgAN, Nefecon, and a portfolio of innovative product candidates.

Nefecon is a proprietary, novel oral, delayed release formulation of budesonide designed to specifically target the presumed origin of the disease and provide a potentially disease modifying treatment of IgAN, for which there is a high unmet medical need. Budesonide is a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism, resulting in limited systemic exposure. IgAN is a progressive, chronic disease that over time results in deterioration of kidney function in patients, many of whom are at risk of developing ESRD, with the need for dialysis or kidney transplant. Nefecon is designed to target the origin of the disease presumed to be located in the ileum, the distal region of the small intestine, which has the highest concentration of the Peyer's patches, which are responsible for the production of pathogenic secretory immunoglobulin A, or IgA, antibodies.

The US Food and Drug Administration, or FDA, approved Nefecon under the brand name TARPEYO under accelerated approval on December 15, 2021 and we reported commercial availability in the United States in January 2022. Under accelerated approval, the indication for TARPEYO (budesonide) delayed release capsules (4mg) is reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio, or UPCR, ≥1.5gram/gram. In June 2023, we submitted a supplemental New Drug Application, or sNDA, to the FDA seeking to convert the accelerated approval to full approval for TARPEYO. On December 20, 2023, the FDA granted full approval to TARPEYO for a new indication to reduce the loss of kidney function in adults with IgAN who are at risk for disease progression. The European Commission, or EC, granted conditional marketing authorization for Nefecon under the name Kinpeygo (budesonide) capsules for the treatment of primary IgAN in adults at risk of rapid disease progression with a UPCR ≥1.5 gram/gram on July 15, 2022 and our licensee STADA Arzneimittel AG, or STADA, announced commercial availability in Germany in September 2022, and in Greece, under a Special Import License since June 2023. On February 1, 2023, the Medicines and Healthcare products Regulatory Agency, or MHRA, of the UK granted Conditional Marketing Authorization for Kinpeygo for the same indication as the EC. STADA has submitted requests to both the EMA, in September 2023, for the EU and to the MHRA, in October 2023, for the UK to convert the current conditional marketing authorization for these territories into a full marketing authorization. Nefecon received conditional approval from China's National Medical Products Administration on November 24, 2023 for the reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR, ≥1.5gram/gram and approval from the Pharmaceutical Administration Bureau of the Macau Special Administrative Region on October 27, 2023 for the same indication. Nefecon received conditional approval from Singapore's Health Science Agency for the reduction of proteinuria in adults with IgAN at risk of rapid disease progression, generally a UPCR ≥1.5 gram/gram to on March 19, 2024.

TARPEYO was the first treatment ever approved for the US market indicated for patients with IgAN. The FDA approved TARPEYO under the accelerated approval pathway based on the reduction in proteinuria and supportive data on the estimated Glomerular Filtration Rate, or eGFR, a measure of kidney function, shown in Part A of our pivotal NefIgArd trial. We reported topline results from the full NefIgArd clinical trial in March 2023. The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in eGFR over the two-year period of nine months of treatment with Nefecon or placebo and 15 months of follow-up off drug. The results indicate that Nefecon was generally well-tolerated and the safety profile was consistent with that observed in Part A of the trial. These results were the basis for the June 2023 sNDA submission to the FDA to convert the accelerated approval to full approval for TARPEYO.

Nefecon as TARPEYO was initially granted seven years orphan drug exclusivity in the United States, expiry December 15, 2028, which was recently extended to December 2030 based on receiving full approval. Kinpeygo, was granted ten years orphan market exclusivity by the EC, expiry July 15, 2032, and by the MHRA, expiring February 1, 2033.

We retain worldwide rights to Nefecon other than in territories where we have established strategic collaborations. In 2019, we entered into an agreement pursuant to which we granted Everest an exclusive license to develop and commercialize Nefecon for the treatment of IgAN in Greater China and Singapore, and in March 2022, we expanded the territory covered by the agreement to include the Republic of Korea. In July 2021, we entered into a license agreement with STADA to commercialize Nefecon for the treatment of IgAN in the European Economic Area, or EEA, the UK and, if approved, in Switzerland. In December 2022, we entered into an exclusive license agreement with Viatris, to register and commercialize Nefecon for the treatment of IgAN in Japan.

We are also developing a novel platform of nicotinamide adenine dinucleotide phosphate, or NADPH, oxidase, or NOX, inhibitors, which we intend to primarily develop for orphan diseases with fibrotic pathology, with a main focus on kidney and liver diseases. From this platform, we are developing setanaxib, a NOX inhibitor, for the treatment of primary biliary cholangitis, or PBC. We are currently evaluating setanaxib in the TRANSFORM study, a Phase 2b clinical trial, in which we randomized the first patient in February 2022. Setanaxib will be administered to approximately 60-70 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA in a global trial conducted in 80-130 investigational centers in North America, Europe, Israel, Australia, and New Zealand. The primary endpoint is alkaline phosphatase (ALP) reduction, with key secondary endpoints including change in liver stiffness and effect on fatigue and pruritus (itching). Following favorable safety data from a Phase 1 study, this trial will evaluate two dosing regimens of 1200mg/daily and 1600mg/daily. We expect to read out data in the third quarter of 2024, and this analysis will determine which dose of setanaxib will be used for a future potential Phase 3 study. Setanaxib was granted fast track designation by the FDA in August 2021. We are also conducting a proof of concept, Phase 2 clinical trial of setanaxib administered in conjunction with pembrolizumab, a check point inhibitor, in squamous cell carcinoma of the head and neck, or SCCHN, in order to explore setanaxib's use as a treatment approach in cancers with high levels of tumors associated fibroblasts, or CAFs. We are also currently conducting a Phase 2 clinical trial of setanaxib in Alport syndrome, which we initiated in November 2023.

Since our inception in 2004, we have devoted substantially all of our resources to conducting research and development of our product candidates, in-licensing and acquiring rights to our product candidates, business planning, building a US commercial operation, launching Nefecon in the US, raising capital and providing general and administrative support for our operations. To date, we have financed our operations primarily with proceeds from the sale of our equity, the upfront and milestone payments from the out-license of Nefecon to Everest, STADA, and Viatris, our debt facility with Athyrium, which we fully drew down and used part of the proceeds from the Credit Agreement to repay in full outstanding obligations under our loan agreement with Kreos and, more recently, from revenue from sales of TARPEYO. Through December 31, 2023, we had received net proceeds of SEK 2,523.8 million from the issuance of equity securities. In August 2021, we completed a directed new share issuance of 2.4 million shares for gross proceeds of SEK 324.0 million from Swedish and international institutional investors. In June and July 2020, we completed a new share issuance of 9.2 million shares, in connection with the initial public offering of our securities on Nasdaq (the "US IPO") and concurrent private placement, for gross proceeds of SEK 891.4 million from US and international institutional investors. In July 2019, we completed a directed new share issuance of 3.5 million shares for gross proceeds of SEK 210.3 million from Swedish and international institutional investors. We believe that our cash as of December 31, 2023 will be sufficient to fund our planned operations and capital expenditure requirements until we are profitable. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. There can be no assurance that Nefecon will be approved by additional regulatory authorities, or that we will be successful in commercializing TARPEYO in the United States, Kinpeygo in the EEA and UK, Nefecon in China and Macau, NEFEGAN in Singapore, or Nefecon in other jurisdictions, if approved. See "Item 3.D.—Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—We may need substantial additional funding in order to fund our operations. Failure to obtain this necessary capital at acceptable terms and when needed may force us to delay, limit or terminate certain or all of our operations and pursuit of our growth strategy."

We have incurred significant operating losses since our inception in 2004. For the years ended December 31, 2023 and 2022, we had a net loss of SEK 466.2 million and SEK 412.3 million, respectively. As of December 31, 2023 and 2022, we had an accumulated loss of SEK 2,305.6 million and SEK 1,836.3 million, respectively. These losses have resulted primarily from costs incurred in connection with research and development activities and administrative and selling activities associated with our operations. We expect to continue to incur significant expenses and may continue to incur operating losses for the foreseeable future, and we expect our expenses to increase in connection with our ongoing development activities and our activities related to developing our commercialization capabilities to support sales, marketing and distribution activities, either independently or in collaboration with others.

Until such time as we can generate increased revenue from product sales and royalties and milestones from our commercial partnerships to cover our costs, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, or other strategic transactions.

We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our development programs.

Basis of Presentation

License Agreement with Everest

In 2019, we entered into a license agreement with Everest, pursuant to which we granted Everest an exclusive, royalty-bearing, non-transferable license to develop, manufacture and commercialize Nefecon for IgAN, which at Everest's option, may be extended to other potential indications if and when we initiate a registrational clinical trial in such indications, which we collectively refer to as the Licensed Product. The territories covered by the Everest license are Greater China, including mainland China, Taiwan, Hong Kong and Macau, the Republic of Korea and Singapore, which we collectively refer to as the Territories. In March 2022, we announced the expansion of the Territories to include the Republic of Korea.

Under the terms of the agreement, we received an initial upfront payment of $15.0 million upon signing the agreement and in March 2022 in connection with the expansion of the agreement, we received an additional upfront payment of $3.0 million. Additionally, as of December 2023, Everest has paid us an aggregate of $21 million in regulatory milestones and is obligated to pay us additional milestone payments of up to $85 million upon achievement of specified regulatory and commercial milestones. Everest is also required to pay typical tiered royalties on annual net sales of the Licensed Product, subject to customary reductions. See "Item 4.B.—Business Overview—License Agreement with Everest."

License Agreement with STADA

In 2021, we entered into a license agreement with STADA, pursuant to which we granted STADA an exclusive, royalty-bearing, non-transferable license to develop, manufacture and commercialize Nefecon for IgAN in the EEA, Switzerland and the UK.

Under the terms of the agreement, we received an initial upfront payment of EUR 20.0 million upon signing the agreement, two milestones totaling EUR 12.5 million and we are eligible to receive future payments upon the satisfaction of specific regulatory and commercial milestones of up to an additional EUR 65.0 million, inclusive of option payments for the development of Nefecon in other potential indications. STADA is also required to pay typical tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties. See "Item 4.B.—Business Overview—License Agreement with STADA."

License Agreement with Viatris

In December 2022, we entered into a license agreement with Viatris, pursuant to which we granted Viatris an exclusive, royalty-bearing, non-transferable license to develop, manufacture and commercialize Nefecon for IgAN in Japan.

Under the terms of the agreement, we received an initial upfront payment of $20 million upon signing the agreement, and we are eligible to receive future payments upon the satisfaction of specific development and commercial milestones of up to an additional $80 million. Viatris is also required to pay typical mid-teens percentage royalties on net sales. See "Item 4.B.—Business Overview—License Agreement with Viatris."

Acquisition of a Controlling Interest in Genkyotex S.A.

In November 2020, we acquired a controlling interest in Genkyotex S.A., or Genkyotex, a biopharmaceutical company specializing in NOX therapies with offices in France and Switzerland. Genkyotex's unique platform enables the identification of orally available small molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis and inflammation. The acquisition of Genkyotex adds a late-stage orphan pipeline asset and platform in inflammation and fibrosis to our product portfolio in orphan diseases. In October 2021, we completed the purchase of the remaining share capital of Genkyotex by a squeeze-out offer, resulting in our ownership of 100% of the current share capital and the delisting of Genkyotex's securities from the Euronext stock exchanges.

We had no acquisition costs related to Genkyotex for the years ended December 31, 2022 and 2023. For the year ending December 31, 2021, acquisition costs related to Genkyotex, excluding transaction costs, amounted to EUR 4.9 million. In addition, in connection with the business combination, we have undertaken to make potential future milestone payments relating to contingent consideration, provided that future regulatory approvals or marketing authorizations regarding setanaxib are obtained. The transaction stipulates the following contingent consideration:

- Milestone 1: EUR 30.0 million if Genkyotex is granted the right to commercially manufacture, market and sell setanaxib in the United States by the FDA.
- Milestone 2: EUR 15.0 million if Genkyotex is granted the right to commercially manufacture, market and sell setanaxib in the EU by the EC.
- Milestone 3: EUR 10.0 million if Genkyotex is, by the FDA or EC, granted the right to commercially manufacture, market and sell setanaxib in the United States or EU for the treatment of IPF or Type 1 Diabetes.

Components of our Results of Operations

Revenue

In the first quarter of 2022, we launched our first commercial product, TARPEYO, in the United States and began to generate revenue from product sales. Revenue from product sales is recognized at the transaction price of goods sold excluding VAT, rebates and returns. At the time of delivery, when the control of the goods passes to the customer, the revenue is recognized in full, as this represents the single performance obligation in the transaction. The customer is defined as the specialty pharmacy who dispenses the good to the end user. As the final price is related to the rebate paid to the patients' insurance company, the transaction price is not known upon delivery. This is accounted for by an accrued estimated rebate deduction based on calculation models considering statistical data, actual amounts incurred and/or historical trends. These liabilities for expected returns and rebates are based on estimates of the amounts earned or to be claimed on the related sales. Furthermore, we estimate the liability for expected returns of obsolete medicines that is recognized in the accounts.

In 2021, we recognized revenue in connection with the execution of the license agreement with STADA and additionally upon triggering payments to us resulting from the satisfaction of a regulatory milestone under the Everest agreement. In 2022, we recognized revenue in connection with the execution of the license agreement with Viatris and additionally upon triggering payments to us resulting from the satisfaction of regulatory milestones under the Everest and STADA agreements, and we are eligible to receive future payments upon the satisfaction of specific clinical, regulatory and commercial milestones, as well as typical tiered royalties from these agreements. In 2023, we recognized revenue resulting from the satisfaction of regulatory milestones under the license agreement with Everest and we recognized revenues from tiered royalties from the license agreements with STADA and Everest. Revenue for license agreements is recognized at a point in time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreements with the parties were signed. Variable remuneration (for example, attributable to future regulatory milestones) is recognized when there is no longer any significant uncertainty as to whether these will occur. Compensation attributable to sales-based milestones or royalties are not recognized until the sale that results in the right to milestones or royalties arises.

We refer to revenue received from product sales and from our license agreements with Viatris, Everest and STADA as "net sales" in our consolidated financial statements. In addition to sales of Nefecon, we may generate revenue in the future from a combination of product sales and collaboration or license agreements, if our development programs for Nefecon, setanaxib and future product candidates are successful and result in approved and marketed products, or if we enter into additional collaboration or license agreements with third parties.

Cost of Sales

Cost of sales includes the cost of inventory sold, labor costs, manufacturing overhead expenses and reserves for expected scrap, as well as shipping and freight costs. Cost of sales also includes royalty costs related to in-license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our development activities, including the development of Nefecon, setanaxib and our other product candidates, and include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct clinical trials on our behalf, as well as contract manufacturing organizations, or CMOs, that manufacture drug products for use in our clinical trials;
- salaries, benefits and other related costs for our personnel engaged in research and development functions;
- costs of outside consultants, including their fees and related travel expenses, directly related to our research and development functions; and
- costs related to compliance with regulatory requirements.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as a prepaid expense or accrued expense. Swedish research and development tax credits on social security costs are recorded as an offset to research and development expense. See "—Income Taxes" below for further details.

From inception until October 2020, our research and development expenses were primarily for the development of Nefecon for the treatment of IgAN and from October 2020 through December 31, 2023, our research and development expenses have primarily been for the development of Nefecon for the treatment of IgAN and the setanaxib platform. As such, we do not track our internal research and development expenses on a product-by-product or indication-by-indication basis for product candidates. Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase as we:

- continue to develop and advance Nefecon, setanaxib, and any other product candidates;
- initiate and continue clinical development for Nefecon and setanaxib for PBC, head and neck cancer and Alport syndrome and other potential indications;
- seek regulatory approvals for Nefecon, setanaxib and/or any product candidates that successfully complete clinical trials;
- continue to build a sales, marketing and distribution infrastructure and scale-up external manufacturing to commercialize Nefecon and any other present or future product candidates that receive approval;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- continue to add clinical and scientific personnel, including personnel to support our product development and potential future commercialization efforts;
- seek to expand our development pipeline, including through potential in-licensing opportunities and strategic acquisitions;
- expand our operations in the United States and Europe; and

- experience any delays or encounter any issues with regards to any of the above, including, but not limited to, failed studies, ambiguous trial results, safety issues or other regulatory challenges, including any unforeseen costs we may incur as a result of clinical trial or supply chain delays or other business interruptions due to health pandemics, geopolitical tensions or other world events.

The process of conducting the necessary clinical trials to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

We also expect to incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into license agreements. See "Item 5.B.—Liquidity and Capital Resources—Contractual Obligations and Commitments."

Marketing and Selling Expenses

Marketing and selling expenses consist of salaries and other related costs for personnel in our commercialization functions including our field sales force, marketing and other commercial support personnel. Marketing and selling expenses also include professional fees and related costs for our marketing program.

We expect that our marketing and selling expenses will increase in the future as we increase our headcount and expand our marketing program to support our commercialization of Nefecon and potential commercialization of our portfolio of product candidates.

Administrative Expenses

Administrative expenses consist of salaries and other related costs for personnel in our executive, finance, corporate and business development and administrative functions. Administrative expenses also include professional fees for legal, intellectual property, accounting, auditing, tax and consulting services, public entity listing costs related travel expenses and facility-related expenses, which include expenses for rent and maintenance of facilities and other operating costs.

We expect that our administrative expenses will increase in the future as we increase our headcount to support our continued development and commercialization of Nefecon and potential commercialization of our portfolio of product candidates. We also expect to continue to incur increased expenses associated with being a dual-listed public company in the United States and Sweden, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance costs and investor and public relations costs.

Other Operating Income

Other operating income consists primarily of realized and unrealized foreign currency transaction gains on operating receivables and liabilities.

Other Operating Expenses

Other operating expenses consist primarily of realized and unrealized foreign currency transaction losses on operating receivables and liabilities.

Financial Income

Financial income consists primarily of interest income earned on cash accounts and realized and unrealized foreign currency transaction gains on financial receivables and liabilities.

Financial Expenses

Financial expenses consist primarily of interest rate expenses and realized and unrealized foreign currency transaction losses on financial receivables and liabilities.

Income Tax

We are subject to corporate taxation in Sweden and taxation in the United States, France and Switzerland for our subsidiaries. Due to the nature of our business, we have generated losses since inception and have therefore not paid Swedish corporation tax to date. The research and development tax credit on social security costs for personnel within research and development received in Sweden and France is recorded as a credit against research and development expenses. The Swedish and France research and development tax credit on social security costs for personnel within research and development is fully refundable to us and is not dependent on current or future taxable income.

As of December 31, 2023, we had SEK 3,881.3 million of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position other than to the extent such tax losses can be used to offset temporary differences. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

	Year ended December 31,		
	2023	2022	Change 2023-2022
	(In thousands of SEK)		
Net sales	1,206,888	802,879	404,009
Cost of sales	(60,463)	(15,201)	(45,262)
Gross profit	**1,146,425**	**787,678**	**358,747**
Operating expenses	(1,519,481)	(1,209,620)	(309,861)
Research and development expenses	(502,223)	(414,749)	(87,474)
Marketing and selling expenses	(727,740)	(515,190)	(212,550)
Administrative expenses	(332,991)	(259,469)	(73,522)
Other operating income	44,608	2,862	41,746
Other operating expenses	(1,135)	(23,074)	21,939
Operating loss	**(373,056)**	**(421,942)**	**48,886**
Financial income	30,387	50,195	(19,808)
Financial expenses	(114,349)	(37,669)	(76,680)
Loss before taxes	**(457,018)**	**(409,416)**	**(47,602)**
Income taxes	(9,168)	(2,851)	(6,317)
Net loss for the year attributable to shareholders	**(466,186)**	**(412,267)**	**(53,919)**
Non-controlling interest	—	—	—
Loss per share before and after dilution, SEK	(8.69)	(7.78)	(0.91)

Net Sales

Net sales increased by SEK 404.0 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. This increase was mainly due to SEK 1,075.8 million in net sales of TARPEYO in the US and SEK 119.4 million in milestones and royalties from our partnerships in Europe and China for the year ended December 31, 2023.

Cost of Sales

Cost of sales increased by SEK 45.3 million to SEK 60.5 million for the year ended December 31, 2023 compared to SEK 15.2 million for the year ended December 31, 2022, driven primarily by increased sales of TARPEYO.

Gross Profit

Gross profit increased by SEK 358.7 million to SEK 1,146.4 million for the year ended December 31, 2023 compared to SEK 787.7 million for the year ended December 31, 2022.

Research and Development Expenses

Research and development expenses increased by SEK 87.5 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. This increase was primarily due to increased costs of SEK 59.2 million for the setanaxib clinical trials. The cost related to the Nefecon clinical trials decreased by SEK 32.6 million. Included in the increase for the full year, was the recognition of a one-time effect from the impairment of SEK 32.1 million regarding in-licensing of Budenofalk.

Marketing and Selling Expenses

Marketing and selling expenses increased by SEK 212.5 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. This increase was primarily due to the increased commercial activities for TARPEYO, where costs related to our selling activities increased by SEK 80.3 million and costs related to our marketing and market access activities increased by SEK 80.9 million.

Administrative Expenses

Administrative expenses increased by SEK 73.5 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. This increase was primarily due to an increase of costs, mainly driven by a larger organization and increased regulatory requirements, for the finance, IT, human relations and the legal function of SEK 51.6 million.

Other Operating Income/Expense

Other operating income increased by SEK 41.7 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to exchange rate impacts on operating receivables and liabilities and change in value of contingent consideration at fair value.

Other operating expense increased by SEK 21.9 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to exchange rate impacts on operating receivables and liabilities.

Financial Income/Expense

Financial income decreased by SEK 19.8 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to change in unrealized currency gains.

Financial expense increased by SEK 76.7 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to an increase of interest rate expenses and fees from borrowing and currency effects from translation effects.

Comparison of Years Ended December 31, 2022 and 2021

	Year ended December 31,		
	2022	2021	Change 2022-2021
	(In thousands of SEK)		
Net sales	802,879	229,347	573,532
Cost of sales	(15,201)	—	(15,201)
Gross profit	**787,678**	**229,347**	**558,331**
Operating expenses	(1,209,620)	(753,803)	(455,817)
Research and development expenses	(414,749)	(357,485)	(57,264)
Marketing and selling expenses	(515,190)	(179,603)	(335,587)
Administrative expenses	(259,469)	(210,630)	(48,839)
Other operating income	2,862	259	2,603
Other operating expenses	(23,074)	(6,344)	(16,730)
Operating loss	**(421,942)**	**(524,456)**	**102,514**
Financial income	50,195	20,336	29,859
Financial expenses	(37,669)	(9,253)	(28,416)
Loss before taxes	**(409,416)**	**(513,373)**	**103,957**
Income taxes	(2,851)	3,836	(6,687)
Net loss for the year attributable to shareholders	**(412,267)**	**(500,293)**	**88,026**
Non-controlling interest	—	(9,244)	9,244
Loss per share before and after dilution, SEK	(7.78)	(9.84)	2.06

Net Sales

Net sales increased by SEK 573.5 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was mainly due to SEK 372.2 million in net sales of TARPEYO in the US and SEK 427.4 million in milestones and royalties from our partnerships in Europe, China and Japan for the year ended December 31, 2022.

Cost of Sales

Cost of sales amounted to SEK 15.2 million for the year ended December 31, 2022; there was no cost of sales in the year ended December 31, 2021.

Gross Profit

Gross profit was SEK 787.7 million for the year ended December 31, 2022, compared to SEK 229.3 million for the year ended December 31, 2021.

Research and Development Expenses

Research and development expenses increased by SEK 57.3 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was primarily due to increased cost related to the setanaxib clinical trials of SEK 37.9 million and increased costs related to the Nefecon trials of SEK 20.2 million.

Marketing and Selling Expenses

Marketing and selling expenses increased by SEK 335.6 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was primarily due to the start of the commercialization of TARPEYO in 2022, where costs related to our selling increased by SEK 198.0 million and costs related to our marketing and market access activities increased by SEK 82.5 million.

Administrative Expenses

Administrative expenses increased by SEK 48.8 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase was primarily due to an increase of costs related to the finance function of SEK 13.0 million and a cost increase related to the IT function of SEK 12.1 million. Additionally, the costs related to our business development activities increased by SEK 8.9 million.

Other Operating Expenses

Other operating expense increased by SEK 16.7 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to a more unfavorable exchange rate impact on operating liabilities.

Financial Income/(Expense)

Financial income increased by SEK 29.9 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to currency effects relating to internal loans.

Financial expense increased by SEK 28.4 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to an increase of interest rate expenses from increased loan balances during the year 2022 compared to 2021.

B. LIQUIDITY AND CAPITAL RESOURCES

Sources of Funds

To date, we have financed our operations primarily with proceeds from the sale of our equity, the upfront payments and related milestone payments from the out-license of Nefecon to Everest, STADA, and Viatris, our debt facility with Athyrium (described below), which we fully drew down and used part of the proceeds from the Credit Agreement to repay in full outstanding obligations under our loan agreement with Kreos and, more recently, from revenue from sales of TARPEYO. In 2021, we recognized revenue in connection with the execution of the license agreement with STADA and additionally upon triggering payments to us resulting from the satisfaction of a regulatory milestone under the Everest agreement. In 2022, we recognized revenue in connection with the execution of the license agreement with Viatris and additionally upon triggering payments to us resulting from the satisfaction of regulatory and clinical milestones under the Everest and STADA agreements, and we are eligible to receive future payments upon the satisfaction of specific clinical, regulatory and commercial milestones, as well as typical tiered royalties from these agreements. In 2023, we recognized revenue resulting from the satisfaction of regulatory milestones under the license agreement with Everest and we recognized revenues from tiered royalties from the license agreements with STADA and Everest. We refer to revenue received from our license agreement with Everest, STADA and Viatris as “net sales” in our consolidated financial statements. In addition to sales of Nefecon, we may generate revenue in the future from a combination of product sales and collaboration or license agreements, if the development programs for Nefecon, setanaxib and future product candidates are successful and result in approved and marketed products, or if we enter into additional collaboration or license agreements with third parties.

Through December 31, 2023, we had received net proceeds of SEK 2,523.8 million from the issuance of equity securities. In August 2021, we completed a directed new share issuance of 2.4 million shares for gross proceeds of SEK 324.0 million from Swedish and international institutional investors. In June and July 2020, we completed a new share issuance of 9.2 million shares, in connection with the US IPO and concurrent private placement, for gross proceeds of SEK 891.4 million from US and international institutional investors. In July 2019, we completed a directed new share issuance of 3.5 million shares for gross proceeds of SEK 210.3 million from Swedish and international institutional investors. We believe that our cash as of December 31, 2023 will be sufficient to fund our planned operations and capital expenditure requirements until we are profitable. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. There can be no assurance that Nefecon will be approved by additional regulatory authorities, or that we and our commercialization partners will successfully commercialize Nefecon in the jurisdictions in which it is approved. See "Item 3.D.—Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—We may need substantial additional funding in order to fund our operations. Failure to obtain this necessary capital at acceptable terms and when needed may force us to delay, limit or terminate certain or all of our operations and pursuit of our growth strategy."

In December 2023, we entered into a credit agreement with Athyrium pursuant to which Athyrium made available to us 92 million Euros, which we fully drew down. We used part of the proceeds from the Credit Agreement to repay in full outstanding obligations under our loan agreement with Kreos Capital VI (UK) Limited and Kreos Capital 2020 Opportunity (UK) Limited. The interest rate on the loan is 9% per annum with a maturity of December 2027. The Credit Agreement contains financial covenants to maintain minimum unrestricted cash (including cash equivalents) and achieve minimum net revenue targets with respect to Nefecon. The Credit Agreement contains affirmative and negative covenants customary for a senior secured loan. The negative covenants under the Credit Agreement limit our and our subsidiaries' abilities to, among other things, dispose of assets, engage in mergers, acquisitions, and similar transactions, incur additional indebtedness, grant liens, make investments, pay dividends or make distributions or certain other restricted payments in respect of equity, prepay other indebtedness, enter into restrictive agreements, undertake fundamental changes or amend certain material contracts, in each case subject to certain exceptions. The Credit Agreement also contains certain customary events of default, including, but not limited to, a failure to comply with the covenants in the Credit Agreement. If an event of default has occurred and continues beyond any applicable cure period, the administrative agent or the required lenders may accelerate all outstanding obligations under the Credit Agreement and/or exercise any other remedies provided under the loan documents. Other than the Athyrium Credit Agreement and our lease obligations described below under "Item 5.B.—Liquidity and Capital Resources—Contractual Obligations and Commitments," we have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years.

In July 2022, we entered into an Open Market Sale Agreement[SM], or the Sales Agreement, with Jefferies, under which we may, at our option, offer and sell ADSs having an aggregate offering price of up to $75.0 million from time to time through Jefferies, acting as sales agent. As of the date of this report, we have not sold any shares pursuant to the Sales Agreement. The Sales Agreement was terminated in June 2023. We did not sell any shares pursuant to the Sales Agreement prior to its termination.

Ukraine

The February 2022 invasion of Ukraine by Russia, the resulting military conflict and retaliatory measures by the United States, UK, the EU, and others in the global community have created global security concerns, including the possibility of expanded regional or global conflict, which have had, are likely to continue to have, short-term and likely longer-term adverse impacts on Ukraine and Europe and around the globe. Potential ramifications include disruption of the supply chain including research activities and complications with the conduct of ongoing and future clinical trials. It is not possible to predict the broader or longer-term consequences of this armed conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and financial markets. Such geo-political instability and uncertainty could materially affect our business and the value of our common shares and our ability to raise capital if and when needed.

Cash Flows

Comparison for the Years Ended December 31, 2023 and 2022

The table below summarizes our cash flows for the years ended December 31, 2023 and 2022.

	Year ended December 31,		
	2023	2022	Variance
	(In thousands of SEK)		
Cash and cash equivalents at beginning of the period	**1,249,094**	**955,507**	**293,587**
Net cash flows (used in) / from operating activities	(434,655)	(311,354)	(123,301)
Net cash flows (used in) / from investing activities	(13,745)	(5,144)	(8,601)
Net cash flows (used in) / from financing activities	199,650	575,990	(376,340)
Net increase (decrease) in cash	(248,750)	259,493	(508,243)
Exchange-rate difference in cash	(26,611)	34,094	(60,706)
Cash and cash equivalents at end of the period	**973,733**	**1,249,094**	**(275,361)**

Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was SEK 434.7 million, primarily resulting from our operating loss of SEK 373.1 million and positive adjustment for non-cash items of SEK 102.5 million and paid interest of SEK 94.5 million.

During the year ended December 31, 2022, net cash used in operating activities was SEK 311.4 million, primarily resulting from our operating loss of SEK 421.9 million and adjustment for non-cash items of SEK 61.3 million and positive net cash changes in our operating assets and liabilities of SEK 88.4 million

Investing Activities

During the year ended December 31, 2023, net cash used for investing activities was SEK 13.7 million primarily related to investment in fixed assets.

During the year ended December 31, 2022, net cash used for investing activities was SEK 5.1 million primarily related to investment in fixed assets and rental deposits.

Financing Activities

During the year ended December 31, 2023, net cash provided by financing activities was SEK 199.7 million primarily related to net increase in borrowing from the repayment of the Kreos loan and draw down of the Athyrium loan.

During the year ended December 31, 2022, net cash provided by financing activities was SEK 576.0 million primarily related to SEK 491.7 million from the drawdown of tranche 2 and 3 of the Kreos loan facility and SEK 95.1 million from exercise of warrant programs.

Comparison for the Years Ended December 31, 2022 and 2021

The table below summarizes our cash flows for the years ended December 31, 2022 and 2021.

	Year ended December 31,		
	2022	2021	Variance
	(In thousands of SEK)		
Cash and cash equivalents at beginning of the period	**955,507**	**996,304**	**(40,797)**
Net cash flows (used in) / from operating activities	(311,354)	(461,588)	150,234
Net cash flows (used in) / from investing activities	(5,144)	(24,340)	19,196
Net cash flows (used in) / from financing activities	575,990	435,162	140,828
Net increase (decrease) in cash	259,493	(50,766)	310,259
Exchange-rate difference in cash	34,094	9,969	24,125
Cash and cash equivalents at end of the period	**1,249,094**	**955,507**	**293,587**

Operating Activities

During the year ended December 31, 2022, net cash used in operating activities was SEK 311.4 million, primarily resulting from our operating loss of SEK 421.9 million and adjustment for non-cash items of SEK 61.3 million and positive net cash changes in our operating assets and liabilities of SEK 88.4 million.

During the year ended December 31, 2021, net cash used in operating activities was SEK 461.6 million, primarily resulting from our operating loss of SEK 524.5 million and adjustment for non-cash items of SEK 66.7 million and negative net cash changes in our operating assets and liabilities of SEK 5.5 million.

Investing Activities

During the year ended December 31, 2022, net cash used for investing activities was SEK 5.1 million primarily related to investment in fixed assets and rental deposits.

During the year ended December 31, 2021, net cash used for investing activities was SEK 24.3 million primarily related to a EUR 1.5 million milestone payment for the Budenofalk license.

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was SEK 576.0 million primarily related to SEK 491.7 million from the drawdown of tranche 2 and 3 of the Kreos loan facility and SEK 95.1 million from exercise of warrant programs.

During the year ended December 31, 2021, net cash provided by financing activities was SEK 435.2 million from a new share issue of net SEK 304.0 million and the drawdown of the first tranche of the Kreos loan facility of net SEK 199.5 million, reduced by SEK 49.3 million used in a simplified public mandatory cash offer of Genkyotex SA.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities. We may need additional funds to meet operational needs and capital requirements for our commercialization activities, clinical trials, other research and development expenditures, and business development activities. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses and our product sales or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We believe that our cash as of December 31, 2023 will be sufficient to fund our planned operations and capital expenditure requirements until we are profitable. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. There can be no assurance that Nefecon will be approved by additional regulatory authorities, or successfully commercialized, if and where approved. See "Item 3.D.—Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—We may need substantial additional funding in order to fund our operations. Failure to obtain this necessary capital at acceptable terms and when needed may force us to delay, limit or terminate certain or all of our operations and pursuit of our growth strategy."

Because of the numerous risks and uncertainties associated with the development of product candidates and programs, and because the extent to which we may enter into collaborations with third parties for development of our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of launching and commercializing product candidates for which we obtain regulatory and marketing approval, including acquiring sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- the amount of revenue from sales of TARPEYO in the United States, Kinpeygo in the EEA and UK, and Nefecon in China, Macau and Singapore and other jurisdictions, if approved;
- the costs and timing of completing development of our product candidates and in-licensing or otherwise acquiring new product candidates;
- our ability to qualify for and maintain adequate coverage and reimbursement by government and payors for our product candidates for which we obtain marketing approval;
- the costs of establishing and maintaining supply and manufacturing processes and relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development of our product candidates and the commercial supply of our product candidates for which we obtain marketing approval;
- our success in obtaining market acceptance of our product candidates, if approved, as viable treatment options with acceptable safety profiles;
- our ability to address any competing technological and market developments;
- the timing and costs of implementing additional internal systems and infrastructure, as needed, including robust quality systems and compliance systems;
- our success in negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future products and product candidates;
- the costs associated with maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- the costs of attracting, hiring and retaining qualified personnel.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operations through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we undertake financing arrangements in the future, the terms of any financing may adversely affect the holdings or the rights of holders of our common shares or ADSs and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of the ADSs to decline. The sale of additional equity or convertible securities would dilute all of our existing shareholders and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ADSs. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, financial condition and results of operations. Further, any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Contractual Obligations and Commitments

Our lease obligations primarily comprise our leased premises. The total lease obligations for 0-5 years were SEK 65.0 million as of December 31, 2023. The lease agreements for leased premises have terms ending from 2024 until 2027 and can be extended unless one of the parties terminates the lease agreements.

In July 2021, we signed a loan agreement of up to the euro equivalent of USD 75.0 million with Kreos Capital. The loan facility was divided into three tranches of USD 25.0 million each. Drawdown of the first USD 25 million tranche was made in September 2021, drawdown of the second USD 25 million tranche was made in June 2022, and drawdown of the third and final tranche was made in December 2022. The interest rate on the loan was 9% per annum with a maturity to December 2025. The loan had no financial covenants. In December 2023, the loan was fully repaid.

In December 2023, we entered into a credit agreement with Athyrium, pursuant to which Athyrium made available to us 92 million Euros, which we fully drew down. The interest rate on the loan is 9% per annum with a maturity of December 2027. The Credit Agreement contains financial covenants to maintain minimum unrestricted cash (including cash equivalents) and achieve minimum net revenue targets with respect to Nefecon. The Credit Agreement contains affirmative and negative covenants customary for a senior secured loan.

We enter into contracts in the normal course of business with CROs and CMOs and other third parties for clinical trials and manufacturing. There are no obligations associated with cancellation provisions, non-cancelable portions of agreement terms or minimum cancellation fees.

License Agreements with Archimedes

We are required to pay Kyowa Kirin Services Ltd., f/k/a Archimedes Development Ltd, or Archimedes, a fixed royalty of 3% of net sales of Nefecon, including TARPEYO sales in the United States and in other jurisdictions, if approved, covered by the license granted to us pursuant to our agreement with Archimedes pursuant to which we were granted (i) an exclusive license to certain patents and joint intellectual property developed with Archimedes and (ii) a non-exclusive license to certain of Archimedes' know-how as necessary or useful to develop and commercialize Nefecon or other product candidates.

Due to the uncertainty of the achievement and timing of the events requiring various payments under these agreements, the amounts to be paid by us are not fixed or determinable at this time and are excluded from the table above.

C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES

For a discussion of our research and development activities, see the sections of this annual report titled "Item 4.B.—Business Overview" and "Item 5.A.—Operating Results."

D. TREND INFORMATION

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events for the period from January 1, 2023 to December 31, 2023 that are reasonably likely to have a material effect on our net revenues, income, profitability, liquidity or capital resources, or that caused the disclosed financial information to be not necessarily indicative of future operating results or financial conditions. For a discussion of trends, see the sections of this annual report titled "Item 4.B.—Business Overview," "Item 5.A.—Operating Results", and "Item 5.B.—Liquidity and Capital Resources."

E. CRITICAL ACCOUNTING ESTIMATES

Our consolidated financial statements for the years ended December 31, 2021, 2022 and 2023, have been prepared in accordance with IFRS as issued by the IASB. See Notes 1 and 2 to our consolidated financial statements appearing at the end of this annual report for a description of our significant accounting judgements and estimates.

The preparation of the consolidated financial statements requires us to make judgements, estimates and assumptions that affect the value of assets and liabilities—as well as contingent assets and liabilities—as reported on the statement of financial position date, and revenues and expenses arising during the fiscal year.

The estimates and associated assumptions are based on information available when the consolidated financial statements are prepared, historical experience and various other factors which are believed to be reasonable under the circumstances, the results of which form the basis of making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond our control. Hence, estimates may vary from the actual values.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or the period of revision and future periods if this revision affects both current and future periods.

(ii) Recently Adopted Accounting Pronouncements and Accounting Pronouncements Not Yet Adopted

A description of recently adopted accounting pronouncements and accounting pronouncements not yet adopted that may potentially impact our financial position and results of operations is disclosed in our consolidated financial statements appearing at the end of this annual report.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. DIRECTORS AND SENIOR MANAGEMENT

Our Board of Directors

Our board of directors is currently comprised of six members, who we refer to individually as a director. Less than a majority of the directors of our board of directors are citizens or residents of the United States.

The following table sets forth certain information with respect to the current members of our board of directors, including their ages as of December 31, 2023:

Name	Age	Position
Elmar Schnee	64	Chairman of the Board of Directors
Elisabeth Björk	62	Director
Fred Driscoll	73	Director
Hilde Furberg	65	Director
Diane Parks	71	Director
Henrik Stenqvist	56	Director

The address for our directors is our registered office, care of Calliditas Therapeutics AB, Kungsbron 1, D5, SE-111 22, Stockholm, Sweden.

Under the rules and regulations of Nasdaq a director will qualify as "independent" if our board of directors affirmatively determines that he or she has no material relationship with us (either directly or as a partner, stockholder or officer of an organization that has a relationship with us). Our board of directors has determined that, of our six directors, no director has a relationship that would interfere with the exercise of independent judgment in carrying out his or her responsibilities as a director and that each of these directors is "independent" as that term is defined under Nasdaq rules. The Swedish Code includes certain independence requirements for the directors, and requires a majority of the directors to be independent of the company and at least two directors to also be independent of major shareholders.

The following is the biographical information of the members of our board of directors:

Elmar Schnee has served as the chairman of our board of directors since May 2019. Since 2012, Mr. Schnee has served as a managing director at Caljem GmbH, a consulting company. From May 2017 to August 2018, Mr. Schnee served as a management advisor to MindMaze SA, a neuro-technology company, where he also served as chief operating officer from June 2016 to April 2017. From October 2011 to November 2013, Mr. Schnee served as chairman and chief executive officer of Cardiorentis Ltd., a biopharmaceutical company. From January 2003 to June 2011, Mr. Schnee held various positions in senior management at Merck KGaA, a global pharmaceutical and chemical group. From November 2005 to June 2006, Mr. Schnee served as Deputy Member of the Executive Board of Merck KGaA responsible for the global pharmaceuticals business. From July 2006 to June 2011, he served as a member of the Executive Board and General Partner of Merck KGaA, with responsibility for global pharmaceutical activities. Prior to Merck KGaA, Mr. Schnee held senior positions in strategy, business development and marketing at UCB SA, Sanofi-Synthélabo SA, Migliara/Kaplan Associates, Inc. and Fisons Pharmaceuticals PLC. From August 2014 until July 2021, Mr. Schnee served as a member of the board of directors of Jazz Pharmaceuticals plc and previously served as a director of Gentium (now a subsidiary of Jazz Pharmaceuticals plc) from May 2012 until April 2014. From April 2017 to June 2022, Mr. Schnee served as Chairman of the board of Santhera Pharmaceuticals Holding AG, a specialty pharmaceutical company. From June 2016 until May 2019, he served on the board of directors of Stallergenes-Greer plc. From November 2013 to August 2015, Mr. Schnee served on the board of directors of Cardiorentis Ltd. From August 2021 to March 2022, Mr. Schnee served on the board of directors of Clinigen plc. Since August 2021, Mr. Schnee currently serves on the boards of directors of six privately-held life sciences companies, Damian Pharma AG, Noorik Biopharmaceuticals AG, MindMaze SA, Procom RX SA, Kuste SA and Moleac Pte Ltd. Mr. Schnee holds both a bachelor's degree in marketing and a master's degree in marketing and general management from the Swiss Institute of Business administration in Zurich.

We believe that Mr. Schnee is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive experience in leadership roles at other biotechnology and pharmaceutical companies.

Elisabeth Björk, M.D., Ph.D. has served as a member of our board of directors since May 2022. Dr. Bjork was the Senior Vice President and Global Head of late-phase development for Cardiovascular, Renal and Metabolism (CVRM) at AstraZeneca, with overall accountability for development strategy and delivery across AstraZeneca's CVRM portfolio between 2012 and 2023. Prior to this role, from February 2008, until June 2012, Dr. Bjork spent time at AstraZeneca in the United States as the Global Product Vice President leading the development of an SGLT2inhibitor, and other key late-phase cardiovascular and gastrointestinal projects. Previously, Dr. Bjork also served as a Clinical Research Physician, Medical Science Director, and CPT team leader at AstraZeneca. Earlier in her career, after training as an endocrinologist, Dr. Bjork worked for 15 years in clinical practice and diabetes research and in January 2002 served as the head of the diabetes and endocrinology unit at Uppsala University Hospital. Dr. Bjork received her M.D. from the Karolinska Institute and her Ph.D. in endocrinology from Uppsala University, where she is also an Associate Professor in Medicine. In addition, Dr. Bjork is a board Member at Chalmers University of Technology, Rocket Pharmaceuticals, Pharvaris NV and Vicore Pharma.

We believe that Ms. Björk is qualified to serve on our board of directors because of her experience, qualifications, attributes and skills, including her extensive experience in biotechnology and pharmaceutical companies.

Fred Driscoll has served as a member of our board of directors since 2023. Mr. Driscoll served as Interim Chief Financial Officer at Invivyd, Inc. from Oct. 2022 to May 2023. Since May 2021 until Nov. 2021, Mr. Driscoll served as Chief Financial Officer at Flexion Therapeutics which was acquired by Pacira Biosciences, a role he previously served from 2013 to 2017, spearheading the initial public offering in 2014. Prior to joining Flexion Therapeutics, he was Chief Financial Officer at Novavax, Inc., a publicly traded biopharmaceutical company, from 2009 to 2013. From 2008 to 2009, Mr. Driscoll served as Chief Executive Officer of Genelabs Technologies, Inc., a publicly traded biopharmaceutical and diagnostics company later acquired by GlaxoSmithKline. He previously served as Genelabs' Chief Financial Officer from 2007 to 2008. From 2003 to 2006, Mr. Driscoll served as Chief Executive Officer at OXiGENE, Inc., a biopharmaceutical company and from 2000 to 2003 as Chief Financial Officer. Mr. Driscoll currently serves as a board member for Cellectar BioSciences, Cue BioPharma and MEI Pharma. Mr. Driscoll has also served as Chairman of the Board and Audit Committee Chair at OXiGENE and as a member of the Audit Committee for Cynapsus, which was sold to Sunovion Pharmaceuticals in 2016. Mr. Driscoll holds a bachelors degree in accounting from Bentley University.

We believe that Mr. Driscoll is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive experience in leadership roles at other biotechnology and pharmaceutical companies and board experience.

Hilde Furberg has served as a member of our board of directors since September 2014, and also served as our Chairperson from December 2015 to December 2016. Ms. Furberg has served as an independent consultant and professional board member since December 2018, including as advisor to Investinor AS since December 2018. Prior to that, Ms. Furberg served as SVP and General Manager/European Head of Rare Diseases at Sanofi Genzyme from November 2010 to November 2018. Ms. Furberg previously worked in companies such as Genzyme and Baxter. Ms. Furberg currently serves on the board of directors of PCI Biotech Holding ASA, Bio-Me, Herantis Pharma, Sedana Medical and Pluvia Biotech. Ms. Furberg previously served on the board of directors of Tappin AS, OncoZenge, Combigen, Blueprint Genetics, Probi, Pronova, Clavis, Bergenbio and Algeta. She received her Master of Science in Chemistry from Oslo University, Norway.

We believe that Ms. Furberg is qualified to serve on our board of directors because of her experience, qualifications, attributes and skills, including her extensive experience in biotechnology and pharmaceutical companies.

Diane Parks has served as a member of our board of directors since May 2019. Ms. Parks previously served as the SVP Head of US Commercial at Kite Pharma, Inc., from January 2016 to July 2018. Prior to that she served as the Vice President Marketing at Pharmacyclics from October 2014 to October 2015. She currently serves as a member of the board of directors for Kura Oncology, Inc., Celularity and Soligenix, Inc. Ms. Parks received her Bachelor of Science degree from Kansas State University and an MBA from Georgia State University.

We believe that Ms. Parks is qualified to serve on our board of directors because of her experience, qualifications, attributes and skills, including extensive sales and marketing experience in the United States.

Henrik Stenqvist has served as a member of our board of directors since May 2022. Mr. Stenqvist has held various Chief Financial Officer positions, including most recently as the Chief Financial Officer of Swedish Orphan Biovitrum (SOBI). Prior to this role, Mr. Stenqvist served as the Chief Financial Officer for Recipharm. Earlier in his career, Mr. Stenqvist served as the Chief Financial Officer at Meda, Regional Finance Director at AstraZeneca and Finance Director at Astra Export & Trading. Mr. Stenqvist received his M.Sc. in Business Administration and Economics from the University of Linköping. Mr. Stenqvist previously served as a board member of MedCapAB, and is a current board member of Midsona AB and Orion Corporation.

We believe that Mr. Stenqvist is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his extensive experience in leadership roles at other biotechnology and pharmaceutical companies.

Board Diversity Matrix (as of December 31, 2023)

Country of Principal Executive Offices:				Sweden
Foreign Private Issuer:				Yes
Disclosure Prohibited under Home Country Law:				No
Total Number of Directors:				6
Part I: Gender Identity				
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Directors	3	3	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction				0
LGBTQ+				0
Did Not Disclose Demographic Background				0

Our Board Diversity Matrix as of December 31, 2022 can be found in our Annual Report on Form 20-F for the year ended December 31, 2022, filed with the SEC on April 26, 2023.

Family Relationships

There are no family relationships among any of our executive officers or directors

Our Executive Officers

The following table sets forth certain information with respect to the current members of our executive officers, including their ages as of December 31, 2023:

Name	Age	Position
Renée Aguiar-Lucander	61	Chief Executive Officer
Frank Bringstrup, M.D.	64	Vice President Regulatory Affairs
Brian Gorman	47	Group General Counsel
Fredrik Johansson	46	Chief Financial Officer
Richard Philipson, M.D.	59	Chief Medical Officer
Lars Stubberud	59	Head of Technical Operations
Maria Törnsén	45	President, North America

The address for our executive officers is our registered office, care of Calliditas Therapeutics AB, Kungsbron 1, D5, SE-111 22, Stockholm, Sweden.

We have formed a management team made up of our executive officers and other key managers. The following is a brief summary of the biographical information of the members of our management team:

Renée Aguiar-Lucander has served as our Chief Executive Officer since May 2017. Prior to joining us, from June 2015 until April 2017, Ms. Aguiar-Lucander served as a non-executive director on a variety of boards. Prior to that, from January 2009 to June 2015, Ms. Aguiar-Lucander served as Partner of Omega Fund Management, an international venture capital company focused on investments within the life science sector. Ms. Aguiar-Lucander received her B.A. in Finance from Stockholm School of Economics and received her M.B.A. from INSEAD.

Frank Bringstrup, M.D. has served as our Vice President of Regulatory Affairs since February 2019. Prior to joining us, from October 2001 to January 2019, Dr. Bringstrup held various positions at Novo Nordisk A/S, including most recently as the Senior Global Regulatory Lead from October 2006 to January 2019. Dr. Bringstrup received his M.D. from University of Copenhagen. He holds a diploma in Managing Medical Product Innovation from the Copenhagen Business School, a diploma in Business Administration from Warwick University, and a post graduate specialist course in public health from the Danish Health Authority.

Brian Gorman, J.D., has served as our Group General Counsel since January 1, 2024. Prior to joining us, Mr. Gorman served as Executive Vice President, Corporate Development and General Counsel at Opiant Pharmaceuticals from July 2021 to September 2023, and served as General Counsel from June 2020 to July 2021. From October 2016 to June 2020, he served as Vice President & Assistant General Counsel of Endo International. Prior to Endo, Mr. Gorman held senior legal leadership roles at AstraZeneca and prior to that, worked at Wyeth Pharmaceuticals (now Pfizer). He began his legal career at the international law firm Cleary Gottlieb Steen & Hamilton. Mr. Gorman received his Juris Doctor from Villanova University School of Law and his bachelor's degree from Gettysburg College.

Fredrik Johansson has served as our Chief Financial Officer since August 2017. Prior to joining us, from March 2015 to January 2017, he was Chief Financial Officer and Chief Operating Officer of Techstep ASA (f/k/a Birdstep Technology), listed on the Oslo Stock Exchange, where he, among other tasks, was in charge of the acquisition and reversed listing of Teki Solutions. Prior to that, Mr. Johansson served as Chief Financial Officer of Phone Family from December 2012 to March 2015. Prior to that, Mr. Johansson served as Chief Financial Officer of Teligent Telecom from October 2009 to June 2012. He studied Business Law at Jönköping International Business School and studied Business and American Law, Economics and Finance at Georgia State University, University of South Carolina and Lund University.

Richard Philipson, M.D. has served as our Chief Medical Officer since July 2020. Dr. Philipson is a physician with 28 years of experience in the pharmaceutical industry from both large pharmaceutical companies and smaller biotechs. Prior to joining us, Dr. Philipson worked as Chief Medical Officer with the U.K.-based biotech company Trizell from July 2016 to July 2020, where he led the Adstiladrin Phase 3 clinical program and Biologics License Application in non-muscle invasive bladder cancer, submitted to the FDA in September 2019. Before Trizell, Dr. Philipson worked for Takeda from June 2014 to July 2016 as an Executive Medical Director. Prior to Takeda, Dr. Philipson spent nearly 16 years at GlaxoSmithKline, where he held a number of senior positions, including Disease Area Head and Acting Chief Medical Officer for the Rare Diseases Unit. Dr. Philipson received a BSc in Biomedical Sciences at London University and an MB MS, from Middlesex Hospital Medical School. He is a Fellow of the Royal College of Physicians and Fellow of the Faculty of Pharmaceutical Medicine.

Lars Stubberud has served as our Head of Technical Operations since March 2023. He previously served as our Head of Pharmaceutical Development and Manufacturing from August 2020 to February 2023. Prior to joining Calliditas, Dr. Stubberud served at Alexion Pharmaceuticals as Senior Director, Head of Quality Europe and College Park Distribution from November 2019 to July 2020 and as Director of Regional Quality Assurance from May 2017 to October 2019. Prior to Alexion, Dr. Stubberud held CMC, regulatory affairs and product development positions at Biogen, Cubist Pharmaceuticals and AstraZeneca. Dr. Stubberud received his Doctor of Pharmacy and Master of Pharmaceutical Sciences from the University of Oslo, Norway.

Maria Törnsén has served as our President, North America since January 2024. Most recently Ms. Törnsén held the position of Chief Commercial Officer at Passage Bio from July 2021 to December 2022, prior to which she was SVP General Manager US at Sarepta Therapeutics from February 2021 to July 2021 and VP General Manager & Head of US Commercial from August 2019 to February 2021. Prior to joining Sarepta she served as VP Global Therapeutic Area Head at Sanofi Genzyme from August 2017 to August 2019. She also held several senior commercial roles at Shire including VP Head of US Sales. Maria is currently a Board Director for Immunic Therapeutics. Ms. Törnsén began her career at Eli Lilly in sales and also worked at Merck KGaA in sales and marketing. Ms. Törnsén received her M.S. in Business Administration and Management and Bachelors of Sciences at Lund University.

General Information About Our Directors and Executive Officers

As of the date of this annual report, none of the members of our board of directors and executive officers has a family relationship with any other member of our board of directors or executive officers.

As of the date of this annual report and except as set out below, none of the members of our board of directors and executive officers for at least the previous five years:

- has been convicted of any fraudulent offenses;
- has been a senior manager or a member of the administrative, management or supervisory bodies of any company at the time of or preceding any bankruptcy, receivership or liquidation;
- has been subject to any official public incrimination and/or sanction by any statutory or regulatory authority (including any designated professional body); or
- has ever been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of any company or from acting in the management or conduct of affairs of any company.

B. COMPENSATION

Compensation of Our Executive Officers and Directors

For the year ended December 31, 2023, the aggregate compensation accrued or paid to the members of our board of directors and executive officers serving during the year was SEK 55.0 million.

During and for the year ended December 31, 2023, our executive officers had performance-based compensation programs and amounts paid to provide pension and healthcare benefits.

Adoption of Clawback Policy

In December 2023, in accordance with Rule 10D-1 promulgated under the Exchange Act and Nasdaq Listing Rule 5608, we adopted an incentive compensation recoupment policy which is filed herewith as Exhibit 97.1.

Non-Executive Director Compensation

The remuneration of our non-executive directors is proposed by the nomination committee and determined by the annual general meeting, based on, inter alia, a review of current practices in other companies.

Equity Incentive Plans

ESOP 2020

The ESOP 2020 is a program under which participants will be granted stock options to acquire common shares in our company. As of December 31, 2023, options to purchase up to an aggregate of 1,364,730 common shares were outstanding. Eligible participants in the ESOP 2020 include our executive officers, employees and consultants. The ESOP 2020 Program is closed for allocation, and no further options may be issued under this program.

The options under the ESOP 2020 are granted for no consideration, though grantees must pay the exercise price of such options to acquire their underlying common shares. The options generally will vest over a three-year period, with 20% vesting on the date of the first anniversary of the grant date, an additional 40% vesting during the second year following the grant date and the remaining 40% vesting during the third year following the grant date. The exercise price of the options will be set at 115% of the volume-weighted average price of the common shares on Nasdaq Stockholm during the ten trading days preceding each grant date. Following the conclusion of the vesting period, the options may be exercised during a one-year period thereafter. The options are not transferrable and may not be pledged. The number of options are subject to customary adjustment for corporate events affecting our capital structure, including a bonus issue, merger, rights issue, share split, reverse share split, reduction of share capital or similar measures. In the event of a public takeover offer, significant asset sale, liquidation, merger or similar transaction, all then unvested options will vest in their entirety following the completion of such transaction.

Our board of directors is responsible for preparing the detailed terms and conditions of the ESOP 2020, in accordance with the terms and guidelines of the ESOP 2020 approved by the shareholders. To this end, our board of directors shall be entitled to make adjustments to meet foreign regulations or market conditions, including resolving on cash or other settlement if deemed favorable for us based on foreign tax regulations. In particular, personnel in the United States may participate in the ESOP 2020 as modified by a US sub-plan. Options granted under the US sub-plan will vest in accordance with the schedules determined by our board of directors at the time of grant. All options granted under the US sub-plan will be classified as "non-qualified stock options" under US federal tax laws. No options granted under the US sub-plan will be exercisable more than four years following the date on which such options were granted (subject to earlier expiration as provided in the ESOP 2020 or the optionee's award agreement). Any adjustments to the number of options and the applicable exercise price are permitted only to the extent and in a manner that complies with Section 409A of the US Internal Revenue Code.

ESOP 2021

The ESOP 2021 is a program under which participants will be granted stock options to acquire common shares in our company. As of December 31, 2022, options to purchase up to an aggregate of 1,434,500 common shares were outstanding. Eligible participants in the ESOP 2021 include our executive officers, employees and consultants. The ESOP 2021 Program is closed for allocation, and no further options may be issued under this program.

The options under the ESOP 2021 are granted for no consideration, though grantees must pay the exercise price of such options to acquire their underlying common shares. The options generally will vest over a three-year period, with 20% vesting on the date of the first anniversary of the grant date, an additional 40% vesting during the second year following the grant date and the remaining 40% vesting during the third year following the grant date. The exercise price of the options will be set at 115% of the volume-weighted average price of the common shares on Nasdaq Stockholm during the ten trading days preceding each grant date. Following the conclusion of the vesting period, the options may be exercised during a one-year period thereafter. The options are not transferrable and may not be pledged. The number of options is subject to customary adjustment for corporate events affecting our capital structure, including a bonus issue, merger, rights issue, share split, reverse share split, reduction of share capital or similar measures. In the event of a public takeover offer, significant asset sale, liquidation, merger or similar transaction, all then unvested options will vest in their entirety following the completion of such transaction.

Our board of directors is responsible for preparing the detailed terms and conditions of the ESOP 2021, in accordance with the terms and guidelines of the ESOP 2021 approved by the shareholders. To this end, our board of directors shall be entitled to make adjustments to meet foreign regulations or market conditions, including resolving on cash or other settlement if deemed favorable for us based on foreign tax regulations. In particular, personnel in the United States may participate in the ESOP 2021 as modified by a US sub-plan. Options granted under the US sub-plan will vest in accordance with the schedules determined by our board of directors at the time of grant. All options granted under the US sub-plan will be classified as "non-qualified stock options" under US federal tax laws. No options granted under the US sub-plan will be exercisable more than four years following the date on which such options were granted (subject to earlier expiration as provided in the ESOP 2021 or the optionee's award agreement). Any adjustments to the number of options and the applicable exercise price are permitted only to the extent and in a manner that complies with Section 409A of the US Internal Revenue Code.

ESOP 2022

The ESOP 2022 is a program under which participants will be granted stock options to acquire common shares in our company. As of December 31, 2023, options to purchase up to an aggregate of 1,884,500 common shares were outstanding. Eligible participants in the ESOP 2022 include our executive officers, employees and consultants. The ESOP 2022 Program is closed for allocation, and no further options may be issued under this program.

The options under the ESOP 2022 are granted for no consideration, though grantees must pay the exercise price of such options to acquire their underlying common shares. The options generally vest over a three-year period, with 20% vesting on the date of the first anniversary of the grant date, an additional 40% vesting during the second year following the grant date and the remaining 40% vesting during the third year following the grant date. The exercise price of the options will be set at 115% of the volume-weighted average price of the common shares on Nasdaq Stockholm during the ten trading days preceding each grant date. Following the conclusion of the vesting period, the options may be exercised during a one-year period thereafter. The options are not transferrable and may not be pledged. The number of options are subject to customary adjustment for corporate events affecting our capital structure, including a bonus issue, merger, rights issue, share split, reverse share split, reduction of share capital or similar measures. In the event of a public takeover offer, significant asset sale, liquidation, merger or similar transaction, all then unvested options will vest in their entirety following the completion of such transaction.

Our board of directors is responsible for preparing the detailed terms and conditions of the ESOP 2022, in accordance with the terms and guidelines of the ESOP 2022 approved by the shareholders. To this end, our board of directors shall be entitled to make adjustments to meet foreign regulations or market conditions, including resolving on cash or other settlement if deemed favorable for us based on foreign tax regulations. In particular, personnel in the United States may participate in the ESOP 2022 as modified by a US sub-plan. Options granted under the US sub-plan will vest in accordance with the schedules determined by our board of directors at the time of grant. All options granted under the US sub-plan will be classified as "non-qualified stock options" under US federal tax laws. No options granted under the US sub-plan will be exercisable more than four years following the date on which such options were granted (subject to earlier expiration as provided in the ESOP 2022 or the optionee's award agreement). Any adjustments to the number of options and the applicable exercise price are permitted only to the extent and in a manner that complies with Section 409A of the US Internal Revenue Code.

ESOP 2023

The ESOP 2023 is a program under which participants will be granted stock options to acquire common shares in our company. As of December 31, 2023, options to purchase up to an aggregate of 1,415,000 common shares were outstanding. Eligible participants in the ESOP 2023 include our executive officers, employees and consultants. We have initially reserved options to purchase up to a maximum of 2,000,000 common shares that may be allocated under the ESOP. Our board of directors may grant options, on one or several occasions, between the date of the 2023 annual general meeting and the date of the 2024 annual general meeting to up to 200 of our employees or consultants. The maximum allocation per individual in each category shall be 300,000 Options for Category 1 (CEO), 250,000 Options for Category 2 (Management) and 100,000 Options for Category 3 (Other key personnel and consultants).

The options under the ESOP 2023 are granted for no consideration, though grantees must pay the exercise price of such options to acquire their underlying common shares. The options generally vest over a three-year period, with 20% vesting on the date of the first anniversary of the grant date, an additional 40% vesting during the second year following the grant date and the remaining 40% vesting during the third year following the grant date. The exercise price of the options will be set at 115% of the volume-weighted average price of the common shares on Nasdaq Stockholm during the ten trading days preceding each grant date. Following the conclusion of the vesting period, the options may be exercised during a one-year period thereafter. The options are not transferrable and may not be pledged. The number of options are subject to customary adjustment for corporate events affecting our capital structure, including a bonus issue, merger, rights issue, share split, reverse share split, reduction of share capital or similar measures. In the event of a public takeover offer, significant asset sale, liquidation, merger or similar transaction, all then unvested options will vest in their entirety following the completion of such transaction.

Our board of directors is responsible for preparing the detailed terms and conditions of the ESOP 2023, in accordance with the terms and guidelines of the ESOP 2023 approved by the shareholders. To this end, our board of directors shall be entitled to make adjustments to meet foreign regulations or market conditions, including resolving on cash or other settlement if deemed favorable for us based on foreign tax regulations. In particular, personnel in the United States may participate in the ESOP 2023 as modified by a US sub-plan. Options granted under the US sub-plan will vest in accordance with the schedules determined by our board of directors at the time of grant. All options granted under the US sub-plan will be classified as "non-qualified stock options" under US federal tax laws. No options granted under the US sub-plan will be exercisable more than four years following the date on which such options were granted (subject to earlier expiration as provided in the ESOP 2023 or the optionee's award agreement). Any adjustments to the number of options and the applicable exercise price are permitted only to the extent and in a manner that complies with Section 409A of the US Internal Revenue Code.

LTIP 2020

On June 25, 2020, our shareholders approved the Board Long Term Incentive Program 2020, or the LTIP 2020, which permits the grant of performance-based share awards, or Share Awards, to our board members. Pursuant to the terms of the LTIP 2020, up to 40,000 shares in the form of Share Awards can be granted. As of December 31, 2022, 29,928 Share Awards had been granted. At the end of the measurement period for the performance vesting, in June 2023, the criteria for vesting was not fulfilled and the Share Awards lapsed.

LTIP 2021

On May 27, 2021, our shareholders approved the Board Long Term Incentive Program 2021, or the LTIP 2021, which permits the grant of performance-based share awards, or Share Awards, to our board members. Pursuant to the terms of the LTIP 2021, up to 32,000 shares in the form of Share Awards can be granted. As of December 31, 2023, 22,882 Share Awards had been granted. The Share Awards shall be subject to performance-based vesting, and vest in three equal annual installments based on the performance of our share price during the relevant measurement period, calculated in accordance with the terms of the LTIP 2021, subject to the board member's continued service through the applicable vesting date. Share Awards granted under the LTIP 2021 may not be transferred. In the event of a "take-over," "asset sale" or "merger" or other similar transaction as each term is defined in the terms of the LTIP 2021, all outstanding Share Awards would vest in their entirety upon the completion of such transaction, and we shall have a right to repurchase all such Share Awards for fair market value.

LTIP 2022

On May 19, 2022, our shareholders approved the Board Long Term Incentive Program 2022, or the LTIP 2022, which permits the grant of performance-based share awards, or Share Awards, to our board members. Pursuant to the terms of the LTIP 2022, up to 50,000 shares in the form of Share Awards can be granted. As of December 31, 2023, 37,136 Share Awards had been granted. The Share Awards are subject to performance-based vesting, and vest in three equal annual installments based on the performance of our share price during the relevant measurement period, calculated in accordance with the terms of the LTIP 2022, subject to the board member's continued service through the applicable vesting date. Share Awards granted under the LTIP 2022 may not be transferred. In the event of a "take-over," "asset sale" or "merger" or other similar transaction as each term is defined in the terms of the LTIP 2022, all outstanding Share Awards would vest in their entirety upon the completion of such transaction, and we shall have a right to repurchase all such Share Awards for fair market value.

LTIP 2023

On May 30, 2023, our shareholders approved the Board Long Term Incentive Program 2023, or the LTIP 2023, which permits the grant of performance-based share awards, or Share Awards, to our board members. Pursuant to the terms of the LTIP 2022, up to 50,000 shares in the form of Share Awards can be granted. As of December 31, 2023, 40,957 Share Awards had been granted. The Share Awards are subject to performance-based vesting, and vest in three equal annual installments based on the performance of our share price during the relevant measurement period, calculated in accordance with the terms of the LTIP 2023, subject to the board member's continued service through the applicable vesting date. Share Awards granted under the LTIP 2023 may not be transferred. In the event of a "take-over," "asset sale" or "merger" or other similar transaction as each term is defined in the terms of the LTIP 2023, all outstanding Share Awards would vest in their entirety upon the completion of such transaction, and we shall have a right to repurchase all such Share Awards for fair market value.

Insurance and Indemnification

To the extent permitted by the Swedish Companies Act, we are empowered to indemnify our directors against any liability they incur by reason of their directorship. We maintain directors' and officers' insurance to insure such persons against certain liabilities.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to our board of directors, executive officers, or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

C. BOARD PRACTICES

Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules. However, our board of directors has determined that, under current listing requirements and rules of Nasdaq and taking into account any applicable committee independence standards, all of our six directors are "independent directors." In making such determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of common shares beneficially owned by the director and his or her affiliated entities (if any). The Swedish Corporate Governance Code, or the Swedish Code, includes certain independence requirements for the directors, and requires a majority of the directors to be independent of the company and its management and at least two directors independent of the company and its management to also be independent of major shareholders.

Role of the Board in Risk Oversight

Our board of directors is responsible for the oversight of our risk management activities and has delegated to the audit committee the responsibility to assist our board in this task. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Composition of Our Board of Directors

Our board of directors is currently composed of six members. Under the rules and regulations of Nasdaq a director will qualify as "independent" if our board of directors affirmatively determines that he or she has no material relationship with us (either directly or as a partner, stockholder or officer of an organization that has a relationship with us). Our board of directors has determined that, of our six directors, no director has a relationship that would interfere with the exercise of independent judgment in carrying out his or her responsibilities as a director and that each of these directors is "independent" as that term is defined under Nasdaq rules. The Swedish Code includes certain independence requirements for the directors and requires a majority of the directors to be independent of the company and its management and at least two directors independent of the company and its management to also be independent of major shareholders.

Our board of directors performs its duties in accordance with the rules of procedure of the board of directors. The rules of procedure are reviewed and adopted by the board of directors annually. Our board of directors, including the chairman is elected by our shareholders at the annual general meeting up until the end of the next annual general meeting, with the possibility of re-election. In addition, our employees may, pursuant to statutory rules regarding the representation of employees on the board of directors, elect employee representatives to the board of directors. Currently the board of directors has no employee representatives. The majority of our board members are considered to be independent under the corporate governance standards of Nasdaq and Nasdaq Stockholm.

The meeting attendance rate for our directors is set out in the table below:

Name	Board Meetings	Audit Committee Meetings	Remuneration Committee Meetings
Elmar Schnee (Chair)	13/13	—	5/5
Elisabeth Björk	13/13	—	5/5
Fred Driscoll (from May 2023)	8/8	5/5	—
Hilde Furberg	13/13	11/11	—
Molly Henderson (until May 2023)	5/5	5/6	—
Diane Parks	13/13	—	5/5
Henrik Stenqvist	13/13	11/11	—

Committees of Our Board of Directors

Our board of directors has two standing committees: an audit committee and a remuneration committee.

Audit Committee

Our audit committee currently consists of Fred Driscoll, Hilde Furberg and Henrik Stenqvist, and assists the board of directors in overseeing our accounting and financial reporting processes. Henrik Stenqvist serves as chairperson of the audit committee.

The audit committee consists exclusively of members of our board who are financially literate, and Henrik Stenqvist and Fred Driscoll are each considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board of directors has determined that all of the members of the audit committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act.

The audit committee is governed by a charter that complies with Nasdaq rules. The audit committee's responsibilities include:

- monitoring our financial reporting;
- monitoring the efficiency of our internal controls, internal auditing and risk management;
- keeping informed of the auditing of the annual report and the consolidated accounts; and
- reviewing and monitoring the impartiality and independence of our auditors and paying close attention to whether our auditors are providing other services besides audit services for us.

Our audit committee reports regularly to our board of directors on the exercise of its functions. It informs our board of directors about all areas in which action or improvement is necessary in its opinion and produces recommendations concerning the necessary steps that need to be taken. The audit review and the reporting on that review cover us and our subsidiaries as a whole. The members of the audit committee are entitled to receive all information which they need for the performance of their function, from our board of directors and employees. Every member of the audit committee shall exercise this right in consultation with the chairperson of the audit committee.

The audit committee has deliberated eleven times in the course of 2023. At these meetings, the main points of discussion were review of the 2022 financial statements, Ernst & Young AB's 2022 audit report, 2023 audit fee proposal, review of interim consolidated financial statements, Ernst & Young AB's report on interim financial statements, updates on internal control activities including SOX remediation, updates on corporate audit activities and review of the 2024 budget.

Remuneration Committee

Our remuneration committee consists of Diane Parks, Elmar Schnee and Elisabeth Bjork. Elmar Schnee serves as chairman of the remuneration committee.

The Remuneration committee's responsibilities include:

- identifying, reviewing and proposing policies relevant to the compensation and benefits of our executive officers;
- reviewing and approving each executive officer's compensation in light of such policies and reporting to the board; and
- overseeing and administering our employee share option scheme or equity incentive plans in operation from time to time.

The remuneration committee has deliberated five times over the course of 2023. The main topics of discussion were management performance reviews, allocation of share-based incentive programs, and 2023 management targets and management remuneration proposals.

Nomination Committee

We are following the Swedish Code of Corporate Governance, or the Swedish Code, and are therefore required to have a nomination committee, which is not a standing committee of our board of directors. According to the Swedish Code, the general meeting shall appoint the members of the nomination committee or resolve on procedures for appointing the members. Such procedures were adopted by our 2023 annual general meeting. The nomination committee shall, pursuant to the Swedish Code, consist of at least three members of which a majority shall be independent in relation to us and our management. In addition, at least one member of the nomination committee shall be independent in relation to the largest shareholder in terms of voting rights or group of shareholders who cooperates in terms of our management.

Ahead of the 2024 annual general meeting, the nomination committee consists of Patrick Sobocki (appointed by Stiftelsen Industrifonden), Spike Loy (appointed by BVF), Karl Tobieson (appointed by Linc AB) and Elmar Schnee (chairman of our board of directors). Karl Tobieson serves as chairman of the nomination committee.

The nomination committee's responsibilities include:

- preparing a proposal for the election of a chairman of the board of directors, the members of the board of directors, the election of a chairman of the annual general meeting, election of auditors, the determination of fees to board members and auditors, and matters pertaining thereto.

Corporate Governance Practices

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with Nasdaq listing requirements, we may rely on home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we may choose to voluntarily follow some Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K upon the occurrence of specified significant events;
- exemption from Section 16 rules requiring insiders to file public reports of their securities ownership and trading activities and providing for liability for insiders who profit from trades in a short period of time;
- exemption from the Nasdaq requirement necessitating disclosure of any waivers of the Code of Business Conduct and Ethics for directors and executive officers;
- exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans and equity issuances;
- exemption from the requirement that our audit committee have review and oversight responsibilities over all "related party transactions," as defined in Item 7.B of Form 20-F;
- exemption from the requirement that our board of directors have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- exemption from the requirement to have independent director oversight of director nominations.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d). We intend to follow Swedish corporate governance practices in lieu of Nasdaq corporate governance requirements as follows:

- We do not intend to follow Nasdaq Rule 5620(c) regarding quorum requirements applicable to meetings of shareholders. Such quorum requirements are not required under Swedish law. The Swedish Companies Act (SFS 2005:551) and our articles of association, which were approved by our shareholders on May 19, 2022 and are currently in effect, provide alternative quorum requirements that are generally applicable to meetings of shareholders.
- We do not intend to follow Nasdaq Rule 5605(b)(2), which requires that independent directors regularly meet in executive sessions where only independent directors are present. Our independent directors may choose to meet in executive sessions at their discretion.
- We do not intend to follow Nasdaq Rule 5605(e) regarding the composition of the nominating committee.

Although we may rely on certain home country corporate governance practices, we must comply with Nasdaq's Notification of Noncompliance requirement (Nasdaq Rule 5625) and the Voting Rights requirement (Nasdaq Rule 5640). Further, we must have an audit committee that satisfies Nasdaq Rule 5605(c)(3), which addresses audit committee responsibilities and authority and requires that the audit committee consist of members who meet the independence requirements of Nasdaq Rule 5605(c)(2)(A)(ii).

Because we are a foreign private issuer, our directors and executive officers are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. They will, however, be subject to the obligations to report changes in securities ownership under Section 13 of the Exchange Act and related SEC rules.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and Nasdaq listing rules.

Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

D. EMPLOYEES

For information regarding our employees, see "Item 4.B.—Business Overview—Employees and Human Capital Disclosure."

E. SHARE OWNERSHIP

For information regarding the share ownership of our directors and members of our executive committee, see "Item 6.B.—Compensation" and "Item 7.A.—Major Shareholders."

F. DISCLOSURE OF A REGISTRANT'S ACTION TO RECOVER ERRONEOUSLY AWARDED COMPENSATION

Not applicable.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. MAJOR SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common shares as of February 29, 2024 for:

- each person who is known by us to own beneficially more than 5% of our total outstanding common shares;
- each member of our board of directors and our executive officers;
- all members of our board of directors and our executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include common shares that can be acquired within 60 days of February 29, 2024. The percentage ownership information shown in the table is based upon 59,580,087 common shares outstanding as of February 29, 2024.

Except as otherwise indicated, all of the shares reflected in the table are common shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of common shares beneficially owned by a person and the percentage ownership of that person, we deemed outstanding common shares subject to options held by that person that are immediately exercisable or exercisable within 60 days of February 29, 2024. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. The information in the table below is based on information known to us or ascertained by us from public filings made by the shareholders.

	Shares beneficially owned	
Name of beneficial owner	**Number**	**Percentage**
5% or Greater Shareholders:		
BVF Partners L.P.(1)	6,260,311	10.5 %
Linc AB(2)	5,962,312	10.0 %
Stiftelsen Industrifonden (3)	3,145,440	5.3 %
Executive Officers and Directors:		
Renée Aguiar-Lucander(4)	939,000	1.6 %
Fredrik Johansson(5)	172,750	*
Richard Philipson, M.D. (6)	125,000	*
Marie Törnsèn	—	—
Frank Bringstrup, M.D.(7)	53,500	*
Elmar Schnee(8)	33,236	*
Hilde Furberg(9)	53,199	*
Diane Parks(10)	8,449	*
Fred Driscoll	—	—
Elisabeth Björk	—	—
Henrik Stenqvist(11)	10,000	*
Brian Gorman	—	—
Lars Stubberud(12)	30,000	*
All directors and executive officers as a group (13 persons)	1,425,134	2.3 %

* Indicates beneficial ownership of less than 1% of the total outstanding common shares.

(1) Based on shareholder information as of December 31, 2022 as provided in a Schedule 13G/A filed with the Securities and Exchange Commission on February 14, 2023. BVF Inc., as the general partner of BVF Partners L.P., may be deemed to beneficially own the shares that are beneficially owned by such funds. Mark Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the shares that are beneficially owned by BVF Inc. The address of the above persons and entities is 44 Montgomery St. 40th floor, San Francisco, CA 94104.

(2) Consists of 5,962,312 common shares held directly by Linc AB. Voting and dispositive power over the shares is held by the board of directors of Linc AB. Bengt Julander is the majority shareholder and chairman of the board of directors of Linc AB. As such, Bengt Julander may be deemed a beneficial owner, for purposes of Section 13(d) of the Securities Act of 1933, as amended, of any securities of the Issuer beneficially owned by Linc AB. The address of Linc AB is Birger Jarlsgatan 36, 114 29 Stockholm, Sweden.

(3) Consists of 3,145,440 common shares, held directly by Stiftelsen Industrifonden. Peter Wolpert is the Chief Executive Officer of Stiftelsen Industrifonden and has voting and dispositive power with respect to the shares reported in the table above. The address of Stiftelsen Industrifonden is Vasagatan 11, 111 91 Stockholm, Sweden.

(4) Consists of 643,000 common shares and 296,000 options.

(5) Consists of 42,750 common shares and 130,000 options.

(6) Consists of 125,000 options.

(7) Consists of 8,500 common shares and 45,000 options.

(8) Consists of 33,236 common shares.

(9) Consists of 53,199 common shares.

(10) Consists of 8,449 common shares.

(11) Consists of 10,000 common shares.

(12) Consists of 30,000 options.

Each of our shareholders is entitled to one vote per common share. None of the holders of our shares have different voting rights from other holders of shares. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

As of February 29, 2024, we had one holder of record of our ADSs in the United States, which is CITIBANK ADR. This shareholder held in the aggregate 5.3% of the 59,580,087 common shares outstanding as of February 29, 2024. The number of record holders in the United States is not representative of the number of beneficial holders nor is it representative of where such beneficial holders are resident since many of these common shares were held by brokers or other nominees. As of December 31, 2023, assuming that all of our common shares represented by ADSs are held by residents of the United States, we estimate that approximately 15.0% of our outstanding common shares were held in the United States by approximately 34 institutional holders of record.

To our knowledge, and other than changes in percentage ownership as a result of the shares issued in connection with our initial US public offering, there has been no significant change in the percentage ownership held by the major shareholders listed above.

B. RELATED PARTY TRANSACTIONS

Other than compensation arrangements described in “Management” elsewhere in this annual report, since January 1, 2023, we have not engaged in any transactions with our executive officers, directors or holders of more than 5% of our share capital, including their affiliates, which we refer to as our related parties.

(iii) Agreements with Our Executive Officers and Directors

We have entered into employment agreements with certain of our executive officers. These agreements contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the executive officers and non-executive directors. The enforceability of the non-competition provisions may be limited under applicable law.

(iv) Related Party Transactions Policy

We have adopted a related party transaction policy requiring that all related party transactions required to be disclosed by a foreign private issuer pursuant to the Exchange Act be approved by the audit committee or another independent body of our board of directors.

C. INTERESTS OF EXPERTS AND COUNSEL

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION

(v) Consolidated financial statements

The consolidated financial statements are included as part of this annual report, starting at page F-1.

(vi) Legal proceedings

From time to time, we may become involved in legal, governmental or arbitration proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal, governmental or arbitration proceeding. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

(vii) Dividend policy

We have no present intention to pay dividends in the foreseeable future. Any recommendation by our board of directors to pay dividends will depend on many factors, including our financial condition (including losses carried-forward), results of operations, legal requirements and other factors. Furthermore, pursuant to Swedish law, the calculation of amounts available for distribution to shareholders, as dividends or otherwise, must be determined on the basis of our non-consolidated statutory accounts prepared in accordance with Swedish accounting rules.

B. SIGNIFICANT CHANGES

Except as disclosed elsewhere in this annual report, we have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

ITEM 9. THE OFFER AND LISTING

A. OFFER AND LISTING DETAILS

Our ADSs have traded on The Nasdaq Global Select Market under the symbol “CALT” since June 5, 2020. Prior to that date, there was no public trading market for our ADSs. Our common shares have traded on Nasdaq Stockholm under the symbol “CALTX” since June 29, 2018. Prior to that date, there was no public trading market for our ADSs or our common shares.

B. PLAN OF DISTRIBUTION

Not applicable.

C. MARKETS

The ADSs have been listed on The Nasdaq Global Select Market under the symbol “CALT” since June 5, 2020, and our common shares have been listed on Nasdaq Stockholm under the symbol “CALTX” since June 29, 2018.

D. SELLING SHAREHOLDERS

Not applicable.

E. DILUTION

Not applicable.

F. EXPENSES OF THE ISSUE

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. SHARE CAPITAL

Not applicable.

B. MEMORANDUM AND ARTICLES OF ASSOCIATION

We are a Swedish public limited company registered with the Swedish Companies Registration Office (corporate registration number 556659-9766). Below are summaries of the material provisions of our articles of association and of related material provisions of the Swedish Companies Act.

Articles of Association

Object of the Company

Our object is set forth in Section 3 of our articles of association and is to, directly or through subsidiaries, conduct research and development as well as the manufacture and sale of pharmaceuticals and medical devices, own and manage shares and other securities as well as other tangible and intangible property, as well as any other business associated therewith.

Powers of the Directors

Our board of directors shall direct our policy and shall supervise the performance of our chief executive officer and his or her actions. Our board of directors may exercise all powers that are not required under the Swedish Companies Act or under our articles of association to be exercised or taken by our shareholders.

Number of Directors

Our articles of association provide that our board of directors shall consist of three to ten members. Our board of directors currently has six members, with no deputy members.

Rights Attached to Shares

The shares shall be issued in two classes, ordinary shares and C-shares. All of the common shares have equal rights to our assets and earnings, and are entitled to one vote at the general meeting. Holders of C-shares are entitled to one tenth vote per share. At the general meeting, every shareholder may vote to the full extent of their shares held or represented, without limitation. Each share entitles the shareholder to the same preferential rights related to issues of shares, warrants and convertible bonds relative to the number of shares they own. The common shares have equal rights to dividends and any surplus capital upon liquidation, whereas the C-shares do not entitle to dividends. Upon liquidation, C-shares carry equivalent right to our assets as other shares, however not to an amount exceeding the quota value of the share. Shareholders' rights can only be changed in accordance with the procedures set out in the Swedish Companies Act. Transfers of shares are not subject to any restrictions. There are no limitations on the rights to own securities.

Exclusive Forum

Our articles of association provide that, unless we consent in writing to the selection of an alternative forum and without any infringement on Swedish forum provisions and without applying Chapter 7, Section 54 of the Swedish Companies Act, the United States District Court for the Southern District of New York shall be the sole and exclusive forum for resolving any complaint filed in the United States asserting a cause of action arising under the Securities Act, or the Federal Forum Provision. We recognize that the proposed Federal Forum Provision may impose additional litigation costs on shareholders in pursuing any such claims, particularly if the shareholders do not reside in or near the State of New York. Additionally, proposed Federal Forum Provision may limit our shareholders' ability to bring a claim in a US judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our shareholders.

Preemptive Rights

Under the Swedish Companies Act, shareholders of any class of shares will generally have a preemptive right to subscribe for shares or warrants issued of any class in proportion to their shareholdings. Shareholders will have preferential rights to subscribe for new shares in proportion to the number of shares they own. If an offering is not fully subscribed for based on subscription rights, shares may be allocated to subscribers without subscription rights. The preemptive right to subscribe does not apply in respect of shares issued for consideration by payment in kind or of shares issued pursuant to convertible debentures or warrants previously issued by the company without preemptive rights for the shareholders.

The preemptive right to subscribe for new shares may be set aside. A share issue with deviation from the shareholders' preemptive rights may be resolved either by the shareholders at a general meeting, or by the board of directors if the board resolution is preceded by an authorization therefor from the general meeting. A resolution to issue shares with deviation from the shareholders' preemptive rights and a resolution to authorize the board of directors to do the same must be passed by two-thirds or, in certain situations, nine-tenths of both the votes cast and the shares represented at the general meeting resolving on the share issue or the authorization of the board of directors.

Voting at Shareholder Meetings

Under the Swedish Companies Act, shareholders entered into the shareholders' register as of the record date are entitled to vote at a general meeting (in person or by appointing a proxyholder). In accordance with our articles of association, shareholders must give notice of their intention to attend the general meeting no later than the date specified in the notice. Shareholders who have their shares registered through a nominee and wish to exercise their voting rights at a general meeting must request to be temporary registered as a shareholder and entered into the shareholders' register four business days prior to the date of the general meeting. The board of directors has the right before a shareholders' meeting to decide that shareholders shall be able to exercise their right to vote by post before the shareholders' meeting. The rights described herein do not apply to holders of ADSs. See "Item 12.D.—American Depositary Shares."

Shareholder Meetings

The general meeting of shareholders is our highest decision-making body and serves as an opportunity for our shareholders to make decisions regarding our affairs. Shareholders who are registered in the share register held by Euroclear Sweden AB six business days before the meeting and have notified us no later than the date specified in the notice described below have the right to participate at our general meetings, either in person or by a representative. All shareholders have the same participation and voting rights at general meetings. At the annual general meeting, inter alia, members of the board of directors are elected, the principles for the appointment of the nomination committee are established, and a vote is held on whether each individual board member and the chief executive officer will be discharged from any potential liabilities for the previous fiscal year. Auditors are elected as well. Decisions are made concerning adoption of annual reports, allocation of earnings, fees for the board of directors and the auditors, guidelines for executive remuneration, the remuneration report and other essential matters that require a decision by the meeting. Most decisions require a simple majority, but the Swedish Companies Act dictates other thresholds in certain instances. See "—Differences in Corporate Law—Shareholder Vote on Certain Transactions."

Shareholders have the right to ask questions to our board of directors and managers at general meetings which pertain to the business of the company and also have an issue brought forward at the general meeting. In order for us to include the issue in the notice of the annual general meeting, a request of issue discussion must be received by us normally seven weeks before the meeting. Any request for the discussion of an issue at the annual general meeting shall be made to the board of directors and any request within the nomination committee's competence shall be made to the nomination committee. The board shall convene an extraordinary general meeting if shareholders who together represent at least 10% of all shares in the company so demand in writing to discuss or resolve on a specific issue.

The arrangements for the calling of general meetings are described below in "—Differences in Corporate Law—Annual General Meeting" and "—Differences in Corporate Law—Special Meeting."

Notices

The Swedish Companies Act requirements for notice are described below in "—Differences in Corporate Law—Notices."

Subject to our articles of association and Nasdaq Stockholm's Rulebook for Issuers, we must publish the full notice of a general meeting by way of press release, on our website and in the Swedish Official Gazette, and must also publish in the Svenska Dagbladet, a daily Swedish newspaper, that such notice has been published. The notice of the annual general meeting will be published six to four weeks before the meeting. The notice must include an agenda listing each item that shall be voted upon at the meeting. The notice of any extraordinary general meetings will be published six to three weeks before the meeting. Pursuant to the Swedish Code of Corporate Governance, which does not carry the force of law but is considered ideal corporate governance practice for Swedish companies whose shares trade on a regulated market, we shall, as soon as the time and venue for the annual general meeting have been decided, and no later than in conjunction with the third quarter report, publish such information on our website.

Record Date

Under the Swedish Companies Act, in order for a shareholder to participate in a shareholders' meeting, the shareholder must have its shares registered in its own name in the share register four business days. In accordance with section 8 of our articles of association, shareholders must give notice of their intention to attend the shareholders' meeting no later than the date specified in the notice.

Amendments to the Articles of Associations

Under the Swedish Companies Act, an amendment of our articles of association requires a resolution passed at a shareholders' meeting. The number of votes required for a valid resolution depends on the type of amendment, however, any amendment must be approved by not less than two-thirds of the votes cast and represented at the meeting. The board of directors is not allowed to make amendments to the articles of association absent shareholder approval.

Provisions Restricting Change in Control of Our Company

Neither our articles of association nor the Swedish Companies Act contains any restrictions on change of control.

Differences in Corporate Law

The applicable provisions of the Swedish Companies Act differ from laws applicable to US corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of, inter alia, the Swedish Companies Act applicable to us and the Delaware General Corporation Law relating to shareholders' rights and protections. We are not subject to Delaware law but are presenting this description for comparative purposes. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and Swedish law.

Number of Directors

Sweden. Under the Swedish Companies Act, a public company shall have a board of directors consisting of at least three directors. More than half of the directors shall be resident within the EEA (unless otherwise approved by the Swedish Companies Registration Office). The actual number of board members shall be determined by a shareholders' meeting, within the limits set out in the company's articles of association. Under the Swedish Code of Corporate Governance, only one director may also be a senior executive of the relevant company or a subsidiary. The Swedish Code of Corporate Governance includes certain independence requirements for the directors, and requires a majority of the directors to be independent of the company and at least two directors to also be independent of major shareholders.

Delaware. Under the Delaware General Corporation Law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws. The Delaware General Corporation Law does not address director independence, though Delaware courts have provided general guidance as to determining independence, including that the determination must be both an objective and a subjective assessment.

Removal of Directors

Sweden. Under the Swedish Companies Act, directors appointed at a general meeting may be removed by a resolution adopted at a general meeting, upon the affirmative vote of a simple majority of the votes cast.

Delaware. Under the Delaware General Corporation Law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (a) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, shareholders may effect such removal only for cause, or (b) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Vacancies on the Board of Directors

Sweden. Under the Swedish Companies Act, if a director's tenure should terminate prematurely, the election of a new director may be deferred until the time of the next annual general meeting, providing there are enough remaining directors to constitute a quorum.

Delaware. Under the Delaware General Corporation Law, vacancies on a corporation's board of directors, including those caused by an increase in the number of directors, may be filled by a majority of the remaining directors unless (a) otherwise provided in the certificate of incorporation or by-laws of the corporation or (b) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Annual General Meeting

Sweden. Under the Swedish Companies Act, within six months of the end of each fiscal year, the shareholders shall hold an annual general meeting at which the board of directors shall present the annual report and auditor's report and, for a parent company which is obliged to prepare group accounts, the group accounts and the auditor's report for the group. Shareholder meetings shall be held in the city stated in the articles of association. The minutes of a shareholders' meeting must be made available on the company's website no later than two weeks after the meeting.

Delaware. Under the Delaware General Corporation Law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws. If a company fails to hold an annual meeting or fails to take action by written consent to elect directors in lieu of an annual meeting for a period of 30 days after the date designated for the annual meeting, or if no date was designated, 13 months after either the last annual meeting or the last action by written consent to elect directors in lieu of an annual meeting, whichever is later, the Delaware Court of Chancery may summarily order a meeting to be held upon the application of any stockholder or director. The Delaware General Corporation Law does not require minutes of stockholders' meetings to be made public.

Special Meeting

Sweden. Under the Swedish Companies Act, the board of directors shall convene an extraordinary general meeting if a shareholder minority representing at least ten per cent of the company's shares or the auditor of the company so demands, and the board of directors may convene an extraordinary general meeting whenever it believes reason exists to hold an extraordinary general meeting prior to the next annual general meeting.

Delaware. Under the Delaware General Corporation Law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

Notices

Sweden. Under the Swedish Companies Act, a shareholders' meeting must be preceded by a notice. The notice of the annual general meeting of shareholders must be issued no sooner than six weeks and no later than four weeks before the date of an annual general meeting. In general, notice of other extraordinary general meetings must be issued no sooner than six weeks and no later than three weeks before the meeting. Publicly listed companies must always notify shareholders of a general meeting by advertisement in a Swedish newspaper, the Swedish Official Gazette, by press release, and on the company's website.

Delaware. Under the Delaware General Corporation Law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

Preemptive Rights

Sweden. Under the Swedish Companies Act, shareholders of any class of shares have a preemptive right (Sw. företrädesrätt) to subscribe for shares issued of any class in proportion to their shareholdings. The preemptive right to subscribe does not apply in respect of shares issued for consideration other than cash or of shares issued pursuant to convertible debentures or warrants previously issued by the company without preemptive rights for the shareholders. The preemptive right to subscribe for new shares may also be set aside by a resolution passed by two thirds or, in certain situations, nine-tenths of the votes cast, and shares represented at the shareholders' meeting resolving upon the issue.

Delaware. Under the Delaware General Corporation Law, unless otherwise provided in a corporation's certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's stock.

Shareholder Vote on Certain Transactions

Sweden. In matters which do not relate to elections and are not otherwise governed by the Swedish Companies Act or the articles of association, resolutions shall be adopted at the general meeting by a simple majority of the votes cast. In the event of a tied vote, the chairman shall have the casting vote. For matters concerning securities of the company, such as new share issuances, and other transactions such as private placements, mergers, and a change from a public to a private company (or vice-versa), the articles of association may only prescribe thresholds which are higher than those provided in the Swedish Companies Act.

Unless otherwise prescribed in the articles of association, the person who receives the most votes in an election shall be deemed elected. In general, a resolution involving the alteration of the articles of association shall be valid only when supported by shareholders holding not less than two-thirds of both the votes cast and the shares represented at the general meeting. The Swedish Companies Act lays out numerous exceptions for which a higher threshold applies, including restrictions on certain rights of shareholders, limits on the number of shares shareholders may vote at the general meeting, directed share issues to directors, employees and other closely related parties, and changes in the legal relationship between shares.

Delaware. Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: (i) the approval of the board of directors; and (ii) approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

C. MATERIAL CONTRACTS

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company," "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions," or elsewhere in this annual report on Form 20-F.

D. EXCHANGE CONTROLS

There is no Swedish legislation affecting the import or export of capital or the remittance of dividends, interest or other payments to non-resident holders of our securities, except that, subject to the provisions in any tax treaty, dividends are subject to withholding tax.

E. TAXATION

General

The taxation discussion set forth below does not purport to be a complete analysis or listing of all potential tax effects relevant to the acquisition, ownership, or disposition of our common shares or ADSs. The statements of United States and Swedish tax laws set forth below are based on the laws in force as of the date of this report and may be subject to any changes in United States or Swedish law, and in any double taxation convention or treaty between the United States and Sweden, occurring after that date, which changes may then have retroactive effect.

Specific tax provisions may apply for certain categories of taxpayers. Your tax treatment if you are a holder of our common shares or ADSs depends in part on your particular situation. If you are a holder of our common shares or ADSs, you should therefore consult a tax advisor as to the tax consequences relating to your particular circumstances resulting from the ownership of our common shares or ADSs.

Certain United States Federal Income Tax Consequences

The following is a description of certain material US federal income tax considerations for US Holders (defined below) with respect to their ownership and disposition of our common shares or ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire common shares or ADSs. This discussion applies only to a US Holder that holds our common shares or ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a US Holder's particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences, the potential application of the Medicare contribution tax, and tax consequences applicable to US Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- US expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons required for US federal income tax purposes to conform the timing of income accruals to their financial statements under Section 451(b) of the Code;
- persons holding common shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to common shares or ADSs;
- persons whose "functional currency" for US federal income tax purposes is not the US dollar;
- brokers, dealers or traders in securities, commodities, or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for US federal income tax purposes;
- regulated investment companies or real estate investment trusts;
- persons who acquired our common shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons holding our common shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States; and

- persons who own (directly, constructively or through attribution) 10% or more (by vote or value) of our outstanding common shares or ADS.

If an entity that is classified as a partnership for US federal income tax purposes holds common shares or ADSs, the US federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding common shares or ADSs and partners in such partnerships are encouraged to consult their tax advisors as to the particular US federal income tax consequences of holding and disposing of common shares or ADSs.

The discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the Convention Between the Government of the United States and the Government of Sweden for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, signed on September 1, 1994 or the US-Sweden Tax Treaty, all as of the date hereof, changes to any of which may affect the tax consequences described herein—possibly with retroactive effect.

A "US Holder" is a holder who, for US federal income tax purposes, is a beneficial owner of common shares or ADSs and is:

(i) an individual who is a citizen or resident of the United States;

(ii) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;

(iii) an estate the income of which is subject to US federal income taxation regardless of its source; or

(iv) a trust if (1) a US court is able to exercise primary supervision over the administration of the trust and one or more US persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a US person under applicable US Treasury Regulations.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Accordingly, a holder of an ADS should be treated for US federal income tax purposes as holding the common shares represented by the ADS.

PERSONS CONSIDERING AN INVESTMENT IN COMMON SHARES OR ADSs SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THEM RELATING TO THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE COMMON SHARES OR ADSs, INCLUDING THE APPLICABILITY OF US FEDERAL, STATE AND LOCAL TAX LAWS.

PFIC Rules

A non-US corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income (determined under applicable Treasury Regulations); or

- at least 50% of its average percentage of gross assets (determined under applicable Treasury Regulations) is attributable to assets that produce passive income or are held for the production of passive income.

If a non-US corporation owns directly or indirectly at least 25% by value of the stock of another entity treated as a corporation or partnership for US federal income tax purposes (or, in the case of a partnership, the non-US corporation satisfies active partner tests with respect to the partnership), the non-US corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of such entity and as receiving directly its proportionate share of the other entity's income.

Based on our analysis of our income, assets, activities and market capitalization for our taxable year ended December 31, 2023, we do not believe that we were a PFIC for our taxable year ended December 31, 2023. Because PFIC status is a fact specific determination that generally cannot be made until the close of the taxable year in question, the calculation of the value of our non-cash assets may be based in part on the value of our common shares or ADSs, the value of which may fluctuate considerably, and we hold a substantial amount of cash and cash equivalents, our PFIC status may change from year to year, it is difficult to predict whether we will be a PFIC for the current taxable year or any future year, and no assurance can be given that we will not be a PFIC for our current taxable year or any future year. Therefore, we have not yet made any determination as to our expected PFIC status for the current year. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the IRS will agree with our conclusion. Furthermore, because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge our classification of certain income and assets as non-passive or our valuation of our tangible and intangible assets, each of which may result in us being treated as a PFIC. Our United States counsel expresses no opinion with respect to our PFIC status for any prior, the current, or any future taxable year.

If we are classified as a PFIC in any year with respect to which a US Holder owns the common shares or ADSs, we will continue to be treated as a PFIC with respect to such US Holder in all succeeding years during which the US Holder owns the common shares or ADSs, regardless of whether we continue to meet the tests described above unless we cease to be a PFIC and the US Holder has made a "deemed sale" election under the PFIC rules. If the "deemed sale" election is made, the US Holder will be deemed to have sold the common shares or ADSs the US Holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the US Holder's common shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the US Holder will not be subject to the rules described below with respect to any "excess distribution" the US Holder receives from us or any gain from an actual sale or other disposition of the common shares or ADSs.

For each taxable year we are treated as a PFIC with respect to US Holders, US Holders will be subject to special tax rules with respect to any "excess distribution" such US Holder receives and any gain such US Holder recognizes from a sale or other disposition (including, under certain circumstances, a pledge) of common shares or ADSs, unless (i) such US Holder makes a "qualified electing fund" election, or QEF Election, with respect to all taxable years during such US Holder's holding period in which we are a PFIC or (ii) our common shares or ADSs constitute "marketable" securities, and such US Holder makes a mark-to-market election as discussed below. Distributions a US Holder receives in a taxable year that are greater than 125% of the average annual distributions a US Holder received during the shorter of the three preceding taxable years or the US Holder's holding period for the common shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a US Holder's holding period for the common shares or ADSs;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the common shares or ADSs cannot be treated as capital, even if a US Holder holds the common shares or ADSs as capital assets. In addition, if we are a PFIC, a US Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries that also are PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such US Holder. US Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

If a US Holder makes an effective QEF Election, the US Holder will be required to include in gross income each year, whether or not we make distributions, as capital gains, such US Holder's pro rata share of our net capital gains and, as ordinary income, such US Holder's pro rata share of our earnings in excess of our net capital gains. However, a US Holder can only make a qualified electing fund election with respect to common shares in a PFIC if such company agrees to furnish such US Holder with certain tax information annually. We do not currently intend to provide US Holders with the information necessary for US Holders to make a QEF Election. Therefore, you should assume that you will not receive such information from us and would therefore be unable to make a QEF Election with respect to any of our common shares or ADSs were we to be or become a PFIC.

US Holders can avoid the interest charge on excess distributions or gain relating to the common shares or ADSs by making a mark-to-market election with respect to the common shares or ADSs, provided that the common shares or ADSs are "marketable." Common shares or ADSs will be marketable if they are "regularly traded" on certain US stock exchanges or on a foreign stock exchange that meets certain conditions. For these purposes, the common shares or ADSs (respectively) will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. It should be noted that only the ADSs and not our common shares are listed on the Nasdaq Global Select Market. The Nasdaq Global Select Market is a qualified exchange for this purpose and, consequently, if the ADSs are regularly traded, the mark-to-market election should be available to a US Holder. Consequently, our common shares may not be marketable if Nasdaq Stockholm (where our common shares are currently listed) does not meet the applicable requirements. Each US Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the common shares or ADSs.

A US Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the common shares or ADSs at the close of the taxable year over the US Holder's adjusted tax basis in the common shares or ADSs. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the US Holder's adjusted basis in the common shares or ADSs over the fair market value of the common shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the common shares or ADSs will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the Internal Revenue Service, or the IRS, unless the common shares or ADSs cease to be marketable.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable." As a result, even if a US Holder validly makes a mark-to-market election with respect to our common shares or ADSs, the US Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for US federal income tax purposes. US Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances. Unless otherwise provided by the US Treasury, each US shareholder of a PFIC is required to make an annual filing containing such information as the US Treasury may require. US Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON YOUR INVESTMENT IN THE COMMON SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE COMMON SHARES OR ADSs.

Taxation of Distributions

Subject to the discussion above under "PFIC rules," distributions paid on common shares or ADSs, other than certain pro rata distributions of common shares or ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under US federal income tax principles). Because we may not calculate our earnings and profits under US federal income tax principles, we expect that distributions generally will be reported to US Holders as dividends. Non-corporate US Holders may qualify for the preferential rates of taxation with respect to dividends on our common shares or ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below) if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. A non-US corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on common shares or ADSs that are readily tradable on an established securities market in the United States. Our ADSs are listed on the Nasdaq Global Select Market, which is an established securities market in the United States, and we expect the ADSs to be readily tradable on the Nasdaq Global Select Market. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States. We are incorporated under the laws of Sweden, and we believe that we qualify as a resident of Sweden for purposes of, and are eligible for the benefits of, the US-Sweden Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the US-Sweden Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion regarding the PFIC rules, such dividends will generally be expected to be "qualified dividend income" in the hands of individual US Holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. However, the qualified dividend income treatment will not apply if we are treated as a PFIC with respect to the US Holder. Each US Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate on dividends with regard to its particular circumstances.

The amount of any dividend will be treated as foreign-source dividend income to US Holders and will not be eligible for the dividends-received deduction generally available to US corporations under the Code. Dividends will generally be included in a US Holder's income on the date of the US Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the US dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into US dollars. If the dividend is converted into US dollars on the date of receipt, a US Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A US Holder may have foreign currency gain or loss if the dividend is converted into US dollars after the date of receipt. Such gain or loss would generally be treated as US-source ordinary income or loss.

Subject to applicable limitations, some of which may vary depending upon your circumstances, Swedish income taxes withheld from dividend payments on shares at a rate not exceeding an applicable rate under the US-Sweden Tax Treaty will be creditable against your US federal income tax liability. Swedish income taxes withheld in excess of the applicable rate under the US-Sweden Tax Treaty will not be eligible for credit against your US federal income tax liability. The rules governing foreign tax credits are complex and US Holders should therefore consult their tax advisors regarding the effect of the receipt of dividends for foreign tax credit limitation purposes.

Sale or Other Taxable Disposition of Common Shares and ADSs

Subject to the discussion above under "PFIC rules," gain or loss realized on the sale or other taxable disposition of common shares or ADSs will be capital gain or loss and will be long-term capital gain or loss if the US Holder held the common shares or ADSs for more than one year. The amount of the gain or loss will equal the difference between the US Holder's tax basis in the common shares or ADSs disposed of, and the amount realized on the disposition, in each case as determined in US dollars. This gain or loss will generally be US-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a US Holder is not paid in US dollars, the amount realized will be the US dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the common shares or ADSs are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the US dollar value of the amount realized in a non-US dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the US dollar amount realized on the date of sale or disposition and the US dollar value of the currency received at the spot rate on the settlement date.

Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain US-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the US Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the US Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding on a duly executed IRS Form W-9 or otherwise establishes an exemption.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a US Holder will be allowed as a credit against the US Holder's US federal income tax liability and may entitle the US Holder to a refund, provided that the required information is timely furnished to the IRS. US Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

Information with Respect to Foreign Financial Assets

Certain US Holders who are individuals (and, under regulations, certain entities) may be required to report information relating to the common shares or ADSs, subject to certain exceptions (including an exception for common shares or ADSs held in accounts maintained by certain US financial institutions), by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. Such US Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a US Holder does not file the required information, the statute of limitations with respect to tax returns of the US Holder to which the information relates may not close until three years after such information is filed. US Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the common shares or ADSs.

Material Swedish Tax Considerations

The following is a summary of certain material Swedish tax issues for holders of common shares or ADSs that are not resident in Sweden for tax purposes. The summary is based on current legislation and is intended to provide general information only. The summary does not cover, inter alia, the special rules regarding tax-free dividends that may be applicable when investors hold common shares or ADSs that are deemed to be held for business purposes (for tax purposes), foreign companies conducting business through a permanent establishment in Sweden, or foreign companies that have been Swedish companies. Each person considering an investment in common shares or ADSs is advised to consult an independent tax advisor as to the tax consequences that could arise from the acquisition, ownership and disposition of the common shares or ADSs.

Taxation of Dividends

For holders not resident in Sweden for tax purposes that receive dividends on common shares or ADSs of a Swedish limited liability company, Swedish withholding tax is normally withheld. The same withholding tax applies to certain other payments made by a Swedish limited liability company, such as payments as a result of redemption of shares and repurchase of shares through an offer directed to all shareholders or all holders of a certain class. The withholding tax rate is 30%. The tax rate is, however, generally reduced under an applicable tax treaty. For example, under the US-Sweden Tax Treaty the tax rate on dividends paid to US holders entitled to the benefits of the US-Sweden Tax Treaty should not exceed 15%. In Sweden, withholding tax deductions are normally carried out by Euroclear Sweden AB or, in respect of nominee-registered shares, by the nominee. The tax treaties Sweden has entered into generally enable the withholding tax deduction to be made in accordance with the tax rate stipulated in the treaty, provided that Euroclear Sweden AB or the nominee, as applicable, has received the required information concerning the tax residency of the investor entitled to the dividend (this applies also under the US—Sweden tax treaty). Furthermore, investors entitled to reduced tax rates under applicable tax treaties may claim a refund from the Swedish tax authorities within five calendar years following the year the dividend was distributed if the full withholding tax rate at 30% has been withheld.

Taxation of Capital Gains

Holders not resident in Sweden for tax purposes are normally not liable for capital gains taxation in Sweden upon disposals of common shares or ADSs. Holders of common shares or ADSs may, however, be subject to taxation in their state of residence.

According to a special rule, private individuals not resident in Sweden for tax purposes are, however, subject to Swedish capital gains taxation upon disposals of common shares or ADSs if they have been residents of Sweden due to a habitual abode in Sweden or a continuous stay in Sweden at any time during the calendar year of disposal or the ten calendar years preceding the year of disposal. In a number of cases though, the applicability of this rule is limited by tax treaties. For example, under the US-Sweden Tax Treaty this rule applies for ten years from the date the private individuals became non-resident of Sweden for tax purposes.

F. DIVIDENDS AND PAYING AGENTS

Not applicable.

G. STATEMENT BY EXPERTS

Not applicable.

H. DOCUMENTS ON DISPLAY

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an annual report containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at www.calliditas.se. We intend to post a link to our annual report on Form 20-F as filed with the SEC on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

The SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding registrants, such as us, that file electronically with the SEC.

With respect to references made in this annual report to any contract or other document of Calliditas Therapeutics AB, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this annual report for copies of the actual contract or document.

I. SUBSIDIARY INFORMATION

Not applicable.

J. ANNUAL REPORT TO SECURITY HOLDERS

We intend to submit any annual report provided to security holders in electronic format as an exhibit to a report on Form 6-K.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative and Qualitative Disclosures about Market Risks

Market risk is the risk that the fair value of, or future cash flows from, a financial instrument will vary due to changes in market prices. The type of market risk that primarily impacts us is foreign currency risk.

Foreign Currency Risk

Translation Exposure

We maintain our consolidated financial statements in our functional currency Swedish Kronor, which is also our functional currency. All amounts, unless otherwise stated, are rounded to the nearest thousand.

Transactions in foreign currency are translated to the functional currency at the exchange rate on the date of the transaction. Monetary assets and liabilities in foreign currency are translated to the functional currency at the exchange rate that applies on the closing date. Exchange rate differences arising on translation are recognized in net profit for the year. Foreign exchange gains and losses on operating receivables and liabilities are recognized in operating profit, while foreign exchange gains and losses on financial receivables and liabilities are recognized as financial items.

Assets and liabilities in foreign operations are translated from the functional currency of the operations to our presentation currency at the exchange rate applicable on the closing date. Income and expenses in a foreign operation are translated to SEK at the average exchange rate which corresponds to an approximation of the exchange rates prevailing on each individual transaction date. Translation differences arising in the translation of foreign operations' functional currencies are recognized in the consolidated statements of comprehensive income.

We recorded foreign currency transaction gains/(losses) of SEK 16.6 million and SEK 7.1 million for the years ended December 31, 2023 and 2022, respectively. These foreign currency transaction gains/(losses) are included in other operating income and other operating expenses in our consolidated financial statements.

We recorded foreign exchange rate difference translation gains of SEK 1.3 million and SEK 46.6 million for the years ended December 31, 2023 and 2022, respectively. These foreign exchange rate gains/(losses) are included in financial income and financial expenses in our consolidated financial statements.

Transaction Exposure

Our transaction exposure from contracted payment flows in foreign currency is limited. However, our transaction exposure has been increasing year by year. The table below sets forth our exposure in each currency for the years ended December 31, 2023, 2022 and 2021.

Currency Exposure 2023 ()%	Revenue	Operating expenses
USD	72 %	16 %
EUR	28 %	58 %
GBP	—	6 %
SEK	—	20 %
Other currencies	—	0 %

Currency Exposure 2022 ()%	Revenue	Operating expenses
USD	68 %	20 %
EUR	32 %	48 %
GBP	—	4 %
SEK	—	27 %
Other Currencies	—	1 %

Currency Exposure 2021 ()%	Revenue	Operating expenses
USD	14 %	43 %
EUR	86 %	36 %
GBP	—	3 %
SEK	—	18 %

Our primary transaction exposure is in Euros and US dollars. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 29.3 million, SEK 23.1 million and SEK 0.9 million for the years ended December 31, 2023, 2022 and 2021, respectively. A 10% stronger US dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately pos. SEK 0.1 million, SEK 9.6 million and SEK 22.4 million for the year ended December 31, 2023, 2022 and 2021, respectively.

Interest Rate Risk

We are currently not exposed to significant interest rate risk. Our only variable interest-bearing financial assets are cash at Swedish banks. Certain European countries have recently experienced (or currently are expected to experience) negative interest rates on certain fixed-income instruments, and similar interest rate conditions may be experienced in other regions. Negative interest rates may magnify our susceptibility to interest rate risk and diminish yield and performance on our investments. Changing interest rates may have unpredictable effects on securities markets in general, directly or indirectly impacting our investments and yield.

Given the short-term nature of these investments, the sensitivity towards interest rate fluctuations is deemed not to be significant. Therefore, the effect of an increase or decrease in interest rates would only have an immaterial effect on our financial results.

As of December 31, 2023, 2022 and 2021, we had SEK 939.5 million, SEK 713.0 million and SEK 189.2 million in debt outstanding, respectively. In July 2021, we signed a loan agreement of up to the euro-equivalent of USD 75 million with Kreos Capital. The loan facility is divided into three tranches of USD 25 million each, which we drew down in September 2021, June 2022 and December 2022. The interest rate on the loan is 9% per annum with a maturity of December 2025. In December 2023, we entered into a credit agreement with Athyrium, Athyrium made available to us 92 million Euros, which we fully drew down. We used part of the proceeds from the Credit Agreement to repay in full outstanding obligations under our loan agreement with Kreos Capital. The interest rate on the loan is 9% per annum with a maturity of December 2027. The Credit Agreement contains financial covenants to maintain minimum unrestricted cash (including cash equivalents) and achieve minimum net revenue targets with respect to Nefecon. The Credit Agreement contains affirmative and negative covenants customary for a senior secured loan.

C. INTERIM PERIODS

Not applicable.

D. SAFE HARBOR

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See "Cautionary Statement with Respect to Forward Looking Statements" at the beginning of this annual report.

E. SMALLER REPORTING COMPANIES

Not applicable.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. DEBT SECURITIES

Not applicable.

B. WARRANTS AND RIGHTS

Not applicable.

C. OTHER SECURITIES

Not applicable.

D. AMERICAN DEPOSITARY SHARES

Citibank, N.A. is the depositary bank for the American Depositary Shares, also referred to as ADSs. Each ADS represents two common shares (or a right to receive two common shares) deposited with Citibank Europe plc, as custodian for the depositary located at 1 North Wall Quay, Dublin 1, Ireland. Each ADS also represents any other securities, cash or other property which may be held by the depositary. The deposited shares, together with our other securities, cash and other property held by the depositary, are referred to as the deposited securities. The depositary's office at which the ADSs are administered is located at 388 Greenwich Street, New York, New York 10013.

A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this annual report.

(viii) Fees and Charges

Persons depositing or withdrawing shares or ADS holders must pay:	**For:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) converting foreign currency to US dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

A. DISCLOSURE CONTROLS AND PROCEDURES

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial officer), has evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b) as of December 31, 2023. While there are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives.

Based upon our evaluation as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer have concluded that thus the previously identified material weaknesses regarding the Entity-level control environment, IT Processes, and Payroll have all been remediated, the disclosure controls and procedures, in accordance with Exchange Act Rule 13a-15(e), as a result of the material weaknesses in our internal control over financial reporting, as discussed below, were not effective.

To mitigate the potential impact of the material weaknesses described below, and prior to filing this annual report, we performed additional analysis and other post-closing procedures to determine that our consolidated financial statements are prepared in accordance with IFRS. Based on these procedures, management has concluded that the consolidated financial statements included in this annual report present fairly, in all material aspects, our financial position as at the end of, and the results of operations and cash flows for, the periods presented in conformity with IFRS.

B. MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed, under the supervision of our Chief Executive Officer and Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external reporting purposes in accordance with IFRS, as issued by the IASB.

Our internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets, provide reasonable assurance that transactions are recorded in the manner necessary to permit the preparation of financial statements in accordance with IFRS, and that receipts and expenditures are only carried out in accordance with the authorization of our management and directors, and provide reasonable assurance regarding the prevention or timely detection of any unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements. Because of its inherent limitations, internal control over financial reporting can provide only reasonable assurance and may not prevent or detect all misstatements. Further, because of changes in conditions, effectiveness of internal control over financial reporting may vary over time. Our system contains self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Our management has conducted an evaluation of the effectiveness of the system of internal control over financial reporting based on the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. Based on this evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our internal control over financial reporting was not effective as of December 31, 2023, due to material weaknesses in our internal control over financial reporting as described below.

A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

All of these material weaknesses are described below.

Financial Statement Close and Reporting Process

We did not adequately design or execute controls that address the relevant financial statement assertions over the Financial Statement Close and Reporting Process. Specifically, we did not adequately design or execute internal controls over 1) certain aspects of management review procedures; 2) certain aspects of journal entry approvals and processing; 3) review of general ledger master data changes; 4) share-based payments; and 5) income taxes.

Net Sales

We did not have effective controls in place over the recording of revenue. Specifically, we did not adequately design or execute controls over the cash receipts, master data, royalty data, and management review of gross-to-net models. Also, management did not design effective controls over the completeness and accuracy of key sources of data used in the performance of controls.

Accounts Payable, Accrued Expenses and Operating Expenses

We did not have effective internal controls in place over the procurement of goods and services and invoice processing, or the completeness, existence, and valuation of accounts payable and accrued liabilities. Specifically, we did not adequately design or execute controls over 1) certain aspects of purchase order processing as it relates to purchase order approvals, invoice processing, master data changes, authorization levels, bank disbursements; and 2) the completeness and accuracy of certain underlying key sources of data used in the performance of these controls.

Remediation Plan

We have initiated a remediation plan that includes steps to increase dedicated resources, improve reporting processes, and enhance related supporting technology. We will continue to enhance documentation of our risks-related controls and their assertions to facilitate tracking and trend analysis of internal control deficiencies to support timely remediation of the remaining material weaknesses. We will continue to leverage an outsourced team to perform independent testing of our internal controls throughout the year. We are committed to strengthen and further improve our internal control environment and implementing measures designed to help ensure that control deficiencies contributing to the remaining material weaknesses are remediated as soon as possible, as further described below. Although we intend to complete the remediation process as promptly as possible, we cannot at this time estimate how long it will take to remediate these material weaknesses, and our remediation plan may not prove to be successful. In addition, we may discover additional material weaknesses that require additional time and resources to remediate.

Our remediation process further includes, but is not limited to:

- enhance variance analysis controls and procedures, as supported by a new consolidated reporting application that was implemented in Q1, 2024;
- enhance balance sheet reconciliation controls and procedures, as supported by a new reconciliation application that is being implemented in Q1 and Q2, 2024;
- re-design control procedures related to review of master data changes for the Chart of Accounts, customers, and vendors;
- re-train control owners on the proper performance and documentation of completeness and accuracy validation procedures over the data produced by the entity (IPE) as part of their review controls;
- re-train control owners on the level of precision required to complete review procedures;

- improve definition, documentation and implementation of succinct review criteria as part of certain management review controls;
- enhance accrual controls and procedures through implementation of a Purchase Order module;
- leverage automated reminders and defined deadlines from our internal controls library application to drive timely performance of control procedures.

We believe that the foregoing efforts should effectively remediate the material weaknesses described in this Item 15 and improve our overall control environment. Because the reliability of the internal control process requires repeatable execution and testing over multiple fiscal quarters, the successful remediation of these material weaknesses will require review and evidence of effectiveness prior to concluding that the controls are effective, and it is possible that additional remediation steps will be necessary.

As such, as we continue to evaluate and work to improve our internal control over financial reporting, our management may decide to take additional measures to address the material weaknesses or modify the remediation steps described above. Until these weaknesses are remediated, we plan to continue to perform additional analyses and other procedures to ensure that our consolidated financial statements are prepared in accordance with IFRS.

C. ATTESTATION REPORT OF THE REGISTERED PUBLIC ACCOUNTING FIRM

The effectiveness of our internal control over financial reporting as of December 31, 2023, has been audited by Ernst & Young AB, an independent public accounting firm. Their report is included beginning on page F-2.

D. CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

The previously identified material weaknesses related to the Entity-level control environment, IT Processes, and Payroll have been remediated. Except for the remediation of these material weaknesses and as described above in "—Disclosure Controls and Procedures," there were no other changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the twelve months ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The audit committee consists exclusively of members of our board who are financially literate, and Fred Driscoll and Henrik Stenqvist are each considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board of directors has determined that all of the members of the audit committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act.

ITEM 16B. CODE OF ETHICS

Our board of directors adopted a code of business conduct and ethics that applies to all of our directors, officers, and employees in March 2020. We have posted a copy of our code of business conduct and ethics on our website at: www.calliditas.se, where you can obtain a copy without charge. Information contained on, or that can be accessed through, our website does not constitute a part of this report and is not incorporated by reference herein. If we make any amendment to the code of business conduct and ethics or grant any waivers, including any implicit waiver, from a provision of the code of business conduct and ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC. Under Item 16B of Form 20-F, if a waiver or amendment of the code of business conduct and ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Ernst & Young AB has served as our independent registered public accounting firm for 2022 and 2023. Our accountants billed the following fees to us for professional services in each of those fiscal years:

Fees	Year Ended December 31, 2023	2022
	(in thousands of SEK)	
Audit Fees	20,951	13,369
Audit-Related Fees	900	3,370
Tax Fees	—	—
All Other Fees	—	—
Total	**21,851**	**16,739**

"Audit Fees" are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that generally the independent accountants provide, such as consents and assistance with and review of documents filed with the SEC.

"Audit-Related Fees" are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees. In 2023 and 2022, "Audit-Related Fees" also include fees billed for assurance and audit-related services regarding our public offerings on Nasdaq.

Auditor Name	Auditor Location	PCAOB ID
Ernst & Young AB	Stockholm, Sweden	1433

Audit Committee's Pre-Approval Policies and Procedures

The audit committee has responsibility for, among other things, appointing, setting compensation of and overseeing the work of our independent registered public accounting firm, or external auditor. In recognition of these responsibilities, the audit committee has adopted a policy governing the pre-approval of all audit and permitted non-audit services performed by our external auditor to ensure that the provision of such services does not impair the external auditor's independence from us and our management. Unless a type of service to be provided by our external auditor has received general pre-approval from the audit committee, it requires specific pre-approval by the audit committee. The payment for any proposed services in excess of pre-approved cost levels requires specific pre-approval by the audit committee.

Pursuant to its pre-approval policy, the audit committee may delegate its authority to pre-approve services to the chairperson of the Audit Committee. The decisions of the chairperson to grant pre-approvals must be presented to the full audit committee at its next scheduled meeting. The audit committee may not delegate its responsibilities to pre-approve services to the management.

The audit committee has considered the non-audit services provided by Ernst & Young AB as described above and believes that they are compatible with maintaining Ernst & Young AB's independence as our external auditor. In accordance with Regulation S-X, Rule 2-01, paragraph (c)(7)(i), no fees for services were approved pursuant to any waivers of the pre-approval requirement.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

We qualify as a foreign private issuer. The Listing Rules of the Nasdaq Stock Market include certain accommodations in the corporate governance requirements that allow foreign private issuers to follow "home country" corporate governance practices in lieu of the otherwise applicable corporate governance standards of the Nasdaq Stock Market. While we may choose to voluntarily follow some Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K upon the occurrence of specified significant events;
- exemption from Section 16 rules requiring insiders to file public reports of their securities ownership and trading activities and providing for liability for insiders who profit from trades in a short period of time;
- exemption from the Nasdaq requirement necessitating disclosure of any waivers of the Code of Business Conduct and Ethics for directors and executive officers;
- exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans and equity issuances;
- exemption from the requirement that our audit committee have review and oversight responsibilities over all "related party transactions," as defined in Item 7.B of Form 20-F;
- exemption from the requirement that our board of directors have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- exemption from the requirement to have independent director oversight of director nominations.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d). We intend to follow Swedish corporate governance practices in lieu of Nasdaq corporate governance requirements as follows:

- We do not intend to follow Nasdaq Rule 5620(c) regarding quorum requirements applicable to meetings of shareholders. Such quorum requirements are not required under Swedish law. The Swedish Companies Act (SFS 2005:551) and our articles of association, which were approved by our shareholders on May 19, 2022 and are currently in effect, provide alternative quorum requirements that are generally applicable to meetings of shareholders.
- We do not intend to follow Nasdaq Rule 5605(b)(2), which requires that independent directors regularly meet in executive sessions where only independent directors are present. Our independent directors may choose to meet in executive sessions at their discretion.
- We do not intend to follow Nasdaq Rule 5605(e) regarding the composition of the nominating committee.

Although we may rely on certain home country corporate governance practices, we must comply with Nasdaq's Notification of Noncompliance requirement (Nasdaq Rule 5625) and the Voting Rights requirement (Nasdaq Rule 5640). Further, we must have an audit committee that satisfies Nasdaq Rule 5605(c)(3), which addresses audit committee responsibilities and authority and requires that the audit committee consist of members who meet the independence requirements of Nasdaq Rule 5605(c)(2)(A)(ii).

Because we are a foreign private issuer, our directors and executive officers are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. They will, however, be subject to the obligations to report changes in securities ownership under Section 13 of the Exchange Act and related SEC rules.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and Nasdaq listing rules. Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J INSIDER TRADING POLICIES

Not applicable.

ITEM 16K CYBERSECURITY

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical systems and information (collectively, our "Information Systems and Data").

Our Information Technology department, with support from members of our Legal and Compliance teams and our Chief Information Officer ("CIO"), helps identify and assess cybersecurity risks and prepare the Company to respond to these risks. We use various methods for monitoring and evaluating threats to our environment including, for example: using manual and automated tools to detect anomalies and attempted attacks, subscribing to reports and services that identify cybersecurity threats, evaluating our and our industry's risk profile, analyzing reports of threats and actors, conducting scans of our environment, evaluating threats reported to us, conducting internal and external audits, conducting threat assessments for internal and external threats, and conducting vulnerability assessments, including penetration tests.

Depending on the environment and system, we implement and maintain various technical, organizational, and physical measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data. These include, in addition to others discussed in this Item 16K, system monitoring, an incident detection and response plan, a disaster recovery plan, encryption and segregation of certain data, network security controls, and measures for the physical security of our technology infrastructure. We provide an annual information security awareness training to our employees and ask them to review certain information security policies on an annual basis.

Our identification, assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, we include information on cybersecurity risk evaluations conducted by management in reports, elements of which are shared with the audit committee of our board of directors. Additionally, our Executive Committee may discuss cybersecurity risks and mitigation activities as part of its general risk management oversight. Our Group General Counsel has functional responsibility for cybersecurity and may elevate cybersecurity topics for the attention of the audit committee and board of directors.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity consultants, threat intelligence service providers, cybersecurity software and service providers, penetration testing firms, dark web monitoring services, forensic investigators, and professional services firms, including legal counsels.

Support elements for a variety of functions across our business are performed by third parties, such as distributors, contract manufacturing organizations, contract research organizations, application providers, and supply chain resources. We consider cyber risks in evaluating third parties and services, and our vendor management processes are tailored to our assessment of a particular vendor's risk profile and criticality to our operations. Those processes may include, for example, some combination of the following: performing a risk assessment or issuing a security questionnaire, reviewing written security programs, performing certain vulnerability scans, conducting security assessment calls with the vendor's security personnel, performing audits on the vendor's compliance with our security requirements, or imposing contractual obligations relating to information security. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify and manage cybersecurity risks associated with a provider.

We have not identified risks from any known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. For a description of the risks from cybersecurity threats that may be reasonably likely to materially affect the Company and how they may do so, see our risk factors under Item 3D. Risk Factors in this Annual Report, including those described in "Risks Related to Our Employee Matters, Managing Our Growth and Other Risks Relating to Our Operations."

Governance

Our board of directors considers the Company's cybersecurity risk as part of its general oversight function and is responsible for overseeing the Executive Committee's implementation and enforcement of our cybersecurity risk management processes.

Our cybersecurity risk assessment and management processes are implemented and maintained by a management team comprised of our CIO, Group General Counsel and CFO who all report to our CEO. This management team is responsible for hiring appropriate personnel, managing spending relating to cybersecurity, providing information on cybersecurity risks, preparing for cybersecurity incidents, reviewing security assessments, approving cybersecurity processes and resources, and managing our response to significant cybersecurity incidents. The management team stays informed about and monitors efforts to prevent, detection, mitigate and remediate cybersecurity incidents through various means, which may include briefings with operational cybersecurity team members, outside threat intelligence sources, and from tooling described above that is deployed in our IT environment.

Individuals responsible for cybersecurity at an operational level within the Company have a minimum of 15 years' experience in the field of information technology. We also have a Cyber Incident Response Team that includes the CIO, CEO, Group General Counsel, CFO, Head of HR and IT Compliance Manager. This group may be expanded as needed to include representatives from our Legal and Corporate Communications teams as well as our Executive Committee, which is responsible for communicating with the audit committee or full board of directors as needed.

The audit committee receives regular reports from the CIO concerning the Company's significant cybersecurity threats and risks and the processes the Company has implemented to address them, as well as cybersecurity incidents deemed significant by the management team. The audit committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

PART III

ITEM 17. FINANCIAL STATEMENTS

See financial statements beginning on page F-1 of this annual report.

ITEM 18. FINANCIAL STATEMENTS

Not applicable.

ITEM 19. EXHIBITS

The Exhibits listed in the Exhibit Index at the end of this annual report are filed as Exhibits to this annual report.

EXHIBIT INDEX

Exhibit	Description	Incorporated by Reference Schedule/ Form	File Number	Exhibit	File Date
1.1*	Articles of Association of the Registrant (English translation)				
2.1	Form of Deposit Agreement	Form F-1/A	333-238244	4.1	06/01/2020
2.2	Form of American Depositary Receipt (included in Exhibit 2.1)				
2.3	Share Purchase Agreement, dated August 13, 2020, by and between the Registrant and the Block Sellers	Form F-1	333-252436	2.1	01/26/2021
2.4*	Description of Securities				
4.1†	License Agreement regarding NEFECON, dated June 10, 2019, by and between the Registrant and Everest Medicines II Limited.	Form F-1	333-238244	10.1	05/14/2020
4.2	Supplemental Agreement and First Amendment to License Agreement regarding NEFECON, dated March 7, 2022, by and between the Registrant and Everest Medicines II Limited	Form 20-F	001-39308	4.2	04/27/2022
4.3	English translation of Lease Agreement, dated as of March 20, 2019, by and between Vasaterminalen AB and the Registrant	Form F-1	333-238244	10.2	05/14/2020
4.4#	English Translation of Warrants 2018/2022 in Calliditas Therapeutics AB (publ)	Form F-1	333-238244	10.4	05/14/2020
4.5#	English Translation of Warrants 2019/2022 in Calliditas Therapeutics AB (publ)	Form F-1	333-238244	10.5	05/14/2020
4.6#	Board Long Term Incentive Program 2020	Form F-1	333-252436	10.6	01/26/2021
4.7#	Board Long Term Incentive Program 2021	Form 20-F	001-39308	4.8	04/27/2022
4.8#	Board Long Term Incentive Program 2022	Form 20-F	001-39308	4.9	04/26/2023
4.9#	Board Long Term Incentive Program 2023	Form S-8	333-272594	99.6	06/12/2023
4.10#	English Translation of Principles for the 2020 ESOP for the Registrant's management and key personnel	Form F-1	333-238244	10.7	05/14/2020
4.11#	ESOP 2020 United States Sub-Plan	Form S-8	333-240126	99.1	07/27/2020

Exhibit	Description	Incorporated by Reference Schedule/ Form	File Number	Exhibit	File Date
4.12#	English Translation of Principles for the 2021 ESOP for the Registrant's management and key personnel	Form 20-F	001-39308	4.11	04/27/2022
4.13#	ESOP 2021 United States Sub-Plan	Form 20-F	001-39308	4.12	04/27/2022
4.14#	English Translation of Principles for the 2022 ESOP for the Registrant's management and key personnel	Form 20-F	001-39308	4.14	04/26/2023
4.15#	ESOP 2022 United States Sub-Plan	Form 20-F	001-39308	4.15	04/26/2023
4.16#*	English Translation of Principles for the 2023 ESOP for the Registrant's management and key personnel				
4.17#	ESOP 2023 United States Sub-Plan	Form S-8	333-272594	99.3	06/12/2023
4.18	Commercialization Agreement dated as of July 21, 2021, by and between the Registrant and STADA Arzneimittel AG	Form 6-K	001-39308	10.1	07/23/2021
4.19	Agreement for the Provision of Loan Facilities dated as of July 15, 2021, by and between the Registrant and the parties named therein	Form 6-K	001-39308	10.1	07/19/2021
4.20	Intellectual Property Security Agreement dated as of July 15, 2021, by and between the Registrant and the parties named therein	Form 6-K	001-39308	10.2	07/19/2021
4.21†+	License Agreement between the Registrant and Viatris Pharmaceuticals Japan Inc., dated December 12, 2022	Form 20-F	001-39308	4.26	04/26/2023
4.22*+	Credit Agreement by and among the Registrant, Athyrium Opportunities IV Co-Invest 1 LP and the parties named therein, dated as of December 27, 2023.				
4.23*+†	Master Manufacturing Services Agreement dated as of December 30, 2020, by and between the Registrant and Patheon Pharmaceuticals, Inc.				
4.24*+†	Product Agreement dated as of December 30, 2020, by and between the Registrant and Patheon Pharmaceuticals, Inc.				
8.1	Subsidiaries of the Registrant	Form 20-F	001-39308	8.1	04/27/2022
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				

Exhibit	Description	Incorporated by Reference Schedule/ Form	File Number	Exhibit	File Date
13.1**	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
13.2**	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
15.1*	Consent of independent registered public accounting firm				
97.1*	Executive Officer Incentive Compensation Clawback Policy				
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				

* Filed herewith.

** Furnished herewith.

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Certain portions of this exhibit have been omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

+ Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Date: April 24, 2024

CALLIDITAS THERAPEUTICS AB
By: /s/ Renée Aguiar-Lucander
Name: Renée Aguiar-Lucander

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The Group

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Calliditas Therapeutics AB

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Calliditas Therapeutics AB (the Company) as of December 31, 2023 and 2022, the related consolidated statements of income, comprehensive income, changes in equity, and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated April 24, 2024 expressed an adverse opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Estimate of variable consideration for revenue recognition

Description of the matter

As is stated in Note 3 of the consolidated financial statements, for the year ended December 31, 2023, the Company's revenues from product sales were SEK 1,087,418 thousands. As more fully described in Notes 2 and 3, revenue from the sale of goods is calculated net of actual and estimated rebates to government payers, among other deductions. The Company's determination of variable consideration at December 31, 2023, requires management to make assumptions about amounts of rebates that will be payable by the Company, as a result of the sale of products for which control has transferred.

Auditing management's estimate of variable consideration was complex, because the calculation involves significant management judgement to determine the rebates owed to government payers.

How We Addressed the Matter in Our Audit

To test the estimate of variable consideration, our audit procedures included, among others, performing analytical procedures to assess the historical accuracy of management's estimates, by comparing previous estimates of payor rebates to the amount of actual payments in subsequent periods. Where available, we tested management's estimate as of December 31, 2023, by comparison to actual invoices received subsequently. We also tested the completeness and accuracy of dispensing data and inputs used by the Company in its determination of the estimated payor mix, by agreeing it to third-party data.

We involved professionals with government pricing subject matter experience, to assist in evaluating management's methodology and calculations used to measure rebates owed to government payors.

Impairment assessment of intangible assets

Description of the matter

Intangible assets amount to SEK 430,754 thousands as of December 31, 2023. As explained in Note 2 and Note 15 of the consolidated financial statements, the Company performs an impairment assessment of intangible assets not yet available for use, on an annual basis or when there is an indication that an asset may be impaired. The Company's impairment assessment of intangible assets, involves the comparison of the recoverable amount of each asset or cash generating unit to their carrying values.

The recoverable amount of intangible assets is estimated based on a probability-adjusted cash flow model, where the amount is determined by estimating the expected future cash flows and present value adjustments, including the probability of reaching the market. Changes in assumptions used by management could have a significant impact on the recoverable amount.

The audit of the impairment assessment of intangible assets was complex, due to the significant judgments made by management to estimate the recoverable amount, including assumptions related to the timing of potential commercialization, the market size, the probability of reaching the market and the discount rate used.

How We Addressed the Matter in Our Audit

We performed audit procedures related to the impairment assessment of intangible assets, which included, among others, testing the completeness and accuracy of inputs utilized by management in the assumptions, including the timing of potential commercialization, expected market size and the probability of the products reaching the market. In doing so, we compared these inputs to third-party statistical data for the clinical indications targeted and to other development projects within the industry.

With the assistance of our valuation specialists, we evaluated the discounted cash flow methodology and assessed the discounts rates used by management, by comparing to underlying source information, testing the mathematical accuracy of the calculations and preparing an independent range of discount rates based on market and peer company observable data and comparing to that used by management.

/s/ Ernst & Young AB

We have served as the Company's auditor since 2004.

Stockholm, Sweden

April 24, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Calliditas Therapeutics AB

Opinion on Internal Control Over Financial Reporting

We have audited Calliditas Therapeutics AB's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, because of the effect of the material weaknesses described below on the achievement of the objectives of the control criteria, Calliditas Therapeutics AB (the Company) has not maintained effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment. Management has identified material weaknesses related to inadequately designed controls and control operations over the financial statement close and reporting process, ineffective controls over the recording of revenue, and ineffective controls over the procurement of goods and services, invoices processing, and the completeness, existence, and valuation of accounts payable and accrued liabilities.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2023 and 2022, the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes. These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the 2023 consolidated financial statements, and this report does not affect our report dated April 24, 2024, which expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young AB

Stockholm, Sweden

April 24, 2024

GROUP

Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31, 2023	2022	2021
Net sales	*3*	1,206,888	802,879	229,347
Cost of sales		(60,463)	(15,201)	—
Gross profit		**1,146,425**	**787,678**	**229,347**
Research and development expenses	*7,8,9,10*	(502,223)	(414,749)	(357,485)
Marketing and selling expenses	*7,8,9,10*	(727,740)	(515,190)	(179,603)
Administrative expenses	*6,7,8,9,10*	(332,991)	(259,469)	(210,630)
Other operating income	*4*	44,608	2,862	259
Other operating expenses	*5*	(1,135)	(23,074)	(6,344)
Operating loss	*7*	**(373,055)**	**(421,943)**	**(524,456)**
Financial income	*11*	30,387	50,195	20,336
Financial expenses	*12*	(114,349)	(37,669)	(9,253)
Loss before income tax		**(457,017)**	**(409,417)**	**(513,373)**
Income tax expense	*13*	(9,168)	(2,851)	3,836
Loss for the year		**(466,185)**	**(412,268)**	**(509,537)**
Attributable to:				
Equity holders of the Parent Company		(466,185)	(412,268)	(500,293)
Non-controlling interests		—	—	(9,244)
		(466,185)	**(412,268)**	**(509,537)**
Loss per share				
Before and after dilution to ordinary equity holders of the Parent Company	*14*	(8.69)	(7.78)	(9.84)

GROUP

Consolidated Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31, 2023	2022	2021
Loss for the year		**(466,185)**	**(412,268)**	**(509,537)**
Other comprehensive income				
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	*20,25*	(14,538)	36,287	(20,111)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		**(14,538)**	**36,287**	**(20,111)**
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:				
Remeasurement gain/(loss) on defined benefit plans	*28*	(3,071)	2,763	1,993
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods		**(3,071)**	**2,763**	**1,993**
Other comprehensive income/(loss) for the year		**(17,609)**	**39,050**	**(18,118)**
Total comprehensive loss for the year		**(483,794)**	**(373,218)**	**(527,655)**
Attributable to:				
Equity holders of the Parent Company		(483,794)	(373,218)	(519,189)
Non-controlling interests		—	—	(8,466)
		(483,794)	**(373,218)**	**(527,655)**

GROUP

Consolidated Statements of Financial Position

(SEK in thousands)	Note	December 31, 2023	2022
ASSETS			
Non-current assets			
Intangible assets	*15*	430,754	438,057
Goodwill	*15*	48,584	45,784
Equipment	*16*	16,053	7,468
Right-of-use assets	*8*	38,186	24,452
Non-current financial assets	*3,17,19,32*	24,201	11,210
Deferred tax assets	*18*	26,315	13,798
Total non-current assets		**584,093**	**540,770**
Current assets			
Inventories	*21*	20,428	3,647
Accounts receivable	*20*	180,892	78,703
Other current assets	*19*	15,774	10,018
Prepaid expenses and accrued income	*22*	84,324	70,741
Cash	*23*	973,733	1,249,094
Total current assets		**1,275,152**	**1,412,204**
TOTAL ASSETS		**1,859,245**	**1,952,973**
EQUITY AND LIABILITIES			
Equity	*25*		
Share capital		2,383	2,383
Additional paid-in capital		2,643,227	2,590,890
Reserves		(5,231)	9,307
Retained earnings including net loss for the year		(2,305,573)	(1,836,317)
Total equity attributable to equity holders of the Parent Company		**334,806**	**766,264**
Non-current liabilities			
Provisions	*26*	32,595	11,792
Contingent consideration	*27*	56,561	75,880
Pension liabilities	*28*	3,521	884
Deferred tax liabilities	*18*	41,641	39,752
Non-current interest-bearing liabilities	*19*	939,508	713,030
Non-current lease liabilities	*8,19*	27,088	15,792
Other non-current liabilities	*19,29*	16,381	4,350
Total non-current liabilities		**1,117,295**	**861,479**
Current liabilities			
Accounts payable	*19,20*	100,564	160,404
Current tax liabilities		6,167	5,684
Other current liabilities	*8,19*	19,786	22,697
Accrued expenses and deferred revenue	*30*	280,627	136,446
Total current liabilities		**407,144**	**325,231**
TOTAL EQUITY AND LIABILITIES		**1,859,245**	**1,952,973**

GROUP

Consolidated Statements of Changes in Shareholders Equity

		Attributable to the Equity Holders of the Parent Company						
(SEK in thousands)	Note	Share Capital	Additional Paid-in Capital	Translation Reserve	Retained Earnings incl. Net Loss for the Year	Total	Non-Controlling Interests	Total Equity
Opening equity January 1, 2021		**1,998**	**2,133,179**	**(6,090)**	**(918,596)**	**1,210,491**	**45,809**	**1,256,300**
Loss for the year		—	—	—	(500,293)	(500,293)	(9,244)	(509,537)
Other comprehensive income/(loss) for the year		—	—	(20,889)	1,993	(18,896)	778	(18,118)
Total comprehensive loss for the year		**—**	**—**	**(20,889)**	**(498,300)**	**(519,189)**	**(8,466)**	**(527,655)**
Transactions with owners:								
New share issue		96	323,904	—	—	324,000	—	324,000
Costs attributable to new share issue		—	(20,909)	—	—	(20,909)	—	(20,909)
Contribution from non-controlling interest		—	—	—	—	—	2,282	2,282
Share-based payments	*10*	—	23,567	—	—	23,567	—	23,567
Purchase of non-controlling interests		—	—	—	(9,678)	(9,678)	(39,625)	(49,303)
Total transactions with owners		**96**	**326,562**	**—**	**(9,678)**	**316,979**	**(37,343)**	**279,636**
Closing equity December 31, 2021		**2,094**	**2,459,741**	**(26,979)**	**(1,426,574)**	**1,008,281**	**—**	**1,008,281**
Opening equity January 1, 2022		**2,094**	**2,459,741**	**(26,979)**	**(1,426,574)**	**1,008,281**	**—**	**1,008,281**
Loss for the year		—	—	—	(412,268)	(412,268)	—	(412,268)
Other comprehensive income/(loss) for the year		—	—	36,286	2,763	39,050	—	39,050
Total comprehensive loss for the year		**—**	**—**	**36,286**	**(409,505)**	**(373,218)**	**—**	**(373,218)**
Transactions with owners:								
Issuance of treasury shares		236	—	—	—	236	—	236
Repurchase of treasury shares		—	—	—	(236)	(236)	—	(236)
Exercise of warrants		53	95,070	—	(2)	95,121	—	95,121
Share-based payments	*10*	—	36,080	—	—	36,080	—	36,080
Total transactions with owners		**290**	**131,150**	**—**	**(238)**	**131,201**	—	**131,201**
Closing equity December 31, 2022	*10,25*	**2,383**	**2,590,890**	**9,307**	**(1,836,317)**	**766,264**	—	**766,264**
Opening equity January 1, 2023		**2,383**	**2,590,890**	**9,307**	**(1,836,317)**	**766,264**	**—**	**766,264**
Loss for the year		—	—	—	(466,185)	(466,185)	—	(466,185)
Other comprehensive income/(loss) for the year		—	—	(14,538)	(3,071)	(17,609)	—	(17,609)
Total comprehensive income/(loss) for the year		**—**	**—**	**(14,538)**	**(469,256)**	**(483,794)**	**—**	**(483,794)**
Transactions with owners:								
Share-based payments	*10*	—	52,337	—	—	52,337	—	52,337
Total transactions with owners		**—**	**52,337**	**—**	**—**	**52,337**	**—**	**52,337**
Closing equity December 31, 2023	*10,25*	**2,383**	**2,643,226**	**(5,231)**	**(2,305,573)**	**334,807**	**—**	**334,806**

GROUP

Consolidated Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31, 2023	2022	2021
Operating activities				
Operating loss		(373,055)	(421,943)	(524,456)
Adjustments for non-cash items	*23*	102,478	61,260	66,676
Interest received		32,905	3,553	102
Interest paid		(94,497)	(35,252)	(5,432)
Income taxes paid		(22,747)	(7,392)	(3,949)
Cash flow from operating activities before changes in working capital		**(354,915)**	**(399,774)**	**(467,058)**
Cash flow from changes in working capital				
Changes in inventory		(16,781)	(2,758)	(949)
Changes in operating receivables		(182,589)	(91,878)	(11,712)
Changes in operating liabilities		119,629	183,056	18,131
Cash flow from operating activities		**(434,655)**	**(311,354)**	**(461,588)**
Investing activities				
Purchase of equipment	*16*	(12,788)	(2,512)	(6,588)
Investments in non-current financial assets	*17*	(1,560)	(2,633)	(1,686)
Repayment of non-current financial assets		602	—	—
Purchase of intangible assets	*15*	—	—	(16,066)
Cash flow from investing activities		**(13,745)**	**(5,144)**	**(24,340)**
Financing activities				
New share issue		—	—	324,000
Expenditures attributable to new share issue		—	—	(20,909)
Issuance of treasury shares		—	236	—
Repurchase of treasury shares		—	(236)	—
Exercise of warrants		—	95,121	—
Purchase of non-controlling interests		—	—	(49,303)
Contribution from non-controlling interest		—	—	2,282
New borrowings	*20*	962,889	491,745	199,524
Expenditures attributable to new loans		(26,625)	(1,260)	(14,858)
Repayment of borrowing		(724,479)	—	—
Repayment of lease liabilities		(12,134)	(9,615)	(5,575)
Cash flow from financing activities		**199,650**	**575,990**	**435,162**
Net increase (decrease) in cash		**(248,750)**	**259,493**	**(50,766)**
Cash at beginning of the year		**1,249,094**	**955,507**	**996,304**
Exchange-rate difference in cash		(26,611)	34,094	9,969
Cash at the end of the year	*23*	**973,733**	**1,249,094**	**955,507**

GROUP

Notes to Consolidated Financial Statements

(SEK in thousands, except per share amounts or as otherwise indicated)

Description of Business

Calliditas Therapeutics AB (publ) ("Calliditas" or the "Parent Company"), with corporate registration number 556659-9766, and its subsidiaries (collectively, the "Group") conduct development and commercial activities in pharmaceuticals.

These consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the year ended December 31, 2023, 2022 and 2021, respectively. The Group has chosen to, in addition to periods such as required by IFRS, present a consolidated income statement, statement of comprehensive income, consolidated statement of cash flows and consolidated statement of changes in equity with an additional comparison period.

Calliditas is a commercial stage biopharma company focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. The registered address of the corporate headquarters is Kungsbron 1, D5, Stockholm, Sweden.

Calliditas was founded as a public limited liability company under the laws of Sweden on February 20, 2004 under the name Pharmalink AB and registered with the Swedish Companies Registration Office on April 15, 2004. As of December 31, 2023, Calliditas is the Parent Company of four subsidiaries located in Sweden, France and in the United States. The Swedish subsidiary is Nefecon AB which is conducting no operating activities. The subsidiaries in the United States are Calliditas Therapeutics US Inc and Calliditas NA Enterprises Inc, who are conducting commercialization activates in the United States, respectively. The French subsidiary is Calliditas Therapeutics France SAS located in France which is conducting preclinical activities.

The Board of Directors (the "Board") approved, and authorized for issuance, these consolidated financial statements on April 24, 2024.

Note 1 Material Accounting Policies

Basis for Preparation
These consolidated financial statements have been prepared in accordance with the IFRS (R) Accounting Standards published by the International Accounting Standards Board (IASB). In addition, the consolidated financial statements comply with the recommendation of The Swedish Corporate Reporting Board RFR 1, Supplementary Accounting Regulations for Groups.

Material accounting policies
The Group provides disclosures of material accounting policies and accounting policy is material if the underlying transaction is material and information in the accounting policy is material to understand the transaction, e.g. if the Group has made a policy choice or if the accounting policy is company specific. When the Group applies an accounting policy as described in the applicable IFRS standard, the Group does not provide any disclosure of the applied accounting policy. In addition to material accounting policies described in this note, the Group has decided to present material accounting policies within the corresponding note that the policy relates to.

Primary financial statements
The group has elected to present in addition to minimum periods required under IFRS, a consolidated statement of income, consolidated statement of comprehensive income, consolidated statement of cash flows, and consolidated statement of changes in equity, for an additional comparative period. The Group has decided to present the consolidated statement of income based on function of expense.

Basis for Valuation and Current versus Non-Current Classification
The Group presents assets and liabilities in the statement of financial position based on current/non-current classification. An asset is current when it is expected to be realized within twelve months after the reporting period. All other assets are classified as non-current. A liability is current when it is due to be settled within twelve months after the reporting period. The Group classifies all other liabilities as non-current.

Functional Currency and Reporting Currency
The Parent Company's functional currency is Swedish Kronor (SEK), which is also the presentation currency of the Group. This means that the financial statements are presented in Swedish kronor (SEK) and all amounts, unless otherwise stated, are rounded to the nearest thousand (SEK 000s).

Foreign exchange gains and losses as a result of transactions in foreign currency relating to operating receivables and liabilities are recognized net in operating profit as Other operating income or Other operating expenses, while foreign exchange gains and losses on financial receivables and liabilities are recognized net as financial items.

Cost of Sales
Cost of sales includes the cost of inventory sold, labor costs, manufacturing overhead expenses and reserves for expected scrap, as well as shipping and freight costs. Cost of sales also includes royalty costs related to in-license agreements.

Research and Development
Research and development expenses consist primarily of costs incurred for the Group's development activities, including the development of the Group's product candidates. The Group expenses research and development costs as incurred. The Group recognizes external development costs based on an evaluation of the progress to completion of specific tasks using information provided by Calliditas' service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as a prepaid expense or accrued expense. Research and development tax credits are recognized in Sweden and in France. In Sweden tax credits are recognized on social security costs and in France tax credits are recognized on accredited suppliers. These research and development tax credits are recognized as an offset to research and development expenses in the consolidated statements of income.

Marketing and Selling Expenses
Marketing and selling expenses consist of salaries and other related costs for personnel in the Group and market access, commercialization and business development.

Administrative Expenses
Administrative expenses consist of salaries and other related costs for personnel in the Group, finance, corporate and administrative functions. Administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, related travel expenses and facility-related expenses, which include allocated expenses for rent and maintenance of facilities and other operating costs. Acquisition-related costs are included in administrative expenses in the consolidated statements of income and are expensed as the services are performed.

New and Amended Standards and Interpretations
Updated standards and interpretations from IASB and IFRIC interpretations that came into effect for the year ended December 31, 2023 have had no material impact on the Group. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

Future Standards and New Interpretations
Other future or altered standards or interpretations that the IASB has published are not expected to have any significant impact on the financial statements for the Group.

Cash Flow
The consolidated statement of cash flows is prepared in accordance with the indirect method.

Note 2 Significant Accounting Judgements, Estimates and Assumptions

The preparation of the Group's consolidated financial statements in accordance with IFRS requires management to make judgements, estimates and assumptions that affect the recorded amounts of revenues, expenses, assets and liabilities, and the accompanying disclosures. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

Judgements, estimates and assumptions are evaluated on an ongoing basis. Changes in judgements, estimates and assumptions are recognized in the period the change has occurred if the change only affects that period, and future period if the change affects both the current period and future periods.

Significant accounting judgements, estimates and assumptions are disclosed in detail in the corresponding note to which the judgement, estimate and assumption relate. Significant accounting judgements, estimates and assumptions relates to:

- Revenue recognition - note 3,
- Loss carryforwards - note 13,
- Intangible assets - note 15, and
- Expected credit losses - note 20.

A summarized description of each significant accounting judgment, estimate and assumption is presented below. For additional details of the significant accounting judgments, estimates and assumptions refer to the notes referenced above.

Revenue Recognition

Outlicensing of Product
Revenue for the outlicensing of Nefecon is recognized at the point in time when control of the intellectual property is transferred, while revenue for the provision of certain regulatory services is reported over time as the services are performed. The revenue allocated to the performance obligation for outlicensing is based on the residual approach and the allocation of revenue to the performance obligation for regulatory services is based on the expected costs to provide the service, with the addition of a profit margin based on comparable companies. The identification of and allocation of the transaction price between these performance obligations hence has a significant impact on the Group's revenue recognition, as the revenue recognition patterns differ between the performance obligations.

The revenue contracts also contain variable remuneration in the form of regulatory and commercial milestones. Variable remuneration is initially considered constrained, as there is significant uncertainty as to whether the associated milestones will occur. Compensation attributable to sales-based milestones or royalties is not recognized until the sale that results in the right to the royalties has occurred. Determining whether the criteria for recognition of the variable remuneration has been met hence has significant effects on revenue recognition and requires significant judgment by Management.

Gross to Net Accounting
There are various sales deductions and rebates relating to product sales in the United States that are deducted from the gross sales as part of the revenue recognition process. As the actual sales deductions are not known at the point of sale, estimates are made in determining the initial deduction of rebates, and are then subject to true-up as actual data is obtained.

Intangible Assets

Goodwill and intangible assets, not yet available for use

Goodwill and intangible assets not yet available for use are assessed for impairment at each reporting date based on their recoverable amounts, including key assumptions such as the timing of potential commercialization, market size, market share, probability of reaching the market and the discount rates.

Capitalization of intangible assets
The Group capitalizes expenditures for the development of pharmaceuticals to the extent that it is expected to meet the criteria in accordance with IAS 38 — Intangible Assets. The assessment is based on significant judgments made by management, including the technical feasibility of completing the intangible asset so that it will be available for use or sale and assumptions used to demonstrate that the asset will generate probable future economic benefits (e.g., projected cash flow projections, discount rate). Capitalization of expenditures is generally made in the late stage of the development, for example after full approval, depending on when the criteria are deemed to have been met. The reason for this is that before then it is uncertain whether the expenditure will generate future economic benefits and that financing the completion of the asset is not yet guaranteed.

Loss Allowance for Expected Credit Losses for Accounts Receivable
Management makes loss allowance for expected credit losses for accounts receivable that correspond to their maturity. The estimate is based on any increased credit risk, on individual or collective basis, considering reasonable and supportable information, including that which is forward-looking. The allowance for expected credit risk is an estimate based on maturity structure accounts receivable and specific customer knowledge. Generally, invoices are due for payment within 30-45 days.

Loss Carryforwards
The Groups tax losses carried forward have not been recognized as deferred tax assets in the statement of financial position as of December 31, 2022, except for such circumstances where there are future temporary differences that such losses can be used to offset. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

The Group has identified an uncertain tax position in relation to the ability to use tax loss carried forward in France due to transactions performed historically. The related tax losses carried forward has not been recognized as deferred tax assets in the consolidated statements of financial position.

Key Sources of Estimation Uncertainty
The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year. The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

Note 3 Operating segments and revenue from Contracts with Customers

Material accounting policy - operating segments
An operating segment is a part of the Group that conducts business activities from which it can generate revenue and incur costs, and for which independent financial information is available. Identification of segments is based on internal reporting to the chief operating decision maker (“CODM”). The CODM for the Group is the Chief Executive Officer (“CEO”). The Group does not divide its operations into different segments and the CODM operates and manages the Group’s entire operations as one segment, which is consistent with the Group’s internal organization and reporting system. The Group’s revenue is attributable to the Parent Company in Sweden and to the U.S. subsidiary Calliditas Therapeutics US Inc. The non-current assets are located in Sweden, the U.S., France and Switzerland.

Material accounting policy - revenue from contracts with customers
The Group is in the business of identifying, developing and commercializing novel treatments in orphan indications. Operating revenue mainly comprises of product sales, outlicensing of Nefecon to our partnerships in Europe, China and Japan and royalty revenue. Revenue is recognized as follows:

Product Sales
Revenue from product sales is recognized at the transaction price of goods sold excluding sales tax, rebates and returns. At the time of delivery, when the control of the goods passes to the customer, the revenue is recognized in full, as this represents the single performance obligation in the trans-action. The customer is defined as the specialty pharmacy who dispenses the good to the end user. As the transaction price is dependent on the rebate paid to the patients' insurance company or government payer, the transaction price is not known upon delivery. This is accounted for by an accrued estimated rebate deduction in the Group based on calculation models considering statistical data, actual amounts incurred and/or historical trends. These liabilities for expected returns and rebates are based on estimates of the amounts received or to be claimed on the related sales. Furthermore, the Group estimates the liability for expected returns of obsolete medicines.

Outlicensing of Product
Revenue attributable to outlicensing Nefecon consisted of the agreement with STADA for Europe, the expansion of Everest Medicines to South Korea and the agreement with Viatris for Japan. Revenue for outlicensing is recognized at a point in time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreements with the parties were signed. These contracts with customers consist of fixed consideration as well as variable remuneration in the form of regulatory and commercial milestones, and sales-based royalties. Variable consideration (for example, attributable to future regulatory milestones) is initially considered constrained, as there is significant uncertainty as to whether these will occur. Consideration attributable to sales-based milestones or royalties are not recognized until the sale that results in the right to the milestones or royalties occurs.

Royalty Revenue
Calliditas is, in accordance with agreements, entitled to royalties on goods sold. Revenue recognition is based on royalty reports received, which are based on actual net sales statistics of the licensee. Accrued royalty revenue is recognized in the statement of financial position under prepaid expenses and accrued income.

Significant accounting judgments, estimates and assumptions - revenue recognition

Outlicensing of Product
Revenue for the outlicensing of Nefecon is recognized at the point in time when control of the intellectual property is transferred, while revenue for the provision of certain regulatory services is reported over time as the services are performed. The revenue allocated to the performance obligation for outlicensing is based on the residual approach and consists of the total transaction price for each contract after deducting the stand-alone selling price of all other performance obligations. The allocation of revenue to the performance obligation for regulatory services is based on the expected costs to provide the service, with the addition of a profit margin based on comparable companies. The identification and allocation of the transaction price between these performance obligations hence has a significant impact on the Group's revenue recognition, as the revenue recognition patterns differ between the performance obligations.

Specifically, the significant accounting judgments and estimates within revenue recognition include determining which promises within each contract that are distinct, estimating the expected costs to fulfil the performance obligations that are not based on the residual method, and determining an appropriate profit margin for these. The Group determines the expected costs to complete these performance obligations through an input model based on the expected hours of work required by the Group's personnel, as well as expected costs to be incurred from the Group's suppliers. The Group then determines an appropriate profit margin by identifying comparable peer companies that provide such services separately and bases the margin rate on these. The Group then recognizes revenue for the performance obligation to provide regulatory services as these costs are incurred. These estimates are forward-looking and could be affected by differences between expected and actual costs incurred to fulfil the performance obligations. Management's estimate of the total costs as a measure of progress to completion of the performance obligation hence requires the use of assumptions and estimates.

The revenue contracts also contain variable consideration in the form of regulatory and commercial milestones. Variable consideration is initially considered constrained, as there is significant uncertainty as to whether the associated milestones will occur. Consideration attributable to sales-based milestones or royalties is not recognized until the sale that results in the right to the royalties have occurred. Determining whether the criteria for recognition of the variable remuneration has been met hence has significant effects on revenue recognition and requires significant judgment by Management.

Gross to Net Accounting
Revenue from product sales in the United States is recognized when product is received by the customer and title passes, typically at the time of delivery. There are various sales deductions and rebates that are deducted from the gross sales as part of the revenue recognition process. As the actual sales deductions are not known at the point of sale, estimates are made in determining the initial deduction of rebates, and are then subject to true-up as actual data is obtained. For sales of TARPEYO, returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates or industry averages, if available and those estimates are recorded as a reduction of accounts receivable and as other current liabilities, respectively. Similarly estimates are determined relating to specialty pharma fees, co-pay support redemptions, Medicare/ Medicaid and other rebates, and these estimates are reflected as a component in the accrued expenses and deferred revenue and as a reduction of revenue. Once all related variable considerations are resolved and uncertainties as to collectable amounts are eliminated, estimates are adjusted to actual amounts. Accruals for these estimated amounts are reviewed and adjusted on no less than a quarterly basis, see Note 2.

Set out below is the Group's revenue from contracts with customers:

	Year Ended December 31,		
Type of goods or service	**2023**	**2022**	**2021**
Product sales	1,087,418	375,515	—
Outlicensing of product	82,712	421,689	225,252
Royalty income	36,758	2,287	—
Performance of certain regulatory services	—	3,387	4,095
Total	**1,206,888**	**802,879**	**229,347**

	Year Ended December 31,		
Geographical markets	**2023**	**2022**	**2021**
USA	1,075,829	372,247	—
Europe*	39,614	143,955	201,878
Asia	91,445	286,677	27,469
Total	**1,206,888**	**802,879**	**229,347**

** No net sales were recorded in Sweden in 2023, 2022, and 2021, respectively.*

The Group's revenues in 2023 consisted primarily of net sales of TARPEYO in the U.S., and outlicensing of product which consisted of regulatory milestone fees from Everest Medicines.

	Year Ended December 31,		
Revenue from major customers	**2023**	**2022**	**2021**
Customer A	1,045,288	372,247	—
Customer B	91,415	80,643	27,469
Customer C	39,614	143,955	201,878
Customer D	—	206,034	—
Customers below 10% of revenue	30,571		
Total	**1,206,888**	**802,879**	**229,347**

	Year Ended December 31,		
Performance obligations	**2023**	**2022**	**2021**
Expected returns	3,552	15,849	—
Rebates on sales	36,326	8,445	—
Total	39,878	24,294	—

Contract assets	Year Ended December 31, 2023	2022	2021
Accrued royalties	7,297	2,287	—
Contract liabilities			
Prepaid income	—	—	3,387

Total non-current assets per geographical market	December 31, 2023	2022
Sweden	20,462	43,285
France	3,013	354
Switzerland	497,267	437,508
USA	12,835	17,484
Total	**533,577**	**498,631**

Non-current assets included in the above table includes intangible assets, equipment and right-of-use assets.

Note 4 Other Operating Income

	Year Ended December 31, 2023	2022	2021
Exchange rate differences	17,183	—	149
Pass through costs	7,648	439	—
Net gains on disposal of non-current assets	941	—	110
Change in value of the contingent consideration at fair value	18,835	—	—
Other income	1	2,423	—
Total	**44,608**	**2,862**	**259**

Regarding value of the contingent consideration, see Note 27 Contingent consideration.

Note 5 Other Operating Expenses

	Year Ended December 31, 2023	2022	2021
Exchange rate differences	596	7,133	1,807
Net loss on disposal of equipment	—	—	67
Change in value of the contingent consideration at fair value	—	15,941	4,470
Other expenses	539	—	—
Total	**1,135**	**23,074**	**6,344**

Note 6 Auditors' Fee

	Year Ended December 31,		
	2023	2022	2021
EY			
Audit services	20,951	13,369	6,235
Other audit activities	900	3,370	2,105
Tax advice	—	—	73
Total	**21,851**	**16,739**	**8,413**
KPMG			
Audit services	—	—	472
Other audit activities	—	—	1,178
Total	**—**	**—**	**1,650**
Other auditors			
Audit services	—	—	471
Other audit activities	—	—	79
Total	**—**	**—**	**550**
Total Audit Fee	**21,851**	**16,739**	**10,613**

Audit services relate to the statutory audit of the financial statements and the accounts, as well as the management of the Board of Directors and the CEO. This includes other responsibilities that it is incumbent upon the company's auditor to perform including providing advice or any other assistance that may result from observations in such review or the conduct of such other responsibilities.

Other auditing activities are those services in accordance with a special agreement on financial statements.

Note 7 Costs according to Type of Cost

	Year Ended December 31,		
	2023	2022	2021
Raw materials, consumables and royalties	60,463	3,179	—
Other external expenses	955,895	939,566	549,079
Personnel costs	558,332	248,952	164,206
Depreciation on equipments and right-of-use assets	48,726	12,913	34,433
Other operating expenses	1,134	23,074	6,344
Total	**1,624,550**	**1,227,684**	**754,062**

Note 8 Leases

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities for future remaining lease payments and right-of-use assets representing the right to use the underlying assets.

Right-of-use assets

The Group recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received.

Right-of-use assets are depreciated on a straight-line basis over the esti-mated lease term, which currently is 2 to 8 years for the Group's leases.

Lease liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments less any lease incentives receivable and variable lease payments that depend on an index or a rate. In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the commencement date, because the interest rate implicit in the lease is not readily determinable. Following the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, or a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments). The Group's lease liabilities are included in Non-current lease liabilities and other current liabilities in the consolidated statements of financial position (see Note 8 Leases and 20 Financial Risks).

Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of equipment (i.e., those leases that have a lease term of twelve months or less from the commencement date). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered to be low value. Lease payments on short-term leases and leases of low value assets are recognized as an expense on a straight-line basis over the lease term.

	December 31,	
Right-of-use assets	**2023**	**2022**
Opening balance	24,452	33,300
Additional agreements	10,518	—
Revaluation of agreements	15,887	(427)
Depreciation	(12,360)	(10,807)
Termination of agreement	(113)	—
Exchange differences	(198)	2,386
Net book value	**38,186**	**24,452**

Depreciation on right-of-use assets is included in the consolidated statements of income under	**2023**	**2022**	**2021**
Research and development expenses	1,373	1,073	997
Marketing and selling expenses	3,923	3,743	1,522
Administrative expenses	7,064	5,991	3,192
	12,360	**10,807**	**5,711**

	December 31,	
Lease liabilities	**2023**	**2022**
Non-current lease liabilities	27,088	15,792
Current lease liabilities	12,537	10,374
Total	**39,625**	**26,165**

Lease liabilities are included in the consolidated statements of financial position under Non-current lease liabilities and Other current liabilities. Changes in liabilities arising from financing activities, see Note 23 Cash for further information on leasing liabilities.

	December 31,	
Maturity analysis on future lease liabilities	**2023**	**2022**
<12 months	25,102	16,467
1-2 years	21,509	12,613
>2 years	18,412	10,053
	65,023	**39,133**

Future lease payments in accordance with the above are undiscounted.

The leases primarily comprise of leased premises for the Group. The lease agreements for leased premises have terms ending 2024 until 2030 respectively and can be extended unless one of the parties terminates the lease agreements. The Group cannot determine with reasonable certainty whether the extensions will take place based on the Group's development and has therefore not expected utilization after the terms ending. Future lease payments are linked to the development in the CPI index, but with a limitation on negative index change. Index adjustments are included in the lease liability when they come into force and are then adjusted against the right-of-use asset. Lease of low-value assets consists mainly of storage and office equipment.

	Year Ended December 31,		
	2023	2022	2021
Interest expenses attributable to lease liabilities	2,744	1,604	590
Expenses attributable to short-term lease	6	0	633
Expenses attributable to leasing agreements with low value	225	214	146
Expenses attributable to variable lease payments that are not included in lease liabilities	1,726	303	446
Expenses attributable to lease depreciation	12,360	10,807	5,711
Total expensed during the year	**17,061**	**12,928**	**7,526**
This year's lease payments in the Group	16,784	13,231	6,659

Note 9 Employees and Personnel Costs

Average Number of Employees

	Year Ended December 31,					
	2023		2022		2021	
	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.
Parent Company						
Sweden	58	38 %	45	33 %	29	40 %
	58	**38 %**	**45**	**33 %**	**29**	**40 %**
Subsidiaries						
France	3	—	2	0 %	3	26 %
Switzerland	8	38 %	6	53 %	6	47 %
United States	112	46 %	33	52 %	18	62 %
	123	**44 %**	**41**	**51 %**	**27**	**55 %**
Total for the Group	**181**	**42 %**	**86**	**41 %**	**56**	**47 %**

Wages and Salaries, Pension Costs and Social Security Costs to the Board, Executive Management and Other Employees

	Year Ended December 31,		
Wages and Salaries	**2023**	**2022**	**2021**
Parent Company			
Board and Executive Management[1)]	39,436	33,471	27,792
Other employees	76,055	52,126	33,370
Subsidiaries			
Board and Executive Management	14,783	14,493	4,983
Other employees	315,885	90,055	57,452
Total	**446,159**	**190,145**	**123,597**

[1)] Executive Management includes the Board, CEO and other executive management.

	Year Ended December 31,		
Social Security Costs and Pension Costs	**2023**	**2022**	**2021**
Parent Company			
Pension costs for the Board and Executive Management	3,035	2,167	1,785
Pension costs to other employees	9,343	6,582	4,084
Social security costs	37,634	17,393	17,088
Subsidiaries			
Pension costs for the Board and Executive Management	229	616	167
Pension costs to other employees	7,693	2,647	928
Social security costs	27,346	6,484	8,596
Total	**85,280**	**35,889**	**32,648**

Gender Distribution Among the Board and Senior Executives

	Year Ended December 31,		
	2023	**2022**	**2021**
Percentage of women on the Board	50 %	67 %	60 %
Percentage of men on the Board	50 %	33 %	40 %
Percentage of women among other executive management	29 %	38 %	33 %
Percentage of men among other executive management	71 %	62 %	67 %

Disclosures Regarding Total Remuneration of The Board and Executive Management

	Year Ended December 31, 2023					
	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
Chairman of the Board						
Elmar Schnee	1,020	—	—	—	718	1,738
Board members						
Elisabeth Björk	383	—	—	—	204	586
Frederick Driscoll (from Jun, 23)	303	—	—	—	84	387
Hilde Furberg	458	—	—	—	273	731
Molly Henderson (until May, 23)	295	—	—	—	21	316
Diane Parks	522	—	—	—	273	796
Henrik Stenqvist	558	—	—	—	204	761
Senior executives						
CEO, Renée Aguiar-Lucander	6,725	1,817	3,177	—	6,648	18,367
Other executive management (6 people)	18,737	1,446	5,731	—	8,030	33,945
of which relates to subsidiaries	*8,689*	*229*	*3,768*	—	*2,470*	*15,156*
Total	**29,000**	**3,264**	**8,908**	—	**16,455**	**57,626**

	Year Ended December 31, 2022					
	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
Chairman of the Board						
Elmar Schnee	975	—	—	—	647	1,622
Board members						
Elisabeth Björk (from May, 2022)	188	—	—	—	74	261
Hilde Furberg	413	—	—	—	239	651
Lennart Hansson (until May, 2022)	200	—	—	—	33	233
Molly Henderson	590	—	—	—	227	817
Diane Parks	490	—	—	—	239	729
Henrik Stenqvist (from May, 2022)	275	—	—	—	74	349
Senior executives						
CEO, Renée Aguiar-Lucander	5,938	760	2,293	—	4,056	13,048
Other executive management (7 people)	17,784	2,023	5,146	—	8,083	33,037
of which relates to subsidiaries	*7,516*	*616*	*3,152*	—	*3,824*	*15,109*
Total	**26,853**	**2,783**	**7,440**	**—**	**13,671**	**50,747**

	Year Ended December 31, 2021					
	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
Chairman of the Board						
Elmar Schnee	898	—	—	—	465	1,363
Board members						
Hilde Furberg	336	—	—	—	162	498
Lennart Hansson	360	—	—	—	162	522
Molly Henderson	539	—	—	—	124	663
Diane Parks	421	—	—	—	162	583
Senior executives						
CEO, Renée Aguiar-Lucander	4,860	760	1,840	—	3,270	10,730
Other executive management (5 people)	11,279	1,193	2,335	—	5,561	20,368
of which relates to subsidiaries	*2,775*	*167*	*694*	—	*1,515*	*5,151*
Total	**18,693**	**1,953**	**4,175**	**—**	**9,906**	**34,727**

Remuneration of Executive Management
Remuneration of the CEO and other executive management comprises base salary, pension benefits and variable remuneration. Other executive management comprise the seven (five) individuals who, together with the CEO, comprise Executive Management. Other executive management are: Chief Financial Officer, Chief Medical Officer, Vice President Regulatory Affairs, President, North America, Group General Counsel and Head of Human Resources.

Pensions
All pension commitments are defined-contribution plans for executive management. The payments made by the Group for defined contribution plans are recognized as expense in the statements of consolidated operations for the period to which they relate. The age of retirement for the CEO is 65 and the pension premium is 20% of base salary. Pension commitments for other Swedish executive management are between 15% and 20% of base salary. The age of retirement is 65 for all other executive management. Defined-benefit pension plans occurs only if required by law or other regulations. In such cases, the defined-benefit level shall be limited to the mandatory level. There are no other pension obligations.

Variable Remuneration
Variable remuneration refers to a variable bonus based on a fixed percentage of base salary. Outcome is based on a vesting period of one year and depends on fulfillment of a combination of predetermined personal targets and business targets. The maximum outcome for the CEO and for other executive management is 60% according to the guidelines for remuneration to executive management.

Severance Pay
A notice period of six months applies if employment is terminated by the CEO. A notice period of twelve months applies if employment is terminated by the Group. The CEO is not entitled to separate severance pay but is eligible to receive a salary during the period of notice. A mutual notice period of three to twelve months, with salary paid, applies between the Group and executive management. No severance pay is paid to Board members.

Guidelines for Executive Remuneration
At the 2023 Annual General Meeting the most recently adopted guidelines for executive remuneration was approved. Remuneration within the Group shall be based on principles of performance, competitiveness and fairness. For additional information of the work of the Board of Directors, please see the Corporate Governance Report on pages 88-93.

Executive management refer to the CEO and other members of the executive management, as well as board members. The guidelines shall apply to employment agreements concluded after the listing on Nasdaq Stockholm, as well as to changes in existing agreements after the listing.

The remuneration to the executive management may consist of fixed remuneration, variable remuneration, share and share price-related incentive programs, pension and other benefits. If local conditions justify variations in the remuneration principles, such variations may occur. The fixed remuneration shall reflect the individual's responsibility and experience level. The fixed remuneration shall be reviewed annually. The executive management may be offered variable remuneration paid in cash. Such remuneration may not exceed 60 percent of the annual fixed remuneration. Variable remuneration shall be connected to predetermined and measurable criteria, designed with the aim of promoting the Groups long-term value creation. Remuneration and other terms of employment for the CEO are prepared by the Remuneration Committee and decided by the Board of Directors. Remuneration and other terms of employment for other members of the executive management are decided by the CEO, in accordance with principles decided by the Board of Directors and the Remuneration Committee.

The Board of Directors is entitled to deviate from the guidelines if the Board of Directors, in a certain case, deems that there are good reasons for the deviation. Decisions as to the current remuneration levels and other conditions for employment of the CEO and the other members of the executive management have been resolved by the Board of Directors. There are no previous payments that have not been due.

Note 10 Share-Based Payments

Option Program

Calliditas implements option programs for employees and key consultants in Calliditas. The options are granted free of charge to participants of the program. The options have a three-year vesting period calculated from the grant date, provided that, with customary exceptions, the participants remain as employees of, or continue to provide services to, Calliditas. Once the options are vested, they can be exercised within a one-year period.

Each vested option entitles the holder to acquire one share in Calliditas at a predetermined price. The price per share is to be equivalent to 115% of the weighted average price that the company's shares were traded for on Nasdaq Stockholm during the ten trading days preceding the grant date. The options have, at the time of each issue, been valued according to the Black-Scholes valuation model.

Social security costs attributable to equity-related instruments to employees as remuneration for purchased services shall be expensed over the periods during which the services are performed. The cost should then be measured using the same valuation model used when the options were issued. The provision recognized must be revalued at each reporting period on the basis of a calculation of the social security costs that may be paid when the instruments are exercised.

The cost for the remuneration that is recognized in a period is dependent on the original valuation that was made on the date on which the contracts with the participants in the incentive programs were concluded, the number of months of service required for vesting of their options (accruals are made over this period), the number of options that are expected to be vested under the terms of the plans and a continuous reassessment of the value of the tax benefits for the participants under the plans (for determining provisions for social security expenses). Those estimates which affect the cost in a period and the corresponding increase in equity mainly refer to inputs for the valuation of the options. All the options are classified as equity-settled, as vested options are settled in equity. When the options are exercised, the company issues new shares.

Changes and holdings of options for CEO, other executive management and other employees on the opening and closing balance are presented below.

	Options Outstanding as of				
Holder	**January 1, 2022**	**Change**	**December 31, 2022**	**Change**	**December 31, 2023**
Renée Aguiar-Lucander, CEO	296,000	295,000	591,000	250,000	841,000
Other executive management	535,000	520,000	1,055,000	80,000	1,135,000
Other employees and consultants	1,458,000	848,166	2,306,166	1,816,564	4,122,730
Total	**2,289,000**	**1,663,166**	**3,952,166**	**2,146,564**	**6,098,730**

Calculation of fair value of option program (ESOP)
The fair value on the grant date was calculated using an adapted version of the Black & Scholes valuation model, which takes into consideration the exercise price, the term of the options, share price on the grant date and expected volatility in the share price, and risk-free interest for the term of the options.

	Grant Date	Exercise Date	Fair value Upon Issue of the Options, SEK	Exercise Price, SEK	Volatility	No. of Shares Covered by Options
ESOP 2020:1	July 1, 2020	July 1, 2023	22.14	121.43	39.60 %	829,564
ESOP 2020:2	September 17, 2020	September 17, 2023	22.50	116.78	41.60 %	104,000
ESOP 2020:3	February 4, 2021	February 4, 2024	30.41	145.07	44.30 %	37,000
ESOP 2020:4	March 9, 2021	March 9, 2024	30.41	141.26	45.20 %	394,166
ESOP 2021:1	June 14, 2021	June 14, 2024	35.88	140.71	46.00 %	487,000
ESOP 2021:2	September 29, 2021	September 29, 2024	25.72	109.38	47.52 %	329,500
ESOP 2021:3	March 17, 2022	March 17, 2025	27.64	93.77	43.84 %	618,000
ESOP 2022:1	September 27, 2022	September 27, 2025	26.57	94.66	45.14 %	1,016,500
ESOP 2022:2	March 9, 2023	March 9, 2026	35.90	116.38	53.84 %	455,000
ESOP 2022:3	May 24, 2023	May 24, 2026	39.91	128.54	58.24 %	413,000
ESOP 2023:1	July 25, 2023	July 25, 2026	40.76	97.80	57.74 %	965,000
ESOP 2023:2	December 19, 2023	December 19, 2026	48.84	118.02	59.17 %	450,000
						6,098,730

The total cost of the outstanding option program is presented below. These costs do not affect the Groups consolidated statements of cash flows. The Group has in total 7,000,000 options which are set aside to secure the delivery of shares in connection with the utilization of the option programs. For additional information see Note 25 Equity.

	Year Ended December 31,		
	2023	2022	2021
Share-based payments	50,560	34,549	24,737
Provisions attributable to changes in social security costs (Share-based payments)	20,701	234	9,992
Total	**71,261**	**34,783**	**34,729**

Share Awards
Calliditas implements share awards programs which is a performance-based long-term incentive program for members of the Board of Directors in Calliditas. Calliditas currently has three share award programs ongoing at year-end.

For each share award program, the share awards are vested by 1/3 at the end of each period, provided that the participant is still a member of the Board of Calliditas that day.

In addition to these conditions for vesting, for each share award program, the share awards are subject to performance-based vesting based on the development of Calliditas share price. If Calliditas share price has increased by more than 60 percent, 100 percent of the share awards shall be earned, and if the share price has increased by 20 percent, 33 percent of the share awards shall be vested. In the event of an increase in the share price by between 20 and 60 percent, vesting will be linear. If the share price has increased by less than 20 percent, no vesting will take place. Each share award entitles the holder to receive a share in Calliditas free of charge, provided that the holder is still a member of the Board of Calliditas at the relevant vesting date.

Changes and holdings of share awards for the Board on the opening and closing balance are presented below:

Board LTIP 2020	Share Awards Outstanding as of				
Holder	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Elmar Schnee, Chairman of the Board	14,063	—	14,063	(14,063)	—
Hilde Furberg, Board member	4,327	—	4,327	(4,327)	—
Lennart Hansson, Board member (until May, 2022)	4,327	(1,443)	4,327	(4,327)	—
Diane Parks, Board member	4,327	—	2,884	(2,884)	—
Molly Hendersson, Board member	4,327	—	4,327	(4,327)	—
Total	**31,371**	**—**	**29,928**	**(29,928)**	**—**

Board LTIP 2021	Share Awards Outstanding as of				
Holder	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Elmar Schnee, Chairman of the Board	10,624	—	10,624	—	10,624
Hilde Furberg, Board member	4,086	—	4,086	—	4,086
Lennart Hansson, Board member (until May-22)	4,086	(2,724)	1,362	—	1,362
Diane Parks, Board member	4,086	—	4,086	—	4,086
Molly Hendersson, Board member	4,086	—	4,086	(1,362)	2,724
Total	**26,968**	**(2,724)**	**24,244**	**(1,362)**	**22,882**

Board LTIP 2022	Share Awards Outstanding as of				
Holder	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Elmar Schnee, Chairman of the Board	—	13,926	13,926	—	13,926
Hilde Furberg, Board member	—	5,356	5,356	—	5,356
Diane Parks, Board member	—	5,356	5,356	—	5,356
Molly Hendersson, Board member	—	5,356	5,356	(3,570)	1,786
Henrik Stenqvist, Board member	—	5,356	5,356	—	5,356
Elisabeth Björk, Board member	—	5,356	5,356	—	5,356
Total	**—**	**40,706**	**40,706**	**(3,570)**	**37,136**

Board LTIP 2023	Share Awards Outstanding as of				
Holder	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Elmar Schnee, Chairman of the Board	—	—	—	14,012	14,012
Hilde Furberg, Board member	—	—	—	5,389	5,389
Diane Parks, Board member	—	—	—	5,389	5,389
Fred Driscoll, Board member	—	—	—	5,389	5,389
Henrik Stenqvist, Board member	—	—	—	5,389	5,389
Elisabeth Björk, Board member	—	—	—	5,389	5,389
Total	**—**	**—**	**—**	**40,957**	**40,957**

For each share award program, calculation of fair value of share-based payments (Board LTIP)
Fair value at grant day has been measured using a Monte Carlo simulation of future share price developments. The simulated share price trend has been used to both calculate the outcome of the program and the value of each share at the time of acquisition (present value adjusted to the grant date).

	Exercised Date	Fair Value at Grant Date	Number of Share Awards
Board LTIP 2021	July 1, 2024	62.95	22,882
Board LTIP 2022	July 1, 2025	51.54	37,136
Board LTIP 2023	July 1, 2026	57.90	40,957

The total cost of the outstanding share-based payments is presented below. These total costs do not affect the Groups consolidated statement of cash flows. The Group has in total 72,000 warrants, which are set aside to secure the delivery of shares in connection with the exercise of the share award programs. For additional information see Note 25 Equity.

	Year Ended December 31,		
	2023	2023	2022
Share-based payments	1,776	1,531	876
Provisions attributable to changes in social security costs (Share-based payments)	119	(1,614)	297
Total	**1,895**	**(83)**	**1,173**

Warrants

Calliditas has implemented warrant programs for employees and key consultants in Calliditas. When warrant is exercised, the holder pays a subscription price and then receives one common share in the Parent Company. The warrants have been valued according to the Black & Scholes model, which means the value of the warrant depends on factors including the value of the underlying share, which in this case is the common share.

	Warrants Outstanding as of			Inputs used for the Black & Scholes valuation				
Outstanding Warrants per Year	December 31, 2021	December 31, 2022	Exercise Price, SEK	Price per Warrant in SEK	Value per Share in SEK	Risk-Free Rate	Volatility	Expiration Date
Warrant program 2018/2022	856,586	—	74.30	3.29	46.50	(0.28%)	33 %	2022-03-31
Warrant program 2019/2022	422,500	—	74.50	6.69 *	54.39 *	(0.55%)*	36 %*	2022-12-31
Total	**1,279,086**	**—**						

** Average value*

Changes and holdings of warrants for the Board, CEO, other executive management and other employees and consultants on the opening and closing balance are presented below;

	Warrants Outstanding as of				
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
CEO Renée Lucander	545,000	—	545,000	(545,000)	—
Other executive management	437,500	—	437,500	(437,500)	—
Other employees, consultants and external parties	296,586	—	296,586	(296,586)	—
Total	**1,279,086**	**—**	**1,279,086**	**(1,279,086)**	**—**

Summary of Granted Warrants, Options and Share Awards

	Options		Share Awards		Warrants	
	Number of Shares	Weighted Average Exercise Prices	Number of Shares	Weighted Average Exercise Prices	Number of Shares	Weighted Average Exercise Prices
Outstanding as of January 1, 2022	2,289,000	128.18	109,738	—	1,279,086	74.37
Granted	1,751,000	94.33	40,706	—	—	—
Forfeited	(87,834)	133.33	(4,167)	—	—	—
Exercised	—	—	(51,399)	—	(1,279,086)	74.37
Outstanding as of December 31, 2022	**3,952,166**	**113.07**	**94,878**	—	**—**	**—**
Outstanding as of January 1, 2023	3,952,166	113.07	94,878	—	—	—
Granted	2,333,000	111.16	40,957	—	—	—
Forfeited	(186,436)	104.54	(34,860)	—	—	—
Exercised	—	—	—	—	—	—
Outstanding as of December 31, 2023	**6,098,730**	**112.51**	**100,975**	—	—	**—**
Weighted average share price at the date of exercise	—	—	—	—	—	—

Note 11 Financial Income

Material accounting policy - financial income

Financial income consists of interest income and foreign exchange gains. Foreign exchange gains and losses are presented on a net basis.

	Year Ended December 31,		
	2023	2022	2021
Interest income	29,095	3,553	102
Exchange rate differences	1,292	46,642	20,234
Total	**30,387**	**50,195**	**20,336**

Note 12 Financial Expenses

Material accounting policy - financial expenses
Financial expenses mainly consist of interest expenses and unrealized foreign exchange losses. Foreign exchange gains and losses are netted.

	Year Ended December 31,		
	2023	2022	2021
Interest on lease liabilities	(2,744)	(1,604)	(590)
Other interest expenses	(70,455)	(31,191)	(6,518)
Early repayment of loan	(35,397)	—	—
Other financial expenses	(5,753)	(4,874)	(2,145)
Total	**(114,349)**	**(37,669)**	**(9,253)**

Note 13 Income Tax Expense

Material accounting policy - taxes
Deferred tax is recognized on all temporary differences that arise between the tax value of assets and liabilities and their carrying amounts. Temporary differences attributable to participations in Group companies is not recognized, since it is unlikely that such a reversal will take place in the foreseeable future.

The valuation of deferred tax is based on how the underlying assets or liabilities are expected to be realized or settled. Deferred tax is measured with the application of the tax rates and tax rules decided or announced on the closing date, and that are expected to apply when the deferred tax asset in question is realized or the deferred tax liability is settled. Deferred tax liabilities and deferred tax assets are offset as far as possible within the framework of local laws and regulations on taxation.

Significant accounting judgments, estimates and assumptions - loss carryforwards
The Group's tax losses carried forward have not been recognized as deferred tax assets in the statement of financial position as of December 31, 2022, except for such circumstances where there are future temporary differences that such losses can be used to offset. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

The Group has identified an uncertain tax position in relation to the ability to use tax loss carried forward in France due to transactions performed historically. The related tax losses carried forward has not been recognized as deferred tax assets in the consolidated statements of financial position.

	Year Ended December 31,		
	2023	2022	2021
Current income taxes	(23,484)	(11,539)	(4,581)
Deferred tax	14,316	8,688	8,417
Income tax expense recognized in the consolidated statements of income	**(9,168)**	**(2,851)**	**3,836**

Reconciliation of effective tax rate	Year Ended December 31, 2023	2022	2021
Accounting loss before income tax	(457,017)	(409,417)	(513,373)
Tax in accordance with applicable tax rate in Sweden 20.6%	94,145	84,340	105,755
Tax effect of:			
Effect of other tax rates for foreign subsidiaries	(16,159)	(11,857)	11,481
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(68,074)	(64,150)	(101,785)
Non-deductible expenses	(22,406)	(11,184)	(11,615)
Non-taxable income	3,326	—	—
Income tax expense recognized in the consolidated statements of income	**(9,168)**	**(2,851)**	**3,836**
At the effective income tax rate	**(2)%**	**(1)%**	**1 %**

In 2021, the Group has costs attributable to new share issue amounted to SEK 20,909, which are recognized directly against equity. These costs are deductible for tax purposes.

The Group has SEK 3,881,336 and SEK 3,562,440 of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position as of December 31, 2023 and 2022, respectively. The tax losses carried forward are allocated between Sweden of SEK 1,772,890, France of SEK 1,209,163 and Switzerland of SEK 899,283, where the tax losses carried forward in Sweden and France may be carried forward indefinitely, but in Switzerland there is a time limit of seven years. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized or to the extent when there are temporary differences against which these will be able to be offset.

Note 14 Earnings per Share

Loss per share before and after dilution	Year Ended December 31, 2023	2022	2021
Net loss for the year attributable to equity holders of the Parent Company	(466,186)	(412,267)	(500,293)
Weighted-average number of common shares outstanding	53,672,069	53,022,550	50,829,255
Loss per share before and after dilution	**(8.69)**	**(7.78)**	**(9.84)**

For calculation of earnings per share after dilution, the weighted-average number of outstanding ordinary shares is adjusted for the dilution effect of all potential ordinary shares, with the exception of treasury shares held by Calliditas. The Parent Company has a category of potential common stock with dilution effect: stock options. These potential common shares are attributable to the options and performance shares granted during the years 2020 – 2023. For additional information see Note 10 Share-Based Payments. If the profit for the year is negative, the options are not considered dilutive. The options also do not impact the numerator in the earnings per share calculation, including the addition of the value of remaining future services to report during the vesting period, exceeding the average market price for the period. There is no dilution effect for issued options with entitlement to subscribe to 6,098,730 shares, since the Group is in a loss position in 2023, 2022, and 2021 respectively. Further, there is no dilution effect for issued share awards with entitlement to receive 100,975 shares, due to performance-based vesting.

For disclosures regarding the number of outstanding shares, refer to Note 25 Equity.

Note 15 Intangible Assets and Impairment Testing

Material accounting policy - intangible assets

Research and development expenses
Development expenditures are recognized as an intangible asset when related development projects meet the criteria for capitalization. The most important criteria for capitalization are that the final product of the development process will generate future economic benefits or the ability of cost-savings capacity, including the technical feasibility of completing the intangible asset. Research and development expense are otherwise recognized as operating expenses. Full market approval has not yet been obtained for the Group's products and, accordingly, the Group deems that the conditions for capitalizing development expenditures are not met.

Amortization
Until full regulatory market approval has been granted, amortization will not commence in respect of "Licenses and similar rights" that are separately acquired. Following market approval from regulatory authorities, "Licenses and Similar Rights" will be amortized on a straight-line basis over the expected useful life. The Group's expected finite useful lives are: – Licenses and similar rights – 6-15 years

Impairment of intagible assets
The Group bases its impairment measurement on intangible assets on a probability-adjusted cash flow model. The value of licenses is measured by estimating the expected future cash flows and present value adjustments to take into account the development risk. The valuation takes into account cash flow from potential commercialization during the expected useful life and does not include calculation of any residual value thereafter. The most critical assumptions mainly consist of assumptions about the timing of potential commercialization, market size, market share and probability of reaching the market.

When assessing the impairment requirement for goodwill, this is grouped at the lowest levels for which there are separately identifiable cash flows. Calliditas has made the assessment that the Group's operations as a whole comprise a cash-generating unit.

Significant accounting judgments, estimates and assumptions - intangible assets
The Group's intangible assets are attributable to the Group acquiring the rights to the NOX platform, as well as goodwill in connection with the acquisition of Genkyotex SA. For goodwill and intangible assets not yet available for use the Group assesses for impairment at each reporting date based on their recoverable amounts, including key assumptions such as the timing of potential commercialization, market size, market share, probability of reaching the market and the discount rates.

Goodwill and intangible assets, not yet available for use
The Group conducts impairment testing, at least annually, for goodwill and intangible assets not yet available for use. The recoverable amount of the cash-generating unit is determined by calculating the value in use. This calculation requires certain judgments and assumptions to be made. As of December 31, 2023, the Group's goodwill amounted to SEK 48,584 and other intangible assets amounted to SEK 430,754.

Capitalization expenditures for the development
The Group capitalizes expenditures for the development of pharmaceuticals to the extent that it is expected to meet the criteria in accordance with IAS 38 — Intangible Assets. The decision to capitalize is based on significant judgments made by management, including the technical feasibility of completing the intangible asset so that it will be available for use or sale and assumptions used to demonstrate that the asset will generate probable future economic benefits (e.g., projected cash flow projections, discount rate). The Group's expenditures for the development of pharmaceuticals were not deemed to meet the capitalization criteria for the year ended December 31, 2023, and was thus expensed. Capitalization of expenditures are generally made in late stage of the development, for example after full approval, depending on when the criteria are deemed to have been met. The reason for this is that before then it is uncertain whether the expenditure will generate future economic benefits and that financing the completion of the asset is not yet guaranteed.

US Food and Drug Administration (FDA) has granted accelerated approval for TARPEYO® in the U.S. and the European Commission has granted conditional marketing authorization for Kinpeygo® in Europe (EEA). Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial and, accordingly, the conditions for capitalizing development expenditures may change to be reflected in the assumptions when they occur.

	December 31,	
	2023	2022
Licenses and similar rights		
Cost at opening balance	468,711	390,166
Disposal for the year	(62,697)	—
Exchange differences on translation	24,740	78,545
Cost at closing balance	**430,754**	**468,711**
Impairment		
Impairment at opening balance	(30,654)	(27,975)
Impairment	(32,132)	—
Disposal for the year	62,697	—
Exchange differences on translation	89	(2,679)
Impairment at closing balance	**—**	**(30,654)**
Net book value	**430,754**	**438,057**
Goodwill		
Cost at opening balance	45,784	37,227
Exchange differences on translation	2,800	8,557
Cost at closing balance	**48,584**	**45,784**

Intangible assets consist of licenses and similar rights of SEK 430,754 and goodwill of SEK 48,584 as of December 31, 2023.

Intangible assets are from the acquisition of the NOX-platform and associated goodwill. The net book value of the NOX-platform amounts to SEK 430,753 as of December 31, 2023. The NOX-platform constitutes a technology, including the lead compound setanaxib, enables the identification of orally available small molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis and inflammation. The estimated fair value of the NOX platform was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence. During the year, an impairment of SEK 32.1 million was recognized, and was related to the in-licensing Budenofalk. The decision to close was attributed to regulatory challenges.

Impairment Testing

Goodwill
The assessment of the value of the Group's goodwill is based on the fair value less cost of disposals for the smallest cash-generating unit, which for Calliditas is deemed to be the full Group. The impairment measurement is based on a probability-adjusted cash flow model, measured at Level 3 of the fair value hierarchy, where the most critical assumptions mainly consist of assumptions about the timing of potential commercialization, market size, market share and probability of reaching the market. The period for the forecast cash flow extends to 2035, where no terminal growth rate has been taken into account. As of December 31, 2023, the Group's goodwill amounted to SEK 48,584. There is no impairment for the year ended December 31, 2023.

The following table shows the discount rate used before tax:

Parameter, %	Year Ended December 31, 2023	2022
Discount rate Goodwill	12.2	12.0

Intangible assets, not yet available for use

These assets consist of the NOX platform, which are tested, at least, annually for impairment requirement. The assessment of the value of the technology and the rights is based on the fair value less cost of disposals of the assets. The fair value less cost of disposals is based on cash flows that are expected to be generated over the remaining life of the asset.

The following table shows the discount rate used before tax:

Parameter, %	Year Ended December 31, 2023	2022
Discount rate NOX platform	12.2	12.0

When the technology and the rights are tested for impairment requirement, a number of assumptions are made, where the most critical assumptions mainly consist of the timing of potential commercialization, market size, market share, probability of reaching the market and the discount rate. The earlier in the chain of development the project is, the higher the risk. As it passes through the defined phases of development, the likelihood of reaching the market increases. The review of the technology and the rights showed no impairment requirement except for impairment of Budenofalk 3 mg oral capsule amounted to SEK 32,132.

Note 16 Equipment

	December 31, 2023	2022
Cost at opening balance	11,167	7,073
Acquisition for the year	12,788	2,512
Disposal for the year	(65)	—
Exchange differences	260	1,582
Cost at closing balance	**24,150**	**11,167**
Depreciation at opening balance	(3,700)	(764)
Depreciation for the year	(4,234)	(2,106)
Exchange differences	(164)	(830)
Depreciation at closing balance	**(8,098)**	**(3,700)**
Net book value	**16,053**	**7,468**

Depreciation on equipment is included in the statement of income under the sub-items:	December 31, 2023	2022	2021
Research and development expenses	1,315	579	59
Marketing and selling expenses	1,057	806	176
Administrative expenses	1,862	721	230
	4,234	**2,106**	**465**

Equipment is depreciated on a straight-line basis over the expected useful life.

The Group's expected useful life is:
- Equipment – 5 years
- Computers – 5 years

Note 17 Non-Current Financial Assets

	December 31,	
	2023	2022
Cost at opening balance	11,210	3,915
Additional acquisition	1,560	7,064
Reclassification from current receivables	12,214	—
Disposal for the year	(602)	—
Exchange differences	(181)	231
Net book value	**24,201**	**11,210**

Non-current financial assets comprise of bank guarantees/deposits amounted to SEK 7,637 and SEK 6,851 as of December 31, 2023 and 2022, respectively. Other non-current receivables amounted to SEK 16,564 and SEK 4,359 as of December 31, 2023 and 2022, respectively. Additional acquisitions are significantly related to future increases in production capacity. In the cash flow, the acquisitions are reported within operating activities.

Note 18 Deferred Tax Assets and Deferred Tax Liabilities

Deferred tax assets and liabilities as of December 31, 2023	Deferred Tax Assets	Deferred Tax Liabilities	Net
Intangible assets	—	(59,487)	(59,487)
Tangible assets	—	(608)	(608)
Lease assets	—	(2,198)	(2,198)
Lease liabilities	2,465	—	2,465
Other liabilities	3,516	—	3,516
Personnel-related items	20,931	—	20,931
Tax loss carried forward	17,846	—	17,846
Other items	2,209	—	2,209
Total	**46,967**	**(62,293)**	**(15,326)**
Offsetting	(20,652)	20,652	—
Tax assets/liabilities, net	**26,315**	**(41,641)**	**(15,326)**

Tax losses carried forward of SEK 17,846 have been recognized as deferred tax assets in the statement of financial position as of December 31, 2023 due to future temporary differences that such asset can be used to offset.

For information regarding recognition of deferred tax losses, see Note 13 Income Tax Expense.

Change in deferred tax, 2023	Cost at Opening Balance	Recognized in Profit or Loss	Exchange Differences	Cost at Closing Balance
Intangible assets	(56,789)	765	(3,463)	(59,487)
Tangible assets	(766)	136	22	(608)
Lease assets	(3,060)	788	74	(2,198)
Lease liabilities	3,442	(894)	(83)	2,465
Other liabilities	3,218	444	(146)	3,516
Personnel-related items	10,653	11,289	(1,011)	20,931
Tax loss carried forward	17,037	(229)	1,038	17,846
Other items	311	2,017	(119)	2,209
Total	**(25,954)**	**14,316**	**(3,688)**	**(15,326)**

Deferred tax assets and liabilities as of December 31, 2022	Deferred Tax Assets	Deferred Tax Liabilities	Net
Intangible assets	—	(56,789)	(56,789)
Tangible assets	—	(766)	(766)
Lease assets	—	(3,060)	(3,060)
Lease liabilities	3,442	—	3,442
Other liabilities	3,218	—	3,218
Personnel related items	10,653	—	10,653
Tax loss carried forward	17,037	—	17,037
Other items	311	—	311
Total	**34,661**	**(60,615)**	**(25,954)**
Offsetting	(20,863)	20,863	—
Tax assets/liabilities, net	**13,798**	**(39,752)**	**(25,954)**

Tax losses carried forward of SEK 17,037 have been recognized as deferred tax assets in the statement of financial position as of December 31, 2022 due to future temporary differences that such asset can be used to offset.

For information regarding recognition of deferred tax losses, see Note 13 Income Tax Expense.

Change in deferred tax, 2022	Cost at Opening Balance	Recognized in Profit or Loss	Exchange Differences	Cost at Closing Balance
Intangible assets	(46,175)	—	(10,614)	(56,789)
Tangible assets	(238)	(477)	(51)	(766)
Lease assets	(2,672)	23	(411)	(3,060)
Lease liabilities	2,942	45	455	3,442
Other liabilities	—	3,122	96	3,218
Personnel-related items	4,140	5,699	814	10,653
Tax loss carried forward	15,319	—	1,718	17,037
Other items	23	276	12	311
Total	**(26,661)**	**8,688**	**(7,981)**	**(25,954)**

Note 19 Financial and Non-Financial Assets and Liabilities

Financial and non-financial assets and liabilities as of December 31, 2023

December 31, 2023	Financial Assets Measured at Fair Value through Profit or Loss	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Assets				
Non-current financial assets	—	24,201	—	24,201
Account receivables	—	180,892	—	180,892
Accrued income	—	7,297	—	7,297
Cash	—	973,733	—	973,733
	—	**1,186,123**	**—**	**1,186,123**

	Financial Liabilities Measured at Fair Value through Profit or Loss	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
Liabilities				
Contingent consideration	56,561	—	—	56,561
Non-current interest-bearing liabilities	—	939,508	—	939,508
Non-current lease liabilities	—	27,088	—	27,088
Other non-current liabilities	—	3,783	12,598	16,381
Accounts payable	—	100,564	—	100,564
Other current liabilities	—	12,537	7,249	19,786
Accrued expenses and deferred revenue	—	134,187	146,440	280,627
	56,561	**1,217,667**	**166,287**	**1,440,515**

Financial and non-financial assets and liabilities as of December 31, 2022

December 31, 2023	Financial Assets Measured at Fair Value through Profit or Loss	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Assets				
Non-current financial assets	—	11,210	—	11,210
Account receivables	—	78,703	—	78,703
Accrued income	—	2,287	—	2,287
Cash	—	1,249,094	—	1,249,094
	—	**1,341,295**	**—**	**1,341,295**

	Financial Liabilities Measured at Fair Value through Profit or Loss	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
Liabilities				
Contingent consideration	75,880	—	—	75,880
Non-current interesting-bearing liabilities	—	713,030	—	713,030
Non-current lease liabilities	—	15,792	—	15,792
Other non-current liabilities	—	1,363	2,987	4,350
Accounts payable	—	160,404	—	160,404
Other current liabilities	—	10,374	12,323	22,697
Accrued expenses and deferred revenue	—	75,754	60,692	136,446
	75,880	**976,717**	**76,002**	**1,128,598**

Financial liabilities valued through profit or loss constitutes of contingent consideration of SEK 56,561 and SEK 78,880 as of December 31, 2023 and 2022, respectively. The fair value of contingent consideration is measured at Level 3 of the fair value hierarchy. For additional information regarding the Group's contingent consideration, see Note 27 Contingent Consideration.

The carrying amount for other items above is an approximation of the fair value, which is why these items are not separated into levels according to the fair value hierarchy.

Note 20 Financial Risks

Significant accounting judgments, estimates and assumptions - expected credit losses
Management makes allowance for expected credit losses for accounts receivable that correspond to their maturity. The estimate is based on any increased credit risk, on an individual or collective basis, considering reasonable and supportable information, including that which is forward-looking. The allowance for expected credit risk is an estimate based on maturity structure accounts receivable and specific customer knowledge. Generally, invoices are due for payment within 30-45 days.

Through its operations, the Group is exposed to a variety of financial risks: credit risk, market risk (currency risk, interest rate risk and other price risk), refinancing risk, liquidity risk and external risk. The Group's overall risk management focuses on the unpredictability of the financial markets and it endeavors to minimize potentially unfavorable effects on the Group's financial results.

The Group's financial transactions and risks are managed centrally through the Group's CFO and CEO. The overall objective for financial risks is to provide cost-efficient financing and liquidity management and to ensure that all payment commitments are managed in a timely manner.

The Board prepares written policies for both the overall risk management and for specific areas, such as credit risks, currency risks, interest rate risks, refinancing risks, liquidity risks and the use of derivative instruments and investment of surplus liquidity.

Credit Risk
Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument, leading to a financial loss for the Group. The Group's exposure to credit risk, except for accounts receivable as described below, is limited to deposits with banks with high credit ratings, which means the Group is of the opinion that there is no material credit risk related to deposits with bank.

Credit risk accounts receivable
The payment terms amount to 30-45 days depending on the counterparty. Of accounts receivables net, SEK 113,115 is to an individual major customer as of December 31, 2023.

Expected Credit losses

	December 31,	
Accounts receivable	**2023**	**2022**
Gross accounts receivables	181,931	79,873
Provisions, expected credit losses	(1,039)	(1,170)
Net accounts receivables	**180,892**	**78,703**
Maturity structure accounts receivable		
Accounts receivables, not yet due	181,931	79,873
Provisions, expected credit losses	(1,039)	(1,170)
Net book value	**180,892**	**78,703**
Provisions for expected credit losses		
Opening balance, expected credit loss provisions	(1,170)	—
This year provisions	—	(1,170)
Reversed provisions	87	—
Exchange differences	44	—
Closing balance, expected credit loss provisions	**(1,039)**	**(1,170)**

The credit quality of receivables that are not past due or written down is deemed to be good. See Note 3 Revenue from Contracts with Customers for further information.

Market Risks
Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The type of market risk that impacts the Group is currency risk. The Group does not currently have any loans or holdings that expose the group to interest rate risk or other price risk.

Interest Rate Risk
Interest rate risk is the risk that would be adversely impacted by changes in interest rates resulting from increased interest costs. Calliditas exposure to interest rate risk mainly occurs through external loans and cash. Calliditas financing sources primarily consist of equity and borrowings. In the case of interest-bearing liabilities, the Group is exposed to interest rate risk. The Group does not currently have any variable interest rate and as of December 31, 2023 the carrying amount of Non-current interest-bearing liabilities are in all material respect an approximation of the present value.

Foreign Currency Risk
Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The primary exposure derives from the Group's purchases in foreign currencies. This exposure is known as transaction exposure. Currency risk is also found in the translation of the assets and liabilities of foreign operations to the Parent Company's functional currency, known as translation exposure.

Transaction Exposure
Transaction exposure from contracted payment flows in foreign currency is limited in the Group. Refer to the table below for exposure in each currency.

Currency exposure 2023 (%)	Revenue	Operating expenses
USD	72 %	16 %
EUR	28 %	58 %
GBP	—	6 %
SEK	—	20 %
Other currencies	—	0 %

Currency exposure 2022 (%)	Revenue	Operating expenses
USD	68 %	20 %
EUR	32 %	48 %
GBP	—	4 %
SEK	—	27 %
Other currencies	—	1 %

Currency exposure 2021 (%)	Revenue	Operating expenses
USD	14 %	43 %
EUR	86 %	36 %
GBP	—	3 %
SEK	—	18 %

As presented in the table above, the Group's primary transaction exposure is in Euro and U.S. dollar. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 29,332 (SEK 23,132, SEK 909). A 10% stronger U.S. dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately pos. SEK 49 (SEK 9,624, SEK 22,402).

Translation Exposure
The Group also has translation exposure that arises on the translation of earnings and net assets of foreign subsidiaries to the Swedish Kronor. Translation against U.S. dollar amounted to SEK 85,240 and SEK 48,771 as of December 31, 2023 and 2022, respectively. A 10% stronger Swedish Krona against the U.S. dollar would have a positive impact on equity of approximately SEK 8,524 and SEK 4,877 as of December 31, 2023 and 2022, respectively. Translation against Euros amounted to SEK 391,568 and SEK 446,646 as of December 31, 2023 and 2022, respectively. A 10% stronger Swedish Krona against Euros would have a positive impact on equity of approximately SEK 39,157 and SEK 44,665 as of December 31, 2023 and 2022, respectively. Translation against Swiss franc amounted to (SEK 794,449) and (SEK 537,550) as of December 31, 2023 and 2022, respectively. A 10% stronger Swedish Krona against Swiss franc would have a negative impact on equity of approximately SEK 79,445 and SEK 53,755 as of December 31, 2023 and 2022, respectively.

The Group also has a translation exposure arising from the translation of foreign accounts payable to the Swedish Kronor. This exposure amounted to SEK 24,606 and SEK 19,377 as of December 31, 2023 and 2022, respectively, and in U.S. dollars SEK 68,391 and SEK 80,655 in Euros as of December 31, 2023 and 2022, respectively. A 10% stronger U.S. dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 2,461 and SEK 1,938 as of December 31, 2023 and 2022, respectively. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 6,839 and SEK 8,065 as of December 31, 2023 and 2022, respectively.

Refinancing Risk
Refinancing risk refers to the risk that cash are not available and the risk that financing cannot be secured at a reasonable cost or at all. The Group is financed with equity, external loan financing and income from operations. The main risks relate to not receiving further contributions from shareholders, external loans or in the event of continued negative cash flow from operations.

Liquidity Risk
Liquidity risk is the risk that the Group encounters difficulties in meeting its obligations associated with financial liabilities. The Board manages liquidity risks by continuously monitoring cash flow so that it can reduce liquidity risk and ensure its solvency. Given that the Parent Company currently does not have its own earning ability, the Board carries out long-term work with owners and independent investors to ensure that liquidity is available to the Parent Company when a need arises.

The Group's contractual and undiscounted interest payments and repayments of financial liabilities are presented in the table below. Amounts in foreign currency were translated to SEK at the closing balance rate. Financial instruments with variable interest rates were measured at the rate on the closing balance. Liabilities were included in the earliest period when repayment is required. For future lease payments see Note 8 Leases.

	December 31, 2023		
Maturity analysis	**<6 months**	**6-12 months**	**2-5 years**
Contingent consideration	—	—	56,561
Non-current interest-bearing liabilities	—	—	939,508
Non-current lease liabilities	—	—	27,088
Other non-current liabilities	—	—	16,381
Accounts payable	100,564	—	—
Other current liabilities	11,649	8,138	—
Accrued expenses	255,200	25,427	—

	December 31, 2022		
Maturity analysis	**<6 months**	**6-12 months**	**2-5 years**
Contingent consideration	—	—	75,880
Non-current interest-bearing liabilities	—	—	713,030
Non-current lease liabilities	—	—	15,792
Other non-current liabilities	—	—	4,350
Accounts payable	160,404	—	—
Other current liabilities	13,288	9,409	—
Accrued expenses	121,865	14,581	—

	December 31,	
Non-current interest-bearing liabilities	**2023**	**2022**
Opening balance	713,030	189,164
New borrowings, net	962,889	491,745
Repayment of borrowings	(724,479)	—
Transaction costs paid	(26,625)	(1,260)
Interest expense	41,148	4,874
Exchange difference on translation	(26,455)	28,507
Closing balance	**939,508**	**713,030**

During 2023, Calliditas had signed and fully drawn a term loan of EUR 92 million with funds managed by Athyrium Capital Management, LP. The fair value of the loan at the end of the period amounts to SEK 966,1 million. The net book value of the loan at the end of the period, adjusted for transaction costs and accrued interest expense, is 939,5 million. The interest rate on the loan is 9 % per annum with a maturity to December 2027, which is recognized in Financial expenses. The credit agreement contains quarterly financial covenants specifying minimum cash liquidity and minimum product revenue. The credit agreement contains customary affirmative and negative covenants for a senior secured loan. Failure to maintain compliance with the covenants would result in an event of default under the Athyrium Credit Agreement, which could result in enforcement action, including acceleration of amounts due under the Athyrium Credit Agreement.

Note 21 Inventories

Inventory is recognized as the lower of the acquisition cost and the net realizable value. The acquisition cost for completed goods and goods being manufactured comprises raw materials and other direct costs and applicable indirect manufacturing costs. The net realizable value is the estimated sale price in operating activities after deduction of sales cost.

	December 31,	
	2023	2022
Raw materials	9,058	1,855
Work in progress	4,677	937
Finished goods	6,693	855
Total	**20,428**	**3,647**

Inventories recognized as cost of sales amounted to SEK 22,248, SEK 3,179 in 2023 and 2022, respectively. No inventories were recognized as cost of sales in 2021. Write-downs of inventories amounted to SEK 66 in 2023. No write-downs of inventories have occurred in 2022 and 2021, respectively.

Note 22 Prepaid Expenses

	December 31,	
	2023	2022
Accrued income	7,297	2,287
Prepaid insurance premiums	8,755	9,148
Prepaid interest costs	—	3,693
Prepaid expenses for research and development	43,085	45,454
Prepaid expenses for marketing and selling	16,722	8,194
Other prepaid administration expenses	8,465	1,964
Total	**84,324**	**70,741**

Note 23 Cash

	December 31,	
	2023	2022
Cash at Banks	973,733	1,249,094
Total	**973,733**	**1,249,094**

Cash and Banks balances are primarily in SEK, EUR and USD.

Adjustments for non-cash items in the consolidated statements of cash flows:

	Year Ended December 31,		
	2023	2022	2021
Depreciations and impairments	48,726	12,913	34,433
Change in Provisions	20,888	(3,346)	5,856
Share-based payments	52,591	35,791	21,960
Change of Contingent consideration	(18,835)	15,941	4,470
Other items	(892)	(39)	(43)
Total	**102,478**	**61,260**	**66,676**

Reconciliation of liabilities from financing activities

	January 1, 2023	Cash-Flow	Non-Cash-Items	December 31, 2023
Non-current interest-bearing liabilities	713,030	211,785	14,693	939,508
Lease liabilities	26,165	(12,134)	25,594	39,625
	739,195	**199,651**	**40,287**	**979,133**

	January 1, 2022	Cash-Flow	Non-Cash-Items	December 31, 2022
Non-current interest-bearing liabilities	189,164	490,485	33,381	713,030
Lease liabilities	33,642	(9,615)	2,138	26,165
	222,806	**480,870**	**35,519**	**739,195**

Note 24 Group Companies

Company	Principal Activities	Country of Incorporation	% Equity Interest 2023	2022	2021
Parent Company					
Calliditas Therapeutics AB	Research and development of pharmaceuticals	Sweden	—	—	—
Subsidiaries					
Nefecon AB	Administration of incentive programs issued by the Parent Company	Sweden	100 %	100 %	100 %
Calliditas NA Enterprises Inc	Market access activities in the United States	United States	100 %	100 %	100 %
Calliditas Therapeutics US Inc	Commercial activities in the United States	United States	100 %	100 %	100 %
Calliditas Therapeutics France SAS	Research and development of pharmaceuticals	France	100 %	100 %	100 %
Calliditas Therapeutics Suisse SA	Research and development of pharmaceuticals	Switzerland	100 %	100 %	100 %

Note 25 Equity

Treasury shares
When Callidita's shares classified as equity are repurchased the amount for the purchase price paid is recognized as a reduction in equity. Repurchased shares are classified as own shares and reported as one deduction item under equity. When own shares are subsequently sold or reissued the amount received is reported as an increase in equity and the surplus or deficit resulting from the transaction is transferred to or from other contributed capital.

	Year Ended December 31,		
	2023	2022	2021
Total registered shares at the beginning of the year	59,580,087	52,341,584	49,941,584
New share issue*	—	—	2,400,000
Exercise of warrants	—	1,322,985	—
Issuance of treasury shares	—	5,908,018	—
Shares subscribed but not registered during the year	—	7,500	—
Total registered and subscribed but not registered shares at the end of the year	**59,580,087**	**59,580,087**	**52,341,584**
Shares			
Ordinary shares	59,580,087	59,580,087	52,341,584
Total	**59,580,087**	**59,580,087**	**52,341,584**
- of which shares are held by Calliditas	*5,908,018*	*5,908,018*	—
Total registered and subscribed but not registered shares at the end of the year, net of shares held by Calliditas	**53,672,069**	**53,672,069**	**52,341,584**

	December 31,		
Share Capital	**2023**	**2022**	**2021**
Opening balance	2,383	2,094	1,998
New share issue*	—	—	96
Exercise of warrants	—	53	—
Issuance of treasury shares	—	236	—
Closing balance	**2,383**	**2,383**	**2,094**

** New share issue in August 2021*

*** As of December 31, 2022, there was an on-going issue of 7,500 shares under registration related to the exercise under the Warrant Program 2019/2022. These shares have been included in the weighted-average number of shares outstanding for the period.*

Share Capital
All shares have been fully paid and no shares are reserved for sale. All shares are common shares, confer the same entitlement to capital, and carry one vote. The quotient value is SEK 0.04 per share.

Transactions in Treasury Shares
As of December 31, 2023, Calliditas had 5,908,018 ordinary shares held as treasury shares by the Parent Company. At the Annual General Meeting 2023, authorization was given that Calliditas can transfer (sale) these ordinary shares with the purpose to finance an acquisition of operations, to procure capital to finance the development of projects, repayment of loans or to commercialize Calliditas' products. No transfer (sale) of treasury shares have occurred as of December 31, 2023. The total number of issued shares as of December 31, 2023, is presented in the tables above.

Translation Reserve
The reserves pertain in their entirety to translation reserves. The translation reserve includes all exchange rate differences arising on the translation of the financial statements from foreign operations.

	December 31,		
Translation Reserve	**2023**	**2022**	**2021**
Opening balance	9,307	(26,979)	(6,090)
Change of the year	(14,538)	36,286	(20,889)
Closing balance	**(5,231)**	**9,307**	**(26,979)**

Note 26 Provisions

Material accounting policy-provisions
A provision differs from other liabilities as there is uncertainty in the time of payment or the size of the amount to settle the provision. A provision is reported in the group's statement of financial position when there is an existing legal or informal obligation as a result of an event that has occurred, and it is likely that an outflow of financial resources will be required to settle the obligation and a reliable estimate of the amount may be done. Provisions are made with the amount that is the best estimate of what is required to settle the existing obligation at the balance sheet date. Where the effect of when in time payment takes place is significant, provisions are calculated by discounting the expected future cash flow.

Provisions as of December 31, 2023	**Social Security Costs on Share-Based Payment**	**Other provisions**	**Provisions, net**
Opening balance	11,792	—	11,792
Provisions for the year	21,109	—	21,109
Exchange differences	(306)	—	(306)
Total	**32,595**	**—**	**32,595**

Provisions as of December 31, 2022	**Social Security Costs on Share-Based Payment**	**Other provisions**	**Provisions, net**
Opening balance	13,084	1,446	14,530
Provisions for the year	1,027	—	1,027
Amounts claimed for the year	(204)	—	(204)
Reversal of unused amounts	(2,666)	(1,573)	(4,239)
Exchange differences	551	127	678
Total	**11,792**	**—**	**11,792**

Social Security Costs on Share-Based Payment
There is uncertainty as to when social security costs for share-based payments will be paid in the future, and what amount they will ultimately be adjusted to as it is dependent on market values at the time when performance shares are used.

Note 27 Contingent Consideration

Material accounting policy - contingent consideration
The Group's contingent consideration is classified as financial liabilities that are recognized at fair value through profit or loss. Measurement is both initially and in subsequent periods made at fair value in the Group's consolidated statements of financial position, where changes in fair value are recognized in the Group's consolidated statements of income. The components of the change in fair value relating to exchange rate effects are recognized in net financial items and other changes in fair value are recognized in operating profit or loss.

	December 31,	
	2023	2022
Opening balance	75,880	54,399
Change for the year	(18,835)	15,942
Exchange differences	(484)	5,539
Net book value	**56,561**	**75,880**

Contingent Consideration
In connection with the business combination of Genkyotex SA, the Group has undertaken to make potential future milestone payments relating to contingent consideration, provided that future regulatory approvals or marketing authorizations regarding setanaxib are obtained. The transaction stipulates the following contingent consideration:

Milestone 1: EUR 30.0 million if Genkyotex is granted the right to commercially manufacture, market and sell setanaxib in the United States by the FDA.

Milestone 2: EUR 15.0 million if Genkyotex is granted the right to commercially manufacture, market and sell setanaxib in the European Union by the European Commission.

Milestone 3: EUR 10.0 million if Genkyotex is, by the FDA or European Commission, granted the right to commercially manufacture, market and sell setanaxib in the United States or European Union for the treatment of IPF or Type 1 Diabetes.

The fair value of contingent consideration is measured at Level 3 of the fair value hierarchy. Contingent consideration is recognized as a financial liability in the consolidated statements of financial position, which is revalued at fair value each reporting period. Any revaluation gains and losses are recognized in the consolidated statements of income. The contingent consideration has been computed in accordance with the present value method and the probability has been taken into account if and when the various milestones will occur. The calculations are based on a discount rate of 12.2 percent. The most significant input affecting the valuation of the contingent consideration is the company's estimate of the probability of the milestones being reached and the change of the year was primarily derived from the assumptions regarding the probability of success in the clinical trials.

The Group has assessed the weighted average probability of outcome at 19.7% and 20.8% as of December 31, 2023 and 2022, respectively. A 10% higher probability of success in the clinical trials would have a negative impact on profit after tax of approximately SEK 5,656 and SEK 7,588 as of December 31, 2023 and 2022, respectively. A higher probability of success in the clinical trials will increase the fair value of the liability and a lower probability will decrease the fair value. There are no interrelationships between unobservable inputs used in the fair value measurement.

Note 28 Pension Liabilities

Assumption in valuations of the pension obligations

The valuation of pension obligations and pension costs is based on actuarial assumptions.

Defined-Benefit Pension Plan

The defined-benefit pension obligations are based on actuarial principles. Calliditas has defined-benefit pension plans for the subsidiaries in France and Switzerland for retirement, death and disability. The present value of the obligation includes special payroll tax, in accordance with IAS 19, for the Swiss pension plans. Pension expenses are recognized under research and development expenses and administrative expenses in the consolidated statements of income.

	December 31,	
Net obligation per country	2023	2022
Switzerland	(3,394)	(789)
France	(127)	(94)
Total	**(3,521)**	**(884)**

Changes in the defined-benefit pension obligations

	Defined Benefit Plan Obligation (Switzerland)	Defined Benefit Plan Obligation (France)	Fair Value of Plan Assets (Switzerland)	Employee Benefit Obligations
January 1, 2023	**(6,027)**	**(94)**	**5,238**	**(884)**
Service costs	(1,599)	(18)	—	(1,617)
Interest expense	(117)	(4)	119	(1)
Employee contribution	—	—	920	920
Subtotal included in the operating loss in the consolidated statements of income	**(1,716)**	**(21)**	**1,039**	**(698)**
Amounts paid/received	2,441	—	(2,441)	—
Return on assets (excluding interest expenses)	—	—	(67)	(67)
Actuarial gains/(losses) related to changes in demographic assumptions	—	(13)	—	(13)
Actuarial gains/(losses) related to changes in financial assumptions	(2,316)	—	—	(2,316)
Other actuarial gains/(losses)	52	—	—	52
Plan amendment	(433)	—	—	(433)
Subtotal included in other comprehensive income	**(2,697)**	**(13)**	**(67)**	**(2,777)**
Employer contributions	—	—	920	920
Currency translation effect	(397)	2	313	(82)
December 31, 2023	**(8,395)**	**(127)**	**5,001**	**(3,521)**

	Defined Benefit Plan Obligation (Switzerland)	Defined Benefit Plan Obligation (France)	Fair Value of Plan Assets (Switzerland)	Employee Benefit Obligations
January 1, 2022	**(7,942)**	**(111)**	**4,871**	**(3,182)**
Service costs	(1,530)	(26)	—	(1,556)
Interest expense	(27)	(1)	18	(10)
Employee contribution	—	—	887	887
Subtotal included in the operating loss in the consolidated statements of income	**(1,558)**	**(27)**	**906**	**(679)**
Amounts paid/received	2,140	—	(2,140)	—
Return on assets (excluding interest expenses)	—	—	34	34
Actuarial gains/(losses) related to changes in demographic assumptions	—	54	—	54
Actuarial gains/(losses) related to changes in financial assumptions	2,846	—	—	2,846
Other actuarial gains/(losses)	(454)	—	—	(454)
Subtotal included in other comprehensive income	**2,392**	**54**	**34**	**2,480**
Employer contributions	—	—	887	887
Currency translation effect	(1,059)	(9)	679	(390)
December 31, 2022	**(6,027)**	**(94)**	**5,238**	**(884)**

	December 31,	
Distribution by Plan Assets (Switzerland)	**2023**	**2022**
Cash	430	137
Bonds	515	3,048
Mortgage loans	75	655
Shares	1,450	126
Real estate	1,581	901
Other investments	950	372
Total	**5,001**	**5,238**

Of the plan assets above, SEK 515 and SEK 3,048 as of December 31, 2023 and 2022, respectively, has a quoted price in an active market.

For pension obligations in France, there are no plan assets.

Risks connected to defined-benefit pension plans
Through its defined-benefit pension plans for post-employment benefits, the Group is exposed to a number of risks. The most significant risks are:

Life expectancy assumption: Most of the pension commitments entail that the employees covered by the plan will receive life-long benefits and, accordingly, the longer life expectancy assumptions will result in higher pension liabilities. This is particularly significant in the Swiss plan, in which inflation increases result in higher sensitivity to changes in life expectancy assumptions.

Inflation risk: Some of the plan's pension commitments are linked to inflation. Higher inflation leads to higher liabilities (although, in most cases, a ceiling has been set for the level of inflation to protect the plan against exceptional increases in inflation). Most of the plan assets are either unaffected by (fixedrate bonds), or weakly correlated with (shares) inflation, which means that an increase in inflation will also increase the deficit.

Discount rate: A decrease in the interest rate on corporate bonds will increase the liabilities of the plan, although this will partially be offset by an increase in the value of the bond holdings. The Swiss pension plan is covered by The Swiss Federal Act on Occupational Retirement, Survivor's and Disability Pension Plans (BVG).

The French pension plan is covered by the labor law and the collective bargaining agreement of the pharmaceutical industry. The Swiss and French plans are based on final salary.

	December 31,	
Actuarial Assumptions on the Closing Balance	**2023**	**2022**
Swiss pension plan		
Discount rate	1.45	2.30 %
Mortality table	LPP 2020 generation	LPP 2020 generation
Salary revaluation rate	2.00 %	1.00 %
Retirement pension inflation rate	1.00 %	0.50 %
Deposit rate on savings accounts	1.50 %	1.00 %
Turnover rate	10.00 %	10.00 %
Remaining life expectancy after retirement	23.1 years	18.6 years
Retirement age	65 years	65 years

	December 31,	
Sensitivity Analysis	**2023**	**2022**
Pension commitments under current assumptions for Swiss pension plans	8,395	6,027
Discount rate, -0.5%	9,426	6,615
Discount rate, +0.5%	7,511	5,518
Retirement pension inflation rate, -0.5%	7,940	5,797
Retirement pension inflation rate, +0.5%	8,902	6,281
Salary revaluation rate, -0.5%	8,231	5,927
Salary revaluation rate, +0.5%	8,567	6,131

The amounts above show what the value of the pension obligation would have been assuming the change in the individual assumption. The sensitivity analyses are based on a change in one assumption, with all other assumptions remaining constant. In practice, this is highly unlikely to occur and some of the changes in the assumptions may be correlated. When calculating the sensitivity of the defined-benefit obligations to significant actuarial assumptions, the same method (present value of the defined-benefit obligation applying the projected unit credit method at the end of the reporting period) has been applied as when calculating the pension liability recognized in the consolidated statements of financial position.

As the defined benefit pension plans in France are deemed to be insignificant for the Group, no further information has been provided.

Contributions to plans for post-employment benefits are expected to be SEK 941 and SEK 813 in 2023 and 2022, respectively. The weighted average maturity of the obligation is an estimated 23.1 and 18.6 years in 2023 and 2022, respectively.

Note 29 Other Non-Current Liabilities

	December 31,	
	2023	**2022**
Opening balance	4,350	—
Additional liabilities	12,031	4,350
Net book value	**16,381**	**4,350**

Note 30 Accrued Expenses and Deferred Revenue

	December 31,	
	2023	2022
Vacation pay liabilities	11,257	8,310
Accrued salaries and Board fees	52,502	28,186
Social security costs	8,935	7,065
Accrued rebates on sales	36,326	15,849
Accrued expenses for royalty	37,419	12,023
Accrued expenses for research and development	107,302	34,637
Accrued expenses for marketing and selling	10,773	21,543
Accrued expenses for administration	16,113	8,833
Total	**280,627**	**136,446**

Note 31 Related-Party Transactions

For information regarding remuneration of executive management, refer to Note 9 Employees and Personnel Costs and Note 10 Share-Based Payments.

There are no additional agreements or transactions with related parties, other than those described in Notes 9 Employees and Personnel Costs and 10 Share-Based Payments.

Note 32 Pledged Assets, Contingent Liabilities and Other Obligations

The Group is required to pay Kyowa Kirin Services Ltd., f/k/a Archimedes Development Ltd (“Archimedes”) a fixed royalty of 3% of net sales of Nefecon/Tarpeyo covered by the license in according to the Group’s agreement with Archimedes pursuant to which Calliditas were granted (i) an exclusive license to joint intellectual property developed with Archimedes and (ii) a non-exclusive license to certain of Archimedes’ know-how as necessary or useful to develop and commercialize Nefecon or other product candidates.

The Group has exclusive rights to use, develop and market the formulation under the license agreement with Archimedes, and Archimedes only has rights to royalties when the product is sold. The Group will then have an obligation to pay a low single digit percentage of royalties based on net sales until the exclusive license for the patent covering the formulation of Nefecon expires in 2029.

Pledged assets in the group amounted to SEK 943,364 and SEK 6,859 as of December 31, 2023 and 2022, respectively. The year's pledges refer to restricted bank accounts and lease deposits SEK 7,637 and SEK 6,859 as December 31 and 2022, respectively. Other pledge assets for the benefit of lenders, refers to participations in Group companies and financial assets SEK 935,727 as December 31. Financial covenants for interest-bearing liabilities, see note 20.

Note 33 Events After the Reporting Period

In February 2024, Calliditas Therapeutics AB announced that the United States Patent and Trademark Office (USPTO) issued patent no. 11896719, entitled “New Pharmaceutical Compositions, on January 24, 2024 with validity as of today, February 13, 2024. This is Calliditas’ second patent for TARPEYO in the United States, and provides product protection until 2043.

The patent covers a method of treating IgA nephropathy with a composition that encompasses TARPEYO® (budesonide) delayed release capsules, developed under the name “NEFECON®”. Filing for listing in the Orange Book has thus been made. Calliditas intends to file corresponding patent applications in additional territories around the world, including Europe and China. Book has thus been made. Calliditas intends to file corresponding patent applications in additional territories around the world, including Europe and China.

In March 2024, Calliditas Therapeutics AB announced that the FDA has granted an orphan drug exclusivity period of seven years for TARPEYO®, expiring in December 2030 based on when the company obtained full approval with a new indication for this drug product. Following full approval in December 2023, TARPEYO® (budesonide) indicated “to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression”. The exclusivity period reflects the new indication covering all adult patients with primary IgAN at risk of disease progression based on a confirmed reduction of kidney loss reflecting a clinical benefit on kidney function for adult patients with primary IgAN.

N.B. The English text is an in-house translation of the original Swedish text. Should there be any disparities between the Swedish and the English text, the Swedish text shall prevail.

ARTICLES OF ASSOCIATION OF CALLIDITAS THERAPEUTICS AB

Reg. no. 556659-9766

Adopted at the annual general meeting held on 30 May 2023.

1 § Business name

The business name of the company is Calliditas Therapeutics AB. The company is a public company (publ).

2 § Registered office of the company

The registered office of the company is situated in Stockholm, Sweden.

3 § Objects of the company

The company shall, directly or through subsidiaries, conduct research and development as well as the manufacture and sale of pharmaceuticals and medical devices, own and manage shares and other securities as well as other movable and immovable property, as well as business associated therewith.

4 § Share capital and number of shares

The share capital shall be not less than SEK 1,000,000 and not more than SEK 4,000,000. The number of shares shall be not less than 25,000,000 and not more than 100,000,000.

The shares shall be issued in two classes, ordinary shares and C-shares. Ordinary shares shall entitle the holder to one (1) vote per share, whereas C-shares shall entitle the holder to one tenth (1/10) vote per share. Shares of each class may be issued in a quantity corresponding to the entire share capital of the company.

Holders of C-shares are not entitled to dividends. Upon the company's liquidation, C-shares carry equivalent right to the company's assets as other shares, however not to an amount exceeding the quota value of the share.

Where the company resolves to issue new shares by way of a cash issue or a set-off issue, one old share shall entitle the holder to pre-emption rights to one new share of the same class pro rata to the number of shares previously owned by the holder (primary pre-emption rights). Shares that are not subscribed for pursuant to primary pre-emption rights shall be offered to all shareholders for subscription (subsidiary pre-emption rights). Unless shares offered in such manner are sufficient for the subscription which takes place

pursuant to subsidiary pre-emption rights, the shares shall be allotted among the subscribers pro rata to the total number of shares previously owned. Where this is not possible with respect to a particular share(s), shares shall be allotted through drawing of lots.

The provisions above shall not entail any restrictions on the possibility for the company to adopt a resolution regarding a cash issue or set-off issue without regard to shareholders' pre-emption rights.

The provisions above regarding shareholders' pre-emption rights shall apply mutatis mutandis to an issue of warrants or an issue of convertible instruments.

Where the company resolves to issue only one class of shares by way of a cash issue or set-off issue, all of the shareholders, irrespective of the class of share, shall hold pre-emption rights to subscribe for new shares pro rata to the number of shares previously owned.

In the event of a bonus issue, new shares of each class shall be issued pro rata to the number of shares of the same class previously issued. In connection therewith, the owners of existing shares of a certain class shall entitle the holder to new shares of the same class. This shall not entail any restrictions on the possibility of issuing new shares of a new class by means of a bonus issue, following the required amendment to the articles of association.

Reduction of share capital, which in any case shall not fall below the minimum share capital, may, upon the request of an owner of C-shares and a resolution by the company's Board of Directors or the general meeting, take place through redemption of C-shares. A request from a shareholder shall be made in writing. When a resolution on reduction has been passed, an amount corresponding to the reduction amount shall be transferred to the company's reserve fund, if required funds are available. The redemption amount per C- share shall correspond to the quota value of such share.

Following notice of the redemption resolution, holders of shares shall promptly receive payment for the shares, or, if authorization from the Swedish Companies Registration Office (Sw. Bolagsverket) or a court is required, following notice that the final decision has been registered.

5 § **Conversion clause**

C-shares held by the company may, upon decision of the board of directors be reclassified into ordinary shares. Immediately thereafter, the board of directors shall register the

reclassification to the Swedish Companies Registration Office. The reclassification is effected when it has been registered and the reclassification been reflected in the central securities depository register.

6 § Board of Directors

The Board of Directors elected by the shareholders' meeting shall comprise not less than three (3) and not more than ten (10) members.

7 § Auditors

The company shall have one or two (1–2) auditors and not more than two (2) alternate auditors or a registered accounting firm.

8 § Notice to attend shareholders' meetings

Notice of shareholders' meetings shall be published in the Swedish Official Gazette and on the company's website, within such time as set forth in the Swedish Companies Act (2005:551). It shall be announced in Svenska Dagbladet that a notice has been issued.

9 § Participation at shareholders' meetings

Shareholders who wish to participate at a shareholders' meeting shall be registered as shareholders on a transcript of the entire share register as stipulated in Chapter 7, Section 28, third paragraph of the Swedish Companies Act (2005:551) and shall also provide notification of their intention to attend the meeting no later than on the date stipulated in the notice convening the shareholders' meeting. The latter mentioned day must not be a Sunday, any other public holiday, Saturday, Midsummer's Eve, Christmas Eve or New Year's Eve and must not be more than the fifth weekday prior to the meeting. If a shareholder wishes to be joined by proxy (not more than two proxies) at the shareholders' meeting, the number of proxies must be stated in the notice of participation.

10 § Collection of power of attorneys and postal voting

The Board of Directors may collect powers of attorney in accordance with the procedure described in Chapter 7, Section 4, second paragraph of the Swedish Companies Act (2005:551).

The Board of Directors has the right before a shareholders' meeting to decide that shareholders shall be able to exercise their right to vote by post before the shareholders' meeting.

11 § The right for persons not being shareholders to attend a shareholders' meeting

The Board of Directors may resolve that persons not being shareholders of the company shall be entitled, on the conditions stipulated by the Board of Directors, to attend or in any other manner follow the discussions at a shareholders' meeting.

12 § Matters at annual shareholders' meetings

The annual shareholders' meeting is held each year within six months of the end of the financial year.

The following matters shall be addressed at annual shareholders' meetings:

1. Election of a chairman of the meeting;
2. Preparation and approval of the voting register;
3. Approval of the agenda;
4. Election of one or two persons to attest the minutes;
5. Determination of whether the meeting was duly convened;
6. Presentation of the annual report and auditor's report and, where applicable, the consolidated financial statements and auditor's report for the group;
7. Resolutions regarding
   (a) adoption of the income statement and balance sheet and, where applicable, the consolidated income statement and consolidated balance sheet;
   (b) allocation of the company's profit or loss according to the adopted balance sheet;
   (c) discharge from liability for board members and the managing director;
8. Determination of fees for the Board of Directors and the auditors;
9. Election of the Board of Directors and accounting firm or auditors;
10. Any other business incumbent on the meeting according to the Companies Act or the articles of association.

13 § Financial year

The company's financial year shall be the calendar year.

14 § Euroclear company

The company's shares shall be registered in a securities register in accordance with the Swedish Securities Register and Financial Instruments Accounts Act (1998:1479).

15 § US forum

Without any infringement on Swedish forum provisions and without applying Chapter 7, Section 54 of the Swedish Companies Act (2005:551), the United States District Court for

the Southern District of New York shall be the sole and exclusive forum for resolving any complaint filed in the United States asserting a cause of action arising under the U.S. Securities Act of 1933, as amended, unless the Company consents in writing to the selection of an alternative forum.

DESCRIPTION OF SECURITIES

The following description of the capital stock of Calliditas Therapeutics AB ("us," "our," "we" or the "Company") is a summary of the rights of our ordinary shares and C-shares and certain provisions of our articles of association in effect as of May 30, 2023. This summary does not purport to be complete and is qualified in its entirety by the provisions of our articles of association previously filed with the Securities and Exchange Commission and incorporated by reference as an exhibit to the Annual Report on Form 20-F of which this Exhibit 2.4 is a part, as well as to the applicable provisions of Swedish legislation on stock corporations. We encourage you to read our articles of association and applicable Swedish legislation on stock corporations carefully.

Common Shares and C-shares

All of our outstanding common shares and C-shares have been validly issued, fully paid and non-assessable, and do not have any preemptive rights other than under the Swedish Companies Act as described below. The common shares are not redeemable, whereas the C-shares may be reclassified into ordinary shares upon decision of the board of directors. In accordance with our articles of association, the shares shall be issued in two classes, ordinary shares and C-shares, denominated in SEK. As of December 31, 2023, we had 59,580,087 common shares and no C-shares outstanding.

The development in the number of shares since our foundation in 2004 is shown below.

Year	Transaction	Nominal Value	Subscription Price per Share (SEK)	Increase in Number of Shares	Increase in Share Capital (SEK)	Total Number of Shares	Total Share Capital (SEK)
2004	Foundation	100	—	1,000	100,000	1,000	100,000
2004	New share issue	100	25,000	12	1,200	1,012	101,200
2005	New share issue	100	50,562	178	17,800	1,190	119,000
2009	New share issue	100	60,000	132	13,200	1,322	132,000
2012	New share issue	100	52,950	664	66,400	1,986	198,600
2013	New share issue	100	52,950	813	81,300	2,799	279,900
2014	New share issue	100	52,950	189	18,900	2,988	298,800
2014	New share issue	100	52,950	809	80,900	3,797	379,700
2015	New share issue	100	52,950	756	75,600	4,553	455,300
2016	New share issue	100	52,950	752	75,200	5,305	530,500
2017	New share issue	100	52,950	605	60,500	5,910	591,000
2017	Share split (1:10)	10	—	53,190	—	59,100	591,000
2017	New share issue	10	5,295	7,026	70,260	66,126	661,260

2017	New share issue	10	5,295	566	5,660	66,692	666,920
2017	Share split (1:250)	0.04		16,606,308	-	16,673,000	666,920
2018	Conversion of bridge loans in connection with offering	0.04	45.00	2,114,903	84,596.12	18,787,903	751,516.12
2018	New share issue in connection with listing	0.04	45.00	16,414,444	656,577.76	35,202,347	1,408,093.88
2019	New share issue	0.04	60.00	3,505,291	140,211.64	38,707,638	1,548,305.52
2020	New share issue in connection with listing	0.04	89.70	9,937,446	397,497.80	48,645,084	1,945,803.40
2020	Exercise of warrant program	0.04	42.36	1,296,500	52,860.00	49,941,584	1,997,663.40
2021	New share issue	0.04	135.00	2,400,000	96,000.00	52,341,584	2,093,663.36
2022	Exercise of warrant program	0.04	74.30	830,586	33,223.44	53,172,170	2,126,886.80
2022	Exercise of warrant program	0.04	74.30	26,000	1,040	53,198,170	2,127,926.80
2022	Issuance and conversion of C-shares to common shares	0.04	0.04	5,908,018	236,320.72	59,106,188	2,364,247.52
2022	Exercise of warrant program	0.04	74.30	51,399	2,055.96	59,157,587	2,366,303.48
2022	Exercise of warrant program	0.04	74.50	415,000	16,600	59,572,587	2,382,903.48
2023	Exercise of warrant program	0.04	74.50	7,500	300	59,580,087	2,383,203.48

There were no special terms or installment payments for any of the transactions listed above. There have been seven changes in voting rights since we were listed on Nasdaq Stockholm in 2018 through (i) a directed share issue in July 2019, entailing an increase of the number of shares and votes with 3,505,291 and share capital with SEK 140,211.64, (ii) the initial public offering on the Nasdaq Global Select Market in June 2020, entailing an increase of the number of shares with 9,937,446 and share capital with SEK 397,497.80, (iii) exercise of warrants in 2020, entailing an increase of the number of shares and votes with 1,296,500 and share capital with SEK 52,860.00, (iv) a directed share issue in August 2021, entailing an increase of the number of shares and votes with 2,400,000 and share capital with SEK 96,000.00, (v) exercise of warrants in 2022, entailing an increase of the number of shares and votes with 1,322,985 and share capital with SEK 52,919.40, (vi) a directed share issue of C-shares followed by a repurchase by us and a subsequent conversion to common shares in 2022, entailing an increase of the number of shares and votes with 5,908,018 and share capital with SEK 236,320.72 and (vii) exercise of warrants in January 2023, entailing an increase of the number of shares and votes with 7,500 and share capital with SEK 300. During the period as a listed company, there has not been any reduction of amount of share capital.

At the 2023 annual general meeting held on May 30, 2023, our shareholders resolved that for the period until the 2024 annual general meeting, our board of directors would be authorized to, at one or several occasions, to issue new shares, warrants and/or convertibles. Such share issue resolution may be carried out with or without deviation from the shareholders' preferential rights and with or without provisions for contribution in kind, set-off or other conditions. The authorization may only be utilized to such extent that the number of shares issued by virtue of the authorization, or the number of shares created in connection with exercise of warrants or conversion of convertibles, together with any ordinary shares transferred by virtue of the separate authorization to transfer ordinary shares adopted at the annual general meeting, in aggregate does not exceed 20% of the total number of ordinary shares issued at the time of the general meeting's resolution on the proposed authorization, calculated after full exercise of the hereby proposed authorization. On the date of the 2023 annual general meeting, we had 53,672,069 shares outstanding. Ahead of the 2024 annual general meeting, a similar proposal for authorization to the board of directors has been proposed.

The purpose of the authorization is to increase the financial flexibility of the company and the general flexibility of the Board of Directors. Should the Board of Directors resolve on an issue with deviation from the shareholders' preferential rights, the reason for this shall be to finance an acquisition of operations, to procure capital to finance the development of projects, repayments of loans or to commercialize the company' s products. Upon such deviation from the shareholders' preferential rights, the new issue shall be made at market terms and conditions.

Below are summaries of the material provisions of our articles of association and of related material provisions of the Swedish Companies Act.

Share Capital

Articles of Association

Object of the Company

Our object is set forth in Section 3 of our articles of association and is to, directly or through subsidiaries, conduct research and development as well as the manufacture and sale of pharmaceuticals and medical devices, own and manage shares and other securities as well as other tangible and intangible property, as well as any other business associated therewith.

Powers of the Directors

Our board of directors shall direct our policy and shall supervise the performance of our chief executive officer and his or her actions. Our board of directors may exercise all powers that are not required under the Swedish Companies Act or under our articles of association to be exercised or taken by our shareholders.

Number of Directors

Our articles of association provide that our board of directors shall consist of three to ten members. Our board of directors currently has five members, with no deputy members.

Rights Attached to Shares

The shares shall be issued in two classes, ordinary shares and C-shares. All of the common shares have equal rights to our assets and earnings, and are entitled to one vote at the general meeting. Holders of C-shares are entitled to one tenth vote per share. At the general meeting, every shareholder may vote to the full extent of their shares held or represented, without limitation. Each share entitles the shareholder to the same preferential rights related to issues of shares, warrants and convertible bonds relative to the number of shares they own. The common shares have equal rights to dividends and any surplus capital upon liquidation, whereas the C-shares do not entitle to dividends. Upon liquidation, C-shares carry equivalent right to our assets as other shares, however not to an amount exceeding the quota value of the share. Shareholders' rights can only be changed in accordance with the procedures set out in the

Swedish Companies Act. Transfers of shares are not subject to any restrictions. There are no limitations on the rights to own securities.

Exclusive Forum

Our articles of association provide that, unless we consent in writing to the selection of an alternative forum and without any infringement on Swedish forum provisions and without applying Chapter 7, Section 54 of the Swedish Companies Act, the United States District Court for the Southern District of New York shall be the sole and exclusive forum for resolving any complaint filed in the United States asserting a cause of action arising under the Securities Act, or the Federal Forum Provision. We recognize that the proposed Federal Forum Provision may impose additional litigation costs on shareholders in pursuing any such claims, particularly if the shareholders do not reside in or near the State of New York. Additionally, proposed Federal Forum Provision may limit our shareholders' ability to bring a claim in a U.S. judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our shareholders.

Preemptive Rights

Under the Swedish Companies Act, shareholders of any class of shares will generally have a preemptive right to subscribe for shares, warrants or convertible debentures issued of any class in proportion to their shareholdings. If an offering is not fully subscribed for based on subscription rights, shares, warrants or convertible debentures may be allocated to subscribers without subscription rights. The preemptive right to subscribe does not apply in respect of shares issued for consideration by payment in kind or of shares issued pursuant to convertible debentures or warrants previously issued by the company.

The preemptive right may be set aside. An issue with deviation from the shareholders' preemptive rights may be resolved either by the shareholders at a general meeting, or by the board of directors if the board resolution is preceded by an authorization therefor from the general meeting. A resolution to issue shares, warrants or convertible debentures with deviation from the shareholders' preemptive rights and a resolution to authorize the board of directors to do the same must be passed by two-thirds or, in some cases, nine-tenths, of both the votes cast and the shares represented at a general meeting.

Voting at Shareholder Meetings

Under the Swedish Companies Act, shareholders entered into the shareholders' register as of the record date are entitled to vote at a general meeting (in person or by appointing a proxyholder). In accordance with our articles of association, shareholders must give notice of their intention to attend the general meeting no later than the date specified in the notice. Shareholders who have their shares registered through a nominee and wish to exercise their voting rights at a general meeting must request to be temporary registered as a shareholder and entered into the shareholders' register four business days prior to the date of the general meeting. The rights described herein do not apply to holders of ADSs. See "Description of American Depositary Shares."

Shareholder Meetings

The general meeting of shareholders is our highest decision-making body and serves as an opportunity for our shareholders to make decisions regarding our affairs. Shareholders who are registered in the share register held by Euroclear Sweden AB six business days before the meeting and have notified us no later than the date specified in the notice described below have the right to participate at our general meetings, either in person or by a representative. All shareholders have the same participation and voting rights at general meetings. At the annual general meeting, *inter alia*, members of the board of directors are elected, the principles for the appointment of the nomination committee are established, and a vote is held on whether each individual board member and the chief executive officer will be discharged from any potential liabilities for the previous fiscal year. Auditors are elected as well. Decisions are made concerning adoption of annual reports, allocation of earnings, fees for the board of directors and the auditors, guidelines for executive remuneration, the remuneration report and other essential matters that require a decision by the meeting. Most decisions require a simple majority but the Swedish Companies Act

dictates other thresholds in certain instances. See "-Differences in Corporate Law-Shareholder Vote on Certain Transactions."

Shareholders have the right to ask questions to our board of directors and managers at general meetings which pertain to the business of the company and also have an issue brought forward at the general meeting. In order for us to include the issue in the notice of the annual general meeting, a request of issue discussion must be received by us normally seven weeks before the meeting. Any request for the discussion of an issue at the annual general meeting shall be made to the board of directors and any request within the nomination committee's competence shall be made to the nomination committee. The board shall convene an extraordinary general meeting if shareholders who together represent at least 10% of all shares in the company so demand in writing to discuss or resolve on a specific issue.

The arrangements for the calling of general meetings are described below in "—Differences in Corporate Law—Annual General Meeting" and "—Differences in Corporate Law—Special Meeting."

Notices

The Swedish Companies Act requirements for notice are described below in "—Differences in Corporate Law-Notices."

Subject to our articles of association and Nasdaq Nordic Main Market Rulebook for Issuers of Shares, we must publish the full notice of a general meeting by way of press release, on our website and in the Swedish Official Gazette, and must also publish in the Svenska Dagbladet, a daily Swedish newspaper, that such notice has been published. The notice of the annual general meeting will be published six to four weeks before the meeting. The notice must include an agenda listing each item that shall be voted upon at the meeting. The notice of any extraordinary general meetings will be published six to three weeks before the meeting. Pursuant to the Swedish Code of Corporate Governance, which does not carry the force of law but is considered ideal corporate governance practice for Swedish companies whose shares trade on a regulated market, we shall, as soon as the time and venue for the annual general meeting have been decided, and no later than in conjunction with the third quarter report, publish such information on our website.

Record Date

Under the Swedish Companies Act, in order for a shareholder to participate in a shareholders' meeting, the shareholder must have its shares registered in its own name in the share register four business days. In accordance with section 9 of our articles of association, shareholders must give notice of their intention to attend the shareholders' meeting no later than the date specified in the notice.

Amendments to the Articles of Associations

Under the Swedish Companies Act, an amendment of our articles of association requires a resolution passed at a shareholders' meeting. The number of votes required for a valid resolution depends on the type of amendment, however, any amendment must be approved by not less than two-thirds or, in some cases, nine-tenths, of both the votes cast and the shares represented at the meeting. The board of directors is not allowed to make amendments to the articles of association absent shareholder approval.

Provisions Restricting Change in Control of Our Company

Neither our articles of association nor the Swedish Companies Act contains any restrictions on change of control.

Differences in Corporate Law

The applicable provisions of the Swedish Companies Act differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of, inter alia, the Swedish Companies Act applicable to us and the Delaware General Corporation Law relating to shareholders' rights and

protections. We are not subject to Delaware law but are presenting this description for comparative purposes. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and Swedish law.

Number of Directors

Sweden. Under the Swedish Companies Act, a public company shall have a board of directors consisting of at least three directors. More than half of the directors shall be resident within the European Economic Area (unless otherwise approved by the Swedish Companies Registration Office). The actual number of board members shall be determined by a shareholders' meeting, within the limits set out in the company's articles of association. Under the Swedish Code of Corporate Governance, only one director may also be a senior executive of the relevant company or a subsidiary. The Swedish Code of Corporate Governance includes certain independence requirements for the directors, and requires a majority of the directors to be independent of the company and at least two directors to also be independent of major shareholders.

Delaware. Under the Delaware General Corporation Law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws. The Delaware General Corporation Law does not address director independence, though Delaware courts have provided general guidance as to determining independence, including that the determination must be both an objective and a subjective assessment.

Removal of Directors

Sweden. Under the Swedish Companies Act, directors appointed at a general meeting may be removed by a resolution adopted at a general meeting, upon the affirmative vote of a simple majority of the votes cast.

Delaware. Under the Delaware General Corporation Law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by a majority stockholder vote, though in the case of a corporation whose board is classified, stockholders may effect such removal only for cause.

Vacancies on the Board of Directors

Sweden. Under the Swedish Companies Act, if a director's tenure should terminate prematurely, the election of a new director may be deferred until the time of the next annual general meeting, providing there are enough remaining directors to constitute a quorum.

Delaware. Under the Delaware General Corporation Law, vacancies on a corporation's board of directors, including those caused by an increase in the number of directors, may be filled by a majority of the remaining directors.

Annual General Meeting

Sweden. Under the Swedish Companies Act, within six months of the end of each fiscal year, the shareholders shall hold an annual general meeting at which the board of directors shall present the annual report and auditor's report and, for a parent company which is obliged to prepare group

Delaware. Under the Delaware General Corporation Law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as

accounts, the group accounts and the auditor's report for the group. Shareholder meetings shall be held in the city stated in the articles of association. The minutes of a shareholders' meeting must be made available on the company's website no later than two weeks after the meeting.	provided in the certificate of incorporation or by the bylaws. If a company fails to hold an annual meeting or fails to take action by written consent to elect directors in lieu of an annual meeting for a period of 30 days after the date designated for the annual meeting, or if no date was designated, 13 months after either the last annual meeting or the last action by written consent to elect directors in lieu of an annual meeting, whichever is later, the Delaware Court of Chancery may summarily order a meeting to be held upon the application of any stockholder or director. The Delaware General Corporation Law does not require minutes of stockholders' meetings to be made public.
Special Meeting	
Sweden. Under the Swedish Companies Act, the board of directors shall convene an *extraordinary general meeting* if a shareholder minority representing at least 10% of the company's shares or the auditor of the company so demands, and the board of directors may convene an extraordinary general meetings whenever it believes reason exists to hold an extraordinary general meeting prior to the next annual general meeting.	*Delaware*. Under the Delaware General Corporation Law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.
Notices	
Sweden. Under the Swedish Companies Act, a shareholders' meeting must be preceded by a notice. The notice of the annual general meeting of shareholders must be issued no sooner than six weeks and no later than four weeks before the date of an annual general meeting. In general, notice of other extraordinary general meetings must be issued no sooner than six weeks and no later than three weeks before the meeting. Publicly listed companies must always notify shareholders of a general meeting by advertisement in a Swedish newspaper, the Swedish Official Gazette, by press release, and on the company's website.	*Delaware*. Under the Delaware General Corporation Law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.
Preemptive Rights	
Sweden. Under the Swedish Companies Act, shareholders of any class of shares have a preemptive right (*Sw. företrädesrätt*) to subscribe for shares issued of any class in proportion to their shareholdings. The preemptive right to subscribe does not apply in respect of shares issued for consideration other than cash or of shares issued pursuant to convertible debentures or warrants previously granted by the company. The preemptive right to subscribe for new shares may also be set aside by a resolution passed by two thirds of the votes cast and shares represented at the shareholders' meeting resolving upon the issue.	*Delaware*. Under the Delaware General Corporation Law, unless otherwise provided in a corporation's certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's stock.

Shareholder Vote on Certain Transactions

Sweden. In matters which do not relate to elections and are not otherwise governed by the Swedish Companies Act or the articles of association, resolutions shall be adopted at the general meeting by a simple majority of the votes cast. In the event of a tied vote, the chairman shall have the casting vote. For matters concerning securities of the company, such as new share issuances, and other transactions such as private placements, mergers, and a change from a public to a private company (or vice-versa), the articles of association may only prescribe thresholds which are higher than those provided in the Swedish Companies Act.

Unless otherwise prescribed in the articles of association, the person who receives the most votes in an election shall be deemed elected. In general, a resolution involving the alteration of the articles of association shall be valid only when supported by shareholders holding not less than two-thirds of both the votes cast and the shares represented at the general meeting. The Swedish Companies Act lays out numerous exceptions for which a higher threshold applies, including restrictions on certain rights of shareholders, limits on the number of shares shareholders may vote at the general meeting, directed share issues to directors, employees and other closely related parties, and changes in the legal relationship between shares.

Delaware. Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: (i) the approval of the board of directors; and (ii) approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

Stock Exchange Listing

Our common shares are currently traded on Nasdaq Stockholm under the symbol "CALTX." Our ADSs are currently traded on The Nasdaq Global Select Market under the symbol "CALT."

Transfer Agent and Registrar of Shares

Our share register is maintained by Euroclear. The share register reflects only record owners of our common shares. Holders of our ADSs will not be treated as our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the common shares underlying our ADSs. Holders of our ADSs have a right to receive the common shares underlying their ADSs.

American Depositary Shares

Citibank, N.A. is the depositary bank for the American Depositary Shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank Europe plc, located at 1 North Wall Quay, Dublin 1, Ireland.

We have appointed Citibank as depositary bank pursuant to a deposit agreement. A copy of the deposit agreement has been filed with the SEC under cover of a registration statement on Form F-6 (File No. 333-238726). You may obtain a copy of the deposit agreement from the SEC's website (www.sec.gov). Please refer to Registration Number 333-238726 when retrieving such copy.

We are providing you with a summary description of the material terms of the ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

Each ADS represents two common shares, quota value SEK 0.04 per share. As a holder of ADSs, you will not be treated as one of our shareholders and you will not have shareholder rights. You will have the rights of an ADS holder or beneficial owner (as applicable) as provided in the deposit agreement among us, the depositary and holders and beneficial owners of ADSs from time to time.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in two common shares that are on deposit with the depositary bank and/or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary bank or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary bank may agree to change the ADS-to-share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary bank and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary bank, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary bank, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary bank, and the depositary bank (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depositary bank. As an ADS holder you appoint the depositary bank to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of common shares will continue to be governed by the laws of Sweden, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. None of the depositary bank, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary bank will hold on your behalf the shareholder rights attached to the common shares underlying your ADSs. As an owner of ADSs you will be able to exercise the shareholders rights for the common shares represented by your ADSs through the depositary bank only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

The manner in which you own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary bank's services are made available to you. As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary bank in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary bank, commonly referred to as the direct registration system, or DRS. The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary bank. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary bank to the holders of the ADSs. The direct registration system includes automated transfers between the depositary bank and The Depository Trust Company, or DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the holder. When we refer to you, we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the common shares in the name of the depositary bank or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary bank or the custodian the record ownership in the applicable common shares with the beneficial ownership rights and interests in such common shares being at all times vested with the beneficial owners of the ADSs representing the common shares. The depositary bank or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and Distributions

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary bank will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the Swedish laws and regulations.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary bank will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary bank will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary bank holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of Shares

Whenever we make a free distribution of common shares for the securities on deposit with the custodian, we will deposit the applicable number of common shares with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will either distribute to holders new ADSs representing the common shares deposited or modify the ADS-to-share ratio, in which case each ADS you hold will represent rights and interests in the additional common shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-share ratio upon a distribution of common shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary bank may sell all or a portion of the new common shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (*e.g.*, the U.S. securities laws) or if it is not operationally practicable. If the depositary bank does not distribute new ADSs as described above, it may sell the common shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of Rights

Whenever we intend to distribute rights to subscribe for additional common shares, we will give prior notice to the depositary bank and we will assist the depositary bank in determining whether it is lawful and reasonably practicable to distribute rights to subscribe for additional ADSs to holders.

The depositary bank will establish procedures to distribute rights to subscribe for additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depositary bank is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new common shares other than in the form of ADSs.

The depositary bank will *not* distribute the rights to you if:

- we do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; or
- we fail to deliver satisfactory documents to the depositary bank; or
- it is not reasonably practicable to distribute the rights.

The depositary bank will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary bank is unable to sell the rights, it will allow the rights to lapse.

Elective Distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary bank and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable.

The depositary bank will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary bank will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in Sweden would receive upon failing to make an election, as more fully described in the deposit agreement.

Other Distributions

Whenever we intend to distribute property other than cash, common shares or rights to subscribe for additional common shares, we will notify the depositary bank in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary bank in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide to the depositary bank all of the documentation contemplated in the deposit agreement, the depositary bank will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary bank may sell all or a portion of the property received.

The depositary bank will *not* distribute the property to you and will sell the property if:

- we do not request that the property be distributed to you or if we request that the property not be distributed to you; or
- we do not deliver satisfactory documents to the depositary bank; or
- the depositary bank determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary bank will convert into U.S. dollars upon the terms of the deposit agreement the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary bank. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a *pro rata* basis, as the depositary bank may determine.

Changes Affecting Common Shares

The common shares held on deposit for your ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such common shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, your ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the common shares held on deposit. The depositary bank may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the Shares. If the

depositary bank may not lawfully distribute such property to you, the depositary bank may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

Transfer, Combination and Split Up of ADRs

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary bank and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures as the depositary bank deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary bank with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of Common Shares Upon Cancellation of ADSs

As a holder of ADSs, you will be entitled to present your ADSs to the depositary bank for cancellation and then receive the corresponding number of underlying common shares at the custodian's offices. Your ability to withdraw the common shares held in respect of the ADSs may be limited by U.S. and Swedish legal considerations applicable at the time of withdrawal. In order to withdraw the common shares represented by your ADSs, you will be required to pay to the depositary bank the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the common shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depositary bank may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary bank may deem appropriate before it will cancel your ADSs. The withdrawal of the common shares represented by your ADSs may be delayed until the depositary bank receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary bank will only accept ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except for:

- temporary delays that may arise because (i) the transfer books for the common shares or ADSs are closed, or (ii) common shares are immobilized on account of a shareholders meeting or a payment of dividends;
- obligations to pay fees, taxes and similar charges; or
- restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

Voting Rights

As a holder, you generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the common shares represented by your ADSs.

At our request, the depositary bank will distribute to you any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary bank to exercise the voting rights of the securities represented by ADSs. In lieu of distributing such materials, the depositary bank may distribute to holders of ADSs instructions on how to retrieve such materials upon request.

If the depositary bank timely receives valid voting instructions from a holder of ADSs as of the applicable record date(s), it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs in accordance with such voting instructions and in accordance with Swedish law (which may include temporary registration of the securities in the name of the applicable beneficial owner or designated nominee). In order to provide valid voting instructions, an ADS holder may be required to provide us and the depositary with such information about, and documents pertaining to, the applicable holders and beneficial owners of the ADSs being voted.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated in the deposit agreement). Please note that the ability of the depositary bank to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary bank in a timely manner.

Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

Service	Fees
● Issuance of ADSs (e.g., an issuance of ADS upon a deposit of common shares, upon a change in the ADS-to-share ratio, or for any other reason), excluding ADS issuances as a result of distributions of common shares	Up to $0.05 per ADS issued
● Cancellation of ADSs (e.g., a cancellation of ADSs for delivery of deposited property, upon a change in the ADS-to-share ratio, or for any other reason)	Up to $0.05 per ADS cancelled
● Distribution of cash dividends or other cash distributions (e.g., upon a sale of rights and other entitlements)	Up to $0.05 per ADS held
● Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) exercise of rights to purchase additional ADSs	Up to $0.05 per ADS held
● Distribution of securities other than ADSs or rights to purchase additional ADSs (e.g., upon a spin-off)	Up to $0.05 per ADS held
● ADS Services	Up to $0.05 per ADS held on the applicable record date(s) established by the depositary bank
● Registration of ADS transfers (e.g., upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and *vice versa*, or for any other reason)	Up to $0.05 per ADS (or fraction thereof) transferred

Service	Fees
● Conversion of ADSs of one series for ADSs of another series (e.g., upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs (each as defined in the Deposit Agreement) into freely transferable ADSs, and *vice versa*)	Up to $0.05 per ADS (or fraction thereof) converted

As an ADS holder you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of common shares on the share register and applicable to transfers of common shares to or from the name of the custodian, the depositary bank or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the fees, expenses, spreads, taxes and other charges of the depositary bank and/or service providers (which may be a division, branch or affiliate of the depositary bank) in the conversion of foreign currency;
- the reasonable and customary out-of-pocket expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to common shares, ADSs and ADRs; and
- the fees, charges, costs and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges for (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person for whom the ADSs are issued (in the case of ADS issuances) and to the person for whom ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary bank into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS Holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the Holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to the ADS holder. Certain depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the ADS offering. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary bank. You will receive

prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

Amendments and Termination

We may agree with the depositary bank to modify the deposit agreement at any time without your consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the common shares represented by your ADSs (except as permitted by law).

We have the right to direct the depositary bank to terminate the deposit agreement. Similarly, the depositary bank may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary bank must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

After termination, the depositary bank will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and may sell the securities held on deposit. After the sale, the depositary bank will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary bank will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with any termination of the deposit agreement, the depositary bank may make available to owners of ADSs a means to withdraw the common shares represented by ADSs and to direct the depositary of such common shares into an unsponsored American depositary share program established by the depositary bank. The ability to receive unsponsored American depositary shares upon termination of the deposit agreement would be subject to satisfaction of certain U.S. regulatory requirements applicable to the creation of unsponsored American depositary shares and the payment of applicable depositary fees.

Books of Depositary

The depositary bank will maintain ADS holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary bank will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Limitations on Obligations and Liabilities

The deposit agreement limits our obligations and the depositary bank's obligations to you. Please note the following:

- we and the depositary bank are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith;

- the depositary bank disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement;

- the depositary bank disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in common shares, for the validity or worth of the common shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice;

- we and the depositary bank will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement;

- we and the depositary bank disclaim any liability if we or the depositary bank are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our Articles of Incorporation and By-laws or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control;

- we and the depositary bank disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles of Incorporation and By-laws or in any provisions of or governing the securities on deposit;

- we and the depositary bank further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information;

- we and the depositary bank also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of common shares but is not, under the terms of the deposit agreement, made available to you;

- we and the depositary bank may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties;

- we and the depositary bank also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement;

- no disclaimer of any Securities Act liability is intended by any provision of the deposit agreement;

- nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and you as ADS holder; and

- nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

As the above limitations relate to our obligations and the depositary's obligations to you under the deposit agreement, we believe that, as a matter of construction of the clause, such limitations would likely to continue to apply to ADS holders who withdraw the common shares from the ADS facility with respect to obligations or liabilities incurred under the deposit agreement before the cancellation of the ADSs and the withdrawal of the common shares, and such limitations would most likely not apply to ADS holders who withdraw the common shares

from the ADS facility with respect to obligations or liabilities incurred after the cancellation of the ADSs and the withdrawal of the common shares and not under the deposit agreement.

In any event, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder. In fact, you cannot waive our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Taxes

You will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary bank and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary bank may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary bank and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary bank and to the custodian proof of taxpayer status and residence and such other information as the depositary bank and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary bank and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

Foreign Currency Conversion

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary bank may take the following actions in its discretion:

- convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical;
- distribute the foreign currency to holders for whom the distribution is lawful and practical; or
- hold the foreign currency (without liability for interest) for the applicable holders.

Governing Law/Waiver of Jury Trial

The deposit agreement, the ADRs and the ADSs will be interpreted in accordance with the laws of the State of New York. The rights of holders of common shares (including common shares represented by ADSs) are governed by the laws of Sweden.

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our common shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. However, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Resolution on adoption of a long-term incentive program for the company's management and key personnel (item 21)

The Board of Directors of Calliditas Therapeutics proposes the introduction of a long-term incentive program for the company's management and key personnel (including employees and consultants) in accordance with the following.

The Board of Directors proposes that the annual general meeting resolves to implement a long-term incentive program for management and key personnel (including employees and consultants) in Calliditas Therapeutics ("**ESOP 2023**") in accordance with items 21a – 21b below.

The resolutions under items 21a – 21b below are proposed to be conditional upon each other. Should the majority requirement for item 21b below not be met, the Board of Directors proposes that Calliditas Therapeutics shall be able to enter into an equity swap agreement with a third party in accordance with item 21c below and resolutions under items 21a and 21c shall then be conditional upon each other.

ESOP 2023 is a program under which the participants will be granted, free of charge, stock options to acquire shares in Calliditas Therapeutics ("**Options**"), subject to vesting over a three-year period in accordance with the below. The Board of Directors proposes that a maximum of 2,000,000 Options are allocated to the participants.

Proposal regarding adoption of a long-term incentive program for the company's management and key personnel (item 21a)

The rationale for the proposal

ESOP 2023 is intended for members of management and key personnel (including employees and consultants) in Calliditas Therapeutics. The Board of Directors of Calliditas Therapeutics believes that an equity-based incentive program in the form of stock options is a central part of an attractive and competitive remuneration package in order to attract, retain and motivate competent members of management and key personnel (including employees and consultants) in Calliditas Therapeutics, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders.

The proposed program is key for the company's ability to attract, retain and motivate competent key persons in the United States as well as in Europe in the company's operations and commercial functions scaling up the market launch of TARPEYO in the United States and the development of the company's pipeline assets. During the fourth quarter of 2021, the company received accelerated approval in the United States and since January 2022, the company commercializes TARPEYO in the United States. When recruiting and maintaining experienced commercial personnel in the United States and other key employees in the United States and Europe, it is important for Calliditas Therapeutics to be able to offer attractive compensation terms. A competitive equity-based incentive program is a key component in order to be able to attract and retain highly skilled and experienced individuals across clinical development, supply and regulatory areas, as well as relevant capabilities related to Calliditas Therapeutics' commercialization of TARPEYO in the United States.

The Board of Directors of Calliditas Therapeutics believes that ESOP 2023 will fortify the alignment of the interests of the participants and the interests of the shareholders. ESOP 2023 is adapted to the current position and needs of Calliditas Therapeutics. The Board of Directors is of the opinion that ESOP 2023 will increase and strengthen the participants' dedication to Calliditas Therapeutics' operations, improve company loyalty and that ESOP 2023 will be beneficial to both the shareholders and Calliditas Therapeutics.

Conditions for Options

The following conditions shall apply for the Options.

- The Options shall be granted free of charge to the participants.

- The Board of Directors shall resolve upon the allocation of Options between the date of the annual general meeting 2023 and the date of the annual general meeting 2024 (with each respective granting falling on a "**Grant Date**").

- Each Option entitles the holder to acquire one share in Calliditas Therapeutics for a pre-determined exercise price. The exercise price will correspond to 115 percent of the volume weighted average price of the Calliditas Therapeutics share on Nasdaq Stockholm during the ten trading days preceding the Grant Date.

- The Options shall vest over a three-year period, with 20 percent on the first anniversary of the Grant Date, with an annual vesting of 40 percent during the second year after the Grant Date, and with an annual vesting of 40 percent during the third year after the Grant Date, and thereafter be exercisable, provided that the holder, with certain exceptions, still is employed by Calliditas Therapeutics (or, in the case of consultants, still provides services to Calliditas Therapeutics).

- Following the expiry of the vesting period, the Options may be exercised during a one-year period.

- The number of Options shall be subject to customary re-calculation, for example in the event that changes occur in Calliditas Therapeutics' equity capital structure, such as a bonus issue, merger, rights issue, share split or reverse share split, reduction of the share capital or similar measures.

- The Options are non-transferable and may not be pledged.

- The Options may be granted by the parent company as well as any other company within the Calliditas Therapeutics group.

- In the event of a public take-over offer, asset sale, liquidation, merger or any other such transaction affecting Calliditas Therapeutics, the Options will vest in their entirety following the completion of a change of control.

Allocation

The right to receive Options shall accrue to up to 200 employees or consultants of the company. The Board of Directors may grant Options, on one or several occasions, between the date of the annual general meeting 2023 and the date of the annual general meeting 2024. The maximum number of Options that may be allocated to the participants under ESOP 2023 is 2,000,000.

The maximum allocation per individual in each category shall be 300,000 Options for Category 1 (CEO), 250,000 Options for Category 2 (Management) and 100,000 Options for Category 3 (Other key personnel and consultants).

Preparation, administration and the right to amend the terms of the Options

The Board of Directors is responsible for preparing the detailed terms and conditions of ESOP 2023, in accordance with the above-mentioned terms and guidelines. To this end, the Board of Directors shall be entitled to make adjustments to meet foreign regulations or market conditions, including resolving on cash or other settlement if deemed favorable for Calliditas Therapeutics based on foreign tax regulations. The Board of Directors may also make other adjustments if significant changes in Calliditas Therapeutics or its environment would result in a situation where the adopted terms and conditions of ESOP 2023 no longer serve their purpose.

Preparation of the proposal

ESOP 2023 has been initiated by the Board of Directors of Calliditas Therapeutics and has been structured based on an evaluation of prior incentive programs and market practice for comparable European (including Swedish) and American listed companies. ESOP 2023 has been prepared by the Remuneration Committee and reviewed by the Board of Directors.

Dilution

Subject to certain recalculation conditions, the maximum number of shares that may be issued under ESOP 2023 is 2,000,000 which corresponds to a dilution of approximately 3.3 percent on a fully diluted basis. Taking into account also the shares which may be issued pursuant to already allocated warrants under the company's

outstanding incentive programs, the maximum dilution amounts to approximately 10.0 percent on a fully diluted basis.

Information about Calliditas Therapeutics' existing incentive programs can be found on Calliditas Therapeutics' website, www.calliditas.se/en/, under "Remuneration" as well as in the company's annual report.

Scope and costs of the program

ESOP 2023 will be accounted for in accordance with "IFRS 2 – Share-based payments". IFRS 2 stipulates that the Options shall be expensed as personnel costs over the vesting period. Personnel costs in accordance with IFRS 2 do not affect the company's cash flow. Social security costs will be expensed in the income statement according to UFR 7 during the vesting period.

Assuming a share price at the time of allocation of Options of SEK 125, an annual increase in the share price of 10 percent and that all Options are allocated up-front under the assumptions set out under "Dilution" above, the average annual cost for Calliditas Therapeutics according to IFRS 2 is estimated to approximately SEK 22.0 million per year before tax. The average annual social security costs over the vesting period are estimated to approximately a total of SEK 6.9 million, based on the above assumptions, that all Options are fully vested, a vesting period for all Options of three years and social security costs of 31.42 percent. It is envisaged that the social security costs associated with ESOP 2023 will be covered by the cash received from the participants at exercise of Options. If necessary, social security costs will be covered by hedging measures through the issue of warrants (see item 21b below) which would be exercised by a financial intermediary in connection with the exercise of the Options. In either case, the social security costs associated with ESOP 2023 will be fully covered and will hence not affect the company's cash flow.

The total cost of ESOP 2023, including all social security costs, is estimated to amount to approximately SEK 86.7 million under the above assumptions.

Delivery of shares under ESOP 2023

In order to ensure the delivery of shares under ESOP 2023, and if necessary, for hedging of social security costs, the Board of Directors proposes that the annual general meeting resolves to issue and use warrants in accordance with item 21b below.

Proposal regarding issue of warrants (item 21b)

In order to ensure the delivery of shares under ESOP 2023 and, if necessary, for hedging of social security costs, the Board of Directors proposes that the annual general meeting resolves to issue not more than 2,000,000 warrants (which includes warrants to potentially hedge social security costs), whereby the company's share capital could be increased by not more than SEK 80,000.

The right to subscribe for the warrants shall, with deviation from the shareholders' pre-emptive rights, only be granted Nefecon AB, a wholly owned subsidiary of Calliditas Therapeutics. The reason for the deviation from the shareholders' pre-emptive rights is the implementation of ESOP 2023. Nefecon AB shall be entitled to transfer the warrants to participants or a financial intermediary in connection with exercise.

The warrants shall be issued free of charge. The exercise price for subscription for shares based on the warrants shall correspond to the share's quota value.

The full terms and conditions for the warrants are presented in Appendix A and Appendix B.

Equity swap agreement with a third party (item 21c)

Should the majority requirement for item 21b above not be met, the Board of Directors proposes that the annual general meeting resolves that ESOP 2023 instead shall be hedged through an equity swap agreement with a third party on terms in accordance with market practice, whereby the third party in its own name shall be entitled to acquire and transfer shares of Calliditas Therapeutics to the participants.

Majority requirements

Resolution in accordance with item 21b above requires approval of at least nine tenths (9/10) of the shares represented and votes cast at the annual general meeting.

Resolution to issue warrants

In order to ensure the delivery of shares under ESOP 2023 and, if necessary, for hedging of social security costs, the Board of Directors proposes that the annual general meeting resolves to issue not more than 2,000,000 warrants (which includes warrants for potential hedging of social security costs), whereupon the company's share capital may be increased by not more than SEK 80,000 in accordance with the following:

1. The right to subscribe for the warrants shall, with deviation from the shareholders' pre-emptive rights, only vest with Nefecon AB, a wholly owned subsidiary of Calliditas Therapeutics AB (publ). The reason for the deviation from the shareholders' pre-emptive rights is the implementation of ESOP 2023. Nefecon AB shall be entitled to transfer the warrants to participants or a financial intermediary in connection with exercise.

2. The warrants shall be issued free of charge and shall be subscribed for by 31 July 2023. The Board of Directors shall have the right to extend the subscription period.

3. The warrants shall in all other respects be governed by the terms and conditions set forth in Appendix B.

4. The exercise price for subscription for shares based on the warrants shall correspond to the share's quota value.

5. The company's CEO shall be authorized to make such minor adjustments that may be necessary in connection with the registration of the new issue.

6. Notification of subscription of shares by the exercise of Warrants can be made from and including the day of registration of the Warrants with the Swedish Companies' Office until and including 30 June 2028.

[attached separately]

Exhibit 4.22

Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

CREDIT AGREEMENT

Dated as of December 27, 2023

among

CALLIDITAS THERAPEUTICS AB,
as the Borrower,

CERTAIN SUBSIDIARIES OF THE BORROWER,
as the Guarantors,

ATHYRIUM OPPORTUNITIES IV CO-INVEST 1 LP,
as the Administrative Agent

and

THE LENDERS FROM TIME TO TIME PARTY HERETO

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SCHEDULES

EXHIBITS

CREDIT AGREEMENT

This CREDIT AGREEMENT is entered into as of December 27, 2023 among CALLIDITAS THERAPEUTICS AB, a Swedish public limited liability company with Swedish registration number 556659-9766 (the "Borrower"), the Guarantors (defined herein), the Lenders (defined herein) and ATHYRIUM OPPORTUNITIES IV CO-INVEST 1 LP, as the Administrative Agent.

The Borrower has requested that the Lenders provide the Borrower with a term loan facility and the Lenders are willing to do so on the terms and conditions set forth herein.

In consideration of the mutual covenants and agreements herein contained, the parties hereto covenant and agree as follows:

ARTICLE I

DEFINITIONS AND ACCOUNTING TERMS

1.01 Defined Terms.

As used in this Agreement, the following terms shall have the meanings set forth below:

[***].

[***].

"Account Control Agreement" means any account control agreement by and among a Loan Party, the applicable depository bank or securities intermediary (as the case may be) at which a Deposit Account is maintained in the United States and the Administrative Agent, in each case in form and substance reasonably satisfactory to the Administrative Agent.

"Acquisition" means, with respect to any Person, the acquisition by such Person, in a single transaction or in a series of related transactions, of (a) assets of another Person which constitute all or substantially all of the assets of such Person, or of any division, line of business or other business unit of such Person, (b) at least a majority of the Voting Stock of another Person, in each case whether or not involving a merger or consolidation with such other Person and whether for cash, property, services, assumption of Indebtedness, securities or otherwise, or (c) one or more Acquisition Products or a Person or division, line of business or other business unit of another Person holding an Acquisition Product(s).

"Acquisition Product" means any product or service developed, manufactured, marketed, offered for sale, promoted, sold, tested, used or otherwise distributed by a Person other than the Borrower or any of its Subsidiaries; provided, that, for the avoidance of doubt, "Acquisition Product" shall not include Nefecon or any Intellectual Property or other rights associated with Nefecon.

"Administrative Agent" means Athyrium Opportunities IV Co-Invest 1 LP, a Delaware limited partnership, in its capacity as administrative agent under any of the Loan Documents, or any successor administrative agent.

"Administrative Agent's Office" means the Administrative Agent's address and, as appropriate, account as set forth on Schedule 11.02 or such other address or account as the Administrative Agent may from time to time notify the Borrower and the Lenders.

"Affected Financial Institution" means (a) any EEA Financial Institution or (b) any UK Financial Institution.

"Affiliate" means, with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the Person specified.

"Agreement" means this Credit Agreement.

"Agreement Currency" has the meaning set forth in Section 11.20.

"ANDA" means an abbreviated new drug application filed with the FDA pursuant to section 505(j) of the FDCA, along with all supplements and amendments thereto, and any similar application for marketing authorization of a product commonly referred to as a "generic" product required by any country, jurisdiction or Governmental Authority other than the United States.

"Applicable Exit Fee Percentage" means [***] percent ([***]%); provided, that, with respect to any prepayment or repayment of all or any portion of the principal amount of the Loans (or any requirement to prepay or repay all or any portion of the principal amount of the Loans), whether pursuant to Section 2.03, Section 2.05, Section 9.02 or otherwise, if, as of the date of such prepayment or repayment (or, as the case may be, the date such prepayment or repayment is required to be paid), Consolidated Nefecon Net Product and Royalty Revenues for the four fiscal quarter period most recently ended prior to such date for which the Loan Parties were required to deliver financial statements pursuant to Section 7.01(a) or (b) were greater than [***], the "Applicable Exit Fee Percentage" with respect to such prepayment or repayment (or, as the case may be, requirement to prepay or repay) shall be [***] percent ([***]%).

"Applicable Foreign Loan Party Documents" has the meaning set forth in Section 6.28.

"Applicable Percentage" means with respect to any Lender at any time, in respect of the Term Facility, with respect to any Lender at any time, the percentage (carried out to the ninth decimal place) of the Term Facility represented by (a) on or prior to the Closing Date, such Lender's Commitment at such time and (b) thereafter, the outstanding principal amount of such Lender's Term Loans at such time. The initial Applicable Percentage of each Lender is set forth opposite the name of such Lender on Schedule 2.01 or in the Assignment and Assumption or other agreement pursuant to which such Lender becomes a party hereto, as applicable.

"Approved Fund" means any Fund that is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) an entity or an Affiliate of an entity that administers or manages a Lender.

"Assignment and Assumption" means an assignment and assumption entered into by a Lender and an Eligible Assignee (with the consent of any party whose consent is required by Section 11.06(b)), and accepted by the Administrative Agent, in substantially the form of Exhibit D or any other form (including electronic documentation generated by MarkitClear or other electronic platform) approved by the Administrative Agent.

"Athyrium" means Athyrium Capital Management, LP and its successors and assigns.

"Attributable Indebtedness" means, on any date, (a) in respect of any Capital Lease of any Person, the capitalized amount thereof that would appear on a balance sheet of such Person prepared as of such date in accordance with IFRS, (b) in respect of any Synthetic Lease of any Person, the capitalized amount of the remaining lease payments under the relevant lease that would appear on a balance sheet of such Person

prepared as of such date in accordance with IFRS if such lease were accounted for as a Capital Lease, (c) in respect of any [***] of any Person, the outstanding principal amount of such financing, after taking into account reserve accounts and making appropriate adjustments, determined by the Administrative Agent in its reasonable judgment and (d) in respect of any Sale and Leaseback Transaction, the present value (discounted in accordance with IFRS at the debt rate implied in the applicable lease) of the obligations of the lessee for rental payments during the term of such lease.

"Audited Financial Statements" means the audited consolidated balance sheet of the Borrower and its Subsidiaries for the fiscal year ended December 31, 2022, and the related consolidated statements of operations, shareholders' equity and cash flows for such fiscal year of the Borrower and its Subsidiaries, including the notes thereto, audited by independent public accountants of recognized national standing and prepared in conformity with IFRS.

"Bail-In Action" means the exercise of any Write-Down and Conversion Powers by the applicable Resolution Authority in respect of any liability of an Affected Financial Institution.

"Bail-In Legislation" means, (a) with respect to any EEA Member Country implementing Article 55 of Directive 2014/59/EU of the European Parliament and of the Council of the European Union, the implementing law, rule, regulation or requirement for such EEA Member Country from time to time which is described in the EU Bail-In Legislation Schedule and (b) with respect to the United Kingdom, Part I of the United Kingdom Banking Act 2009 (as amended from time to time) and any other law, regulation or rule applicable in the United Kingdom relating to the resolution of unsound or failing banks, investment firms or other financial institutions or their affiliates (other than through liquidation, administration or other insolvency proceedings).

"Board of Directors" means (a) with respect to a corporation, the board of directors of the corporation or any committee thereof duly authorized to act on behalf of such board, (b) with respect to a partnership, the Board of Directors of the general partner of the partnership, (c) with respect to a limited liability company, the managing member or members or any controlling committee of managing members thereof, and (d) with respect to any other Person, the board or committee of such Person serving a similar function.

"Borrower" has the meaning set forth in the introductory paragraph hereto.

"Borrowing" means a borrowing consisting of simultaneous Term Loans made by each of the Lenders pursuant to Section 2.01.

"Business Day" means any day other than a Saturday, Sunday or other day on which commercial banks are authorized to close under the Laws of, or are in fact closed in, the state of New York.

"Businesses" means, at any time, a collective reference to the businesses operated by the Borrower and its Subsidiaries at such time.

"Capital Lease" means, as applied to any Person, any lease of any property by that Person as lessee which, in accordance with IFRS, is required to be accounted for as a capital lease or a finance lease on the balance sheet of that Person.

"Cash Equivalents" means, as at any date, (a) securities issued or directly and fully guaranteed or insured by the United States or any agency or instrumentality thereof (provided, that, the full faith and credit of the United States is pledged in support thereof) having maturities of not more than twelve months from the date of acquisition, (b) Dollar denominated time deposits and certificates of deposit of (i) any domestic

commercial bank of recognized standing having capital and surplus in excess of $500,000,000 or (ii) any bank whose short-term commercial paper rating from S&P is at least A-1 or the equivalent thereof or from Moody's is at least P-1 or the equivalent thereof (any such bank being an "Approved Bank"), in each case with maturities of not more than 270 days from the date of acquisition, (c) commercial paper and variable or fixed rate notes issued by any Approved Bank (or by the parent company thereof) or any variable or fixed rate notes issued by, or guaranteed by, any domestic corporation rated A-1 (or the equivalent thereof) or better by S&P or P-1 (or the equivalent thereof) or better by Moody's and maturing within six months of the date of acquisition, (d) repurchase agreements entered into by any Person with a bank or trust company (including any of the Lenders) or recognized securities dealer having capital and surplus in excess of $500,000,000 for direct obligations issued by or fully guaranteed by the United States in which such Person shall have a perfected first priority security interest (subject to no other Liens) and having, on the date of purchase thereof, a fair market value of at least 100% of the amount of the repurchase obligations, (e) Investments, classified in accordance with IFRS as current assets, in money market investment programs registered under the Investment Company Act of 1940 which are administered by reputable financial institutions having capital of at least $500,000,000 and the portfolios of which are limited to Investments of the character described in the foregoing clauses (a) through (d) and (f) solely with respect to any Foreign Subsidiary, investments of comparable tenor and credit quality to those described in the foregoing clauses (a) through (e) customarily utilized in countries in which such Foreign Subsidiary operates.

"cGCP" means the then current Good Clinical Practices that establish the international ethical and scientific quality standards for designing, conducting, recording and reporting clinical trials that are promulgated or endorsed for the United States by the FDA (including through ICH E6 and 21 CFR Parts 50, 54, 56 and 312) and for outside the United States by comparable Governmental Authorities.

"cGMP" means the then current good manufacturing practices and regulatory requirements for or concerning manufacturing practices for pharmaceutical or biological products (and components thereof) that are promulgated or endorsed for the United States by the FDA (including through 21 CFR Parts 210 and 211) and for outside the United States by comparable Governmental Authorities.

"Change in Law" means the occurrence, after the Closing Date, of any of the following: (a) the adoption or taking effect of any law, rule, regulation or treaty, (b) any change in any law, rule, regulation or treaty or in the administration, interpretation, implementation or application thereof by any Governmental Authority or (c) the making or issuance of any request, rule, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided, that, notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"Change of Control" means the occurrence of any of the following events:

(a) any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, but excluding any employee benefit plan of such person or its subsidiaries, and any person or entity acting in its capacity as trustee, agent or other fiduciary or administrator of any such plan), is or becomes the "beneficial owner" (as defined in Rules 13d-3 and 13d-5 under the Securities Exchange Act of 1934, except that a person or group shall be deemed to have "beneficial ownership" of all securities that such person or group has the right to acquire, whether such right is exercisable immediately or only after the passage of time (such right, an "option right")), directly or indirectly, of Equity Interests representing fifty percent (50%) or more

of the aggregate ordinary voting power in the election of the Board of Directors of the Borrower represented by the issued and outstanding Equity Interests of the Borrower on a fully-diluted basis (and taking into account all such securities that such person or group has the right to acquire pursuant to any option right);

(b) the Borrower shall cease to own and control, of record and beneficially, one hundred percent (100%) of the Equity Interests of any Domestic Subsidiary; or

(c) any "fundamental change" (or any comparable term) or "change of control" (or any comparable term) occurs under any document or agreement evidencing Permitted Convertible Bond Indebtedness.

"Closing Date" means the date hereof.

"Closing Date License Agreements" means (a) that certain Commercialization Agreement dated July 21, 2021, by and between the Borrower and STADA Arzneimittel AG (as in effect on the Closing Date and as may be amended or otherwise modified in a manner not materially adverse to the Administrative Agent or any Lender, the "STADA License Agreement"), (b) that certain Commercialization Agreement dated June 10, 2019, by and between the Borrower and Everest Medicines II Limited, as amended by that certain Supplemental Agreement and First Amendment to License Agreement dated March 7, 2022, (as in effect on the Closing Date and as may be amended or otherwise modified in a manner not materially adverse to the Administrative Agent or any Lender, the "Everest License Agreement"), and (c) that certain Commercialization Agreement dated December 12, 2022, by and between the Borrower and Viatris Pharmaceuticals Japan Inc (as in effect on the Closing Date and as may be amended or otherwise modified in a manner not materially adverse to the Administrative Agent or any Lender, the "Viatris License Agreement").

"CMS" means the U.S. Center for Medicare and Medicaid Services.

"Collateral" means a collective reference to all real and personal property with respect to which Liens in favor of the Administrative Agent, for the benefit of the Secured Parties, are purported to be granted pursuant to and in accordance with the terms of the Collateral Documents; provided, that, for the avoidance of doubt, the "Collateral" shall not include any Excluded Property.

"Collateral Access Agreement" means an agreement in form and substance reasonably satisfactory to the Administrative Agent pursuant to which (a) a lessor of real property in the United States on which Collateral having an aggregate fair market value in excess of $[***] is stored or otherwise located, or (b) a warehouseman, processor or other bailee of inventory or other property owned by any Loan Party in the United States on which the Collateral located thereon has an aggregate fair market value in excess of $[***], in the case of each of clauses (a) and (b), acknowledges the Liens of the Administrative Agent and waives (or, if approved by the Administrative Agent, subordinates) any Liens held by such Person on such property, and permits the Administrative Agent reasonable access to any Collateral stored or otherwise located thereon.

"Collateral Documents" means a collective reference to the Security Agreement, the Pledge Agreement, the Swedish Collateral Documents, the French Securities Account Pledge Agreement, the Mortgages (if any), the Account Control Agreements, the Collateral Questionnaire, the Collateral Access Agreements (if any), the Real Property Security Documents (if any), with respect to any Foreign Loan Party acquired or formed after the Closing Date (it being understood that any Excluded Subsidiary ceasing to be an Excluded Subsidiary but remaining a Subsidiary shall be deemed to be the acquisition of a Subsidiary for purposes thereof), or any property (other than Excluded Property) acquired by any Loan Party

subsequent to the Closing Date, such additional security documents as shall be required by the Administrative Agent in accordance with Section 7.14, and such other security documents as may be executed and delivered by the Loan Parties pursuant to the terms of Section 7.14 or Section 7.21.

"Collateral Questionnaire" means that certain collateral questionnaire, in form and substance reasonably satisfactory to Administrative Agent, dated as of the Closing Date.

"Commitment" means, as to each Lender, its obligation to make a Term Loan to the Borrower pursuant to Section 2.01, in the principal amount set forth opposite such Lender's name on Schedule 2.01. The aggregate principal amount of the Commitments of all of the Lenders as in effect on the Closing Date is NINETY-TWO MILLION EUROS (€92,000,000).

"Communication" means this Agreement, any Loan Document and any document, amendment, approval, consent, information, notice, certificate, request, statement, disclosure or authorization related to any Loan Document.

"Competitor" means, as of any date of determination, (a) any Person that is in the business of developing, manufacturing or commercializing products in competition with the products of the Borrower and its Subsidiaries as of such date of determination and (b) any Person that is an Affiliate of any Competitor described in clause (a) above that is clearly identifiable as an Affiliate of such Competitor solely on the basis of such Affiliate's name; provided, that, a Person that would be a Competitor pursuant to clause (b) above shall not constitute a Competitor if (x) such Person is a bank, financial institution, bona fide debt fund or investment vehicle that is engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of business and no Person described in clause (a) above makes investment decisions for such Person and no investment vehicle managed or advised by a Person described in clause (a) above that is not engaged primarily in making, purchasing, holding or otherwise investing in commercial loans, bonds and similar extensions of credit in the ordinary course makes investment decisions for such Person and (y) such Person does not share any information of the type subject to Section 11.07 with any Person described in clause (a) above or any investment vehicle managed or advised by any Person described in clause (a) above that is not engaged primarily in making, purchasing, holding or otherwise investing in commercial loans, bonds and similar extensions of credit in the ordinary course, in each case described in this clause (y) with respect to which such Person is an Affiliate.

"Compliance Certificate" means a certificate substantially in the form of Exhibit E.

"Consolidated Nefecon Net Product and Royalty Revenues" means, for any period, for the Loan Parties on a consolidated basis, as determined and reported in accordance with IFRS, [***]. Notwithstanding the foregoing, it is understood and agreed that "Consolidated Nefecon Net Product and Royalty Revenues" for the fiscal quarter ended September 30, 2023 shall be deemed to be [***].

"Consolidated Revenues" means, for any period, for the Borrower and its Subsidiaries on a consolidated basis, revenues for such period as determined and reported in accordance with IFRS; provided, that, "Consolidated Revenues" shall exclude the revenues generated by any Subsidiary to the extent that the declaration or payment of dividends or similar distributions by that Subsidiary of the income resulting from such revenues is not at the time permitted by operation of the terms of its Organization Documents or any agreement, instrument, judgment, decree, order, statute, rule or governmental regulation applicable to that Subsidiary.

"Contractual Obligation" means, as to any Person, any provision of any security issued by such Person or of any agreement, instrument or other undertaking to which such Person is a party or by which it or any of its property is bound.

"Control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of a Person, whether through the ability to exercise voting power, by contract or otherwise. "Controlling" and "Controlled" have meanings correlative thereto. Without limiting the generality of the foregoing, a Person shall be deemed to be Controlled by another Person if such other Person possesses, directly or indirectly, power to vote ten percent (10%) or more of the securities having ordinary voting power for the election of directors, managing general partners or the equivalent.

"Controlled Substances Act" means the U.S. Controlled Substances Act (or any successor thereto) and the rules, regulations, guidelines, guidance documents and compliance policy guides issued or promulgated thereunder.

"Convertible Bond Indebtedness" means Indebtedness having a feature which entitles the holder thereof to convert or exchange all or a portion of such Indebtedness into Qualified Capital Stock of the Borrower (or other securities or property following a merger event or other change of the ordinary shares of the Borrower), which conversion or exchange may be settled by the Borrower by payment of cash or any combination of payment of cash and delivery of such Qualified Capital Stock (or such other securities or property) based on the market price of such Qualified Capital Stock (or other securities or property).

"Copyrights" means all copyrights, whether statutory or common law, along with any and all (a) applications for registration, renewals, revisions, extensions, reversions, restorations, derivative works, enhancements, modifications, updates and new releases thereof, (b) income, royalties, damages, claims and payments now and hereafter due and/or payable with respect thereto, including, without limitation, damages and payments for past, present or future infringements thereof, (c) rights to sue for past, present and future infringements thereof, and (d) foreign copyrights and any other rights corresponding thereto throughout the world.

"DEA" means the United States Drug Enforcement Administration and any successor administration thereto.

"Debt Issuance" means the issuance by any Loan Party or any Subsidiary of any Indebtedness other than Indebtedness permitted under Section 8.03.

"Debtor Relief Laws" means the Bankruptcy Code of the United States, and all other liquidation, conservatorship, bankruptcy, assignment for the benefit of creditors, moratorium, rearrangement, receivership, insolvency, reorganization, or similar debtor relief Laws of the United States or other applicable jurisdictions from time to time in effect.

"Deemed Delivery" has the meaning set forth in Section 7.02.

"Default" means any event or condition that constitutes an Event of Default or that, with the giving of any notice, the passage of time, or both, would be an Event of Default.

"Default Rate" has the meaning set forth in Section 2.06(b).

"Defaulting Lender" means, subject to Section 2.12(b), any Lender, as determined by the Administrative Agent, that (a) has failed to perform any of its funding obligations hereunder within three (3) Business Days of the date required to be funded by it hereunder, (b) has notified the Borrower or the

Administrative Agent that it does not intend to comply with its funding obligations hereunder or (c) has, or has a direct or indirect parent company that has, (i) become the subject of a proceeding under any Debtor Relief Law, (ii) had a receiver, conservator, trustee, administrator, assignee for the benefit of creditors or similar Person charged with reorganization or liquidation of its business or a custodian appointed for it, (iii) taken any action in furtherance of, or indicated its consent to, approval of or acquiescence in any such proceeding or appointment or (iv) become the subject of a Bail-In Action; provided, that, a Lender shall not be a Defaulting Lender solely by virtue of the ownership or acquisition of any Equity Interests in that Lender or any direct or indirect parent company thereof by a Governmental Authority.

"Deposit Account" means a "deposit account" (as defined in Article 9 of the Uniform Commercial Code), investment account (including any securities account) or other account in which funds are held or invested to or for the credit or account of any Loan Party.

"Designated Jurisdiction" means any country or territory to the extent that such country or territory is the subject of any Sanction.

"Disposition" or "Dispose" means the sale, transfer, license, lease or other disposition (including any Sale and Leaseback Transaction or any issuance by any Subsidiary of its Equity Interests) of any property by any Loan Party or any Subsidiary, including any sale, assignment, transfer or other disposal, with or without recourse, of any notes or accounts receivable or any rights and claims associated therewith, but excluding the following (collectively, "Permitted Transfers"): (a) the sale, lease, license, transfer or other disposition of inventory in the ordinary course of business, (b) the sale, lease, license, transfer or other disposition in the ordinary course of business of surplus, obsolete or worn out property no longer used or useful in the conduct of business of any Loan Party or any Subsidiary, (c) any sale, lease, license, transfer or other disposition of property to any Loan Party or any Subsidiary (other than [***]); provided, that, if the transferor of such property is a Loan Party, (i) the transferee thereof must be a Loan Party or (ii) to the extent such transaction constitutes an Investment, such transaction is permitted under Section 8.02, (d) the abandonment or other disposition of Intellectual Property that is not material or is no longer used or useful in any material respect in the business of the Borrower and its Subsidiaries, (e) licenses, sublicenses, leases or subleases (other than relating to intellectual property) granted to third parties in the ordinary course of business and not interfering with the business of the Borrower and its Subsidiaries, (f) any Involuntary Disposition, (g) dispositions of cash and Cash Equivalents in the ordinary course of business, (h) dispositions consisting of the sale, transfer, assignment or other disposition of unpaid and overdue accounts receivable in connection with the collection, compromise or settlement thereof in the ordinary course of business and not as part of a financing transaction, (i) the sale, transfer, issuance or other disposition of a de minimis number of shares of the Equity Interests of a Foreign Subsidiary in order to qualify members of the governing body of such Subsidiary if required by applicable Law, (j) to the extent constituting a sale, transfer, license, lease or other disposition, the granting, existence or creation of a Lien (but not the sale, transfer, license, lease or other disposition of the property subject to such Lien) permitted under Section 8.01 (other than by reference to Section 8.05 or this definition (or any sub-clause of either thereof)), (k) Investments permitted under Section 8.02, fundamental changes permitted under Section 8.04 and Restricted Payments permitted under Section 8.06 (in each case, other than by reference to Section 8.05 or this definition (or any sub-clause of either thereof)), (l) the settlement, unwinding or other termination of Swap Contracts not prohibited hereunder in the ordinary course of business, (m) dispositions of property to the extent that (i) such property is exchanged for credit against the purchase price of similar replacement property or (ii) the proceeds (determined on an after-tax basis) of such disposition are applied to the purchase price of similar replacement property, (n) issuances of Qualified Capital Stock of the Borrower, (o) [***], (p) any sale, transfer, lease, Permitted License or other disposition of any product franchise (including, without limitation, any pipeline indications or any other Acquisition Products), in each case, to the extent created or acquired after the Closing Date in a transaction or series of transactions not prohibited by this agreement, (q) any sale, transfer, license, lease or other disposition of any assets (including Equity

Interests) to the extent (i) acquired after the Closing Date in a Permitted Acquisition or other Investment not prohibited hereunder, to the extent such assets are not used or useful to the core or principal business of the Borrower and its Subsidiaries and (ii) such sale, transfer, license, lease or other disposition is made to obtain the approval of any applicable antitrust authority in connection with a Permitted Acquisition, (r) the settlement, unwinding or other termination of Permitted Equity Derivatives in accordance with the terms of Section 8.06, (s) sales, transfers, licenses, leases and other dispositions consummated during any fiscal year resulting in aggregate proceeds to the Borrower and its Subsidiaries for all such transactions taken together of less than [***] in such fiscal year, (t) [***] and (u) Permitted Licenses; provided, further, that, (x) none of the exclusions in the foregoing clauses (a) through (u), shall permit any Nefecon License (other than any Permitted Nefecon License) or any sale, transfer, license, lease or other disposition of Nefecon (other than the sale, transfer or other disposition of inventory of Nefecon in the ordinary course of business) or any Intellectual Property or other rights associated with Nefecon and (y) none of the exclusions in the foregoing clauses (a) through (u) (other than clause (t)) shall permit any sale, transfer, license, lease or other disposition of assets or other property to [***].

"Disqualified Capital Stock" means any Equity Interest which, by its terms (or by the terms of any security into which it is convertible or for which it is exchangeable), or upon the happening of any event, (a) matures (excluding any maturity as the result of an optional redemption by the issuer thereof) or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, or is redeemable at the option of the holder thereof, in whole or in part, prior to the one hundred eighty-first (181st) day after the Maturity Date, (b) requires the payment of any cash dividends at any time prior to the one hundred eighty-first (181st) day after the Maturity Date, (c) contains any repurchase obligation which may come into effect prior to payment in full of all Obligations, or (d) is convertible into or exchangeable (unless at the sole option of the issuer thereof) for (i) debt securities or (ii) any Equity Interests referred to in clause (a), (b) or (c) above, in each case at any time prior to the one hundred eighty-first (181st) day after the Maturity Date; provided, that, any Equity Interest that would not constitute Disqualified Capital Stock but for provisions thereof giving holders thereof (or the holders of any security into or for which such Equity Interests are convertible, exchangeable or exercisable) the right to require the issuer thereof to redeem or repurchase such Equity Interest upon the occurrence of a change in control or an asset sale occurring prior to the one hundred eighty-first (181st) day after the Maturity Date shall not constitute Disqualified Capital Stock if such Equity Interest provides that the issuer thereof will not redeem or repurchase such Equity Interest pursuant to such provisions prior to the Facility Termination Date.

"Dollar" and "$" mean lawful money of the United States.

"Dollar Equivalent" means, for any amount, at the time of determination thereof, (a) if such amount is expressed in Dollars, such amount, (b) if such amount is expressed in Euros, the equivalent of such amount in Dollars determined by using the rate of exchange for the purchase of Dollars with Euros last provided by the applicable Bloomberg source (or such other publicly available source for displaying exchange rates) on the date that is two (2) Business Days immediately preceding the date of determination (or if such service ceases to be available or ceases to provide such rate of exchange, the equivalent of such amount in Dollars as determined by the Administrative Agent using any method of determination it deems appropriate in its sole discretion) and (c) if such amount is denominated in any other currency, the equivalent of such amount in Dollars as determined by the Administrative Agent using any reasonable method of determination it deems appropriate in its sole discretion. Any determination by the Administrative Agent pursuant to clauses (b) and (c) above shall be conclusive absent manifest error.

"Domestic Subsidiary" means any Subsidiary that is organized under the laws of any state of the United States or the District of Columbia.

"Earn Out Obligations" means, with respect to an Acquisition, all obligations of the Borrower or any Subsidiary to make earn out or other contingency payments (including purchase price adjustments, non-competition and consulting agreements, or other indemnity obligations) pursuant to the documentation relating to such Acquisition. For purposes of determining the aggregate consideration paid for an Acquisition at the time of such Acquisition, the amount of any Earn Out Obligations shall be deemed to be the maximum amount of the earn-out payments in respect thereof as specified in the documents relating to such Acquisition. For purposes of determining the amount of any Earn Out Obligations to be included in the definition of Funded Indebtedness, the amount of Earn Out Obligations shall be deemed to be the aggregate liability in respect thereof, as determined in accordance with IFRS.

"EEA Financial Institution" means (a) any credit institution or investment firm established in any EEA Member Country which is subject to the supervision of an EEA Resolution Authority, (b) any entity established in an EEA Member Country which is a parent of an institution described in clause (a) of this definition, or (c) any financial institution established in an EEA Member Country which is a subsidiary of an institution described in clauses (a) or (b) of this definition and is subject to consolidated supervision with its parent.

"EEA Member Country" means any of the member states of the European Union, Iceland, Liechtenstein, and Norway.

"EEA Resolution Authority" means any public administrative authority or any person entrusted with public administrative authority of any EEA Member Country (including any delegee) having responsibility for the resolution of any EEA Financial Institution.

"Electronic Copy" has the meaning specified in Section 11.16.

"Electronic Record" and "Electronic Signature" have the meanings assigned to them, respectively, by 15 USC §7006, as it may be amended from time to time.

"Eligible Assets" means, with respect to any Disposition, any Involuntary Disposition or any Extraordinary Receipts, fixed or capital assets that are used or useful in the same or a reasonably related or complementary line of business as the Borrower and its Subsidiaries were engaged in on the Closing Date and any reasonable extension or expansions thereof or activities incidental thereto.

"Eligible Assignee" means any Person that meets the requirements to be an assignee under Section 11.06 (subject to such consents, if any, as may be required under Section 11.06(b)(iii)).

"EMA" means the European Medicines Agency or any successor entity.

"Environmental Laws" means any and all federal, state, local, foreign and other applicable statutes, laws, regulations, ordinances, rules, judgments, orders, decrees, permits, concessions, grants, franchises, licenses, agreements or governmental restrictions relating to pollution and the protection of the environment or the release of any materials into the environment, including those related to hazardous substances or wastes, air emissions and discharges to waste or public systems.

"Environmental Liability" means any liability, contingent or otherwise (including any liability for damages, costs of environmental remediation, fines, penalties or indemnities), of the Borrower, any other Loan Party or any of their respective Subsidiaries directly or indirectly resulting from or based upon (a) violation of any Environmental Law, (b) the generation, use, handling, transportation, storage, treatment or disposal of any Hazardous Materials, (c) exposure to any Hazardous Materials, (d) the release or threatened release of any Hazardous Materials into the environment or (e) any contract, agreement or other

consensual arrangement pursuant to which liability is assumed or imposed with respect to any of the foregoing.

"Equity Interests" means, with respect to any Person, all of the shares of capital stock of (or other ownership or profit interests in) such Person, all of the warrants, options or other rights for the purchase or acquisition from such Person of shares of capital stock of (or other ownership or profit interests in) such Person, all of the securities convertible into or exchangeable for shares of capital stock of (or other ownership or profit interests in) such Person or warrants (including American depository shares), rights or options for the purchase or acquisition from such Person of such shares (or such other interests), and all of the other ownership or profit interests in such Person (including partnership, member, membership or trust interests therein), whether voting or nonvoting, and whether or not such shares, warrants, options, rights or other interests are outstanding on any date of determination; provided, that, "Equity Interests" shall not include the Permitted Convertible Bond Indebtedness unless and until such Indebtedness is converted or exchanged.

"ERISA" means the Employee Retirement Income Security Act of 1974, as the same may be amended from time to time, and the rules and regulations promulgated thereunder.

"ERISA Affiliate" means any trade or business (whether or not incorporated) under common control with the Borrower within the meaning of Section 414(b) or (c) of the Internal Revenue Code (and Sections 414(m) and (o) of the Internal Revenue Code for purposes of provisions relating to Section 412 of the Internal Revenue Code).

"ERISA Event" means (a) a Reportable Event with respect to a Pension Plan, (b) the withdrawal of the Borrower or any ERISA Affiliate from a Pension Plan subject to Section 4063 of ERISA during a plan year in which such entity was a "substantial employer" as defined in Section 4001(a)(2) of ERISA or a cessation of operations that is treated as such a withdrawal under Section 4062(e) of ERISA, (c) a complete or partial withdrawal by the Borrower or any ERISA Affiliate from a Multiemployer Plan, (d) the filing of a notice of intent to terminate, the treatment of a Pension Plan amendment as a termination under Sections 4041 or 4041A of ERISA, (e) the institution by the PBGC of proceedings to terminate a Pension Plan, (f) any event or condition which constitutes grounds under Section 4042 of ERISA for the termination of, or the appointment of a trustee to administer, any Pension Plan, (g) the determination that any Pension Plan is considered an at-risk plan or a plan in endangered or critical status within the meaning of Sections 430, 431 and 432 of the Internal Revenue Code or Sections 303, 304 and 305 of ERISA, or (h) the imposition of any liability under Title IV of ERISA, other than for PBGC premiums due but not delinquent under Section 4007 of ERISA, upon the Borrower or any ERISA Affiliate.

"EU Bail-In Legislation Schedule" means the EU Bail-In Legislation Schedule published by the Loan Market Association (or any successor person), as in effect from time to time.

"Euro" and "€" means the single currency of the Participating Member States.

"Euro Equivalent" means, at any time, with respect to any amount denominated in Dollars, the equivalent amount thereof in Euros as determined by the Administrative Agent by reference to Bloomberg (or such other publicly available service for displaying exchange rates), to be the exchange rate for the purchase of Euros with Dollars at approximately 11:00 a.m. on the date two (2) Business Days prior to the date as of which the foreign exchange computation is made; provided, that, if no such rate is available, the "Euro Equivalent" shall be determined by the Administrative Agent using any reasonable method of determination it deems appropriate in its sole discretion (and such determination shall be conclusive absent manifest error).

"Event of Default" has the meaning set forth in Section 9.01.

"Excluded Accounts" means (a) deposit accounts established solely as payroll, escrow, trust, employee benefit and other zero balance accounts, (b) deposit accounts constituting cash collateral for Indebtedness permitted by Section 8.03(i) and (c) other deposit accounts, so long as at any time the aggregate balance in all such accounts does not exceed $500,000.

"Excluded Property" means, with respect to any Loan Party, including any Person that becomes a Loan Party after the Closing Date as contemplated by Section 7.12, (a) any leasehold interest of such Loan Party in real property, (b) solely with respect to any U.S. Loan Party, any personal property located in the United States (including, without limitation, motor vehicles) in respect of which perfection of a Lien is not either (x) governed by the Uniform Commercial Code or (y) effected by appropriate evidence of the Lien being filed in either the United States Copyright Office, the United States Patent and Trademark Office or the equivalent foreign office, unless requested by the Administrative Agent or the Required Lenders, (c) any property which, subject to the terms of Section 8.09, is subject to a Lien of the type described in Section 8.01(i) pursuant to documents which prohibit such Loan Party from granting any other Liens in such property, (d) any permit, lease, license, contract or other agreement if the grant of a security interest in such permit, lease, license, contract or other agreement in the manner contemplated by the Collateral Documents, under the terms thereof or under applicable Law, is prohibited and would result in the termination thereof or give the other parties thereto the right to terminate, accelerate or otherwise alter such Loan Party's rights, titles and interests thereunder (including upon the giving of notice or the lapse of time or both); provided, that, (i) any such limitation described in the foregoing clause (d) on the security interests granted under the Collateral Documents shall only apply to the extent that any such prohibition is not rendered ineffective pursuant to the Uniform Commercial Code or any other applicable Law, in each case, that has the effect of permitting the grant of a security interest and preventing any termination, acceleration or alteration of such Loan Party's rights, titles and interests thereunder as a result of such grant of a security interest and (ii) in the event of the termination or elimination of any such prohibition or the requirement for any consent contained in any applicable Law, permit, lease, license, contract or other agreement, or upon the granting of any such consent, or waiving or terminating any requirement for such consent, a security interest in such permit, lease, license, contract or other agreement shall be automatically and simultaneously granted under the Collateral Documents and such permit, lease, license, contract or other agreement shall be included as Collateral, (e) any United States intent-to-use trademark applications to the extent that, and solely during the period in which, the grant of a security interest therein would impair the validity or enforceability of such intent-to-use trademark applications under applicable federal law; provided, that, upon submission and acceptance by the United States Patent and Trademark Office of a statement of use or an amendment to allege use pursuant to 15 U.S.C. Section 1060(a) (or any successor provision), such intent-to-use trademark application shall no longer constitute "Excluded Property" and shall be considered Collateral, (f) Excluded Accounts and (g) any real or personal property as to which the Administrative Agent and the Borrower agree in writing that the costs or other consequences of obtaining a security interest or perfection thereof are excessive in view of the benefits to be obtained by the Secured Parties therefrom.

"Excluded Subsidiary" means (a) any Foreign Subsidiary, the grant or perfection of a security interest in the assets of such Foreign Subsidiary in support of, or the guaranteeing of, the Obligations would be prohibited by applicable Law in the jurisdiction of formation or incorporation of such Foreign Subsidiary (as reasonably determined by the Borrower with the consent of the Administrative Agent, such consent not to be unreasonably conditioned, delayed or denied), (b) any Foreign Subsidiary with respect to which the Administrative Agent and the Borrower agree in writing that the cost or other consequences (including, for the avoidance of doubt, any material adverse tax consequences) of such Foreign Subsidiary guaranteeing the Obligations are excessive in view of the benefits to be obtained by the Secured Parties therefrom, (c) any Immaterial Foreign Subsidiary, and (d) any Subsidiary that satisfies both of the following conditions: (i) such Subsidiary does not own, license or otherwise control Nefecon or any Intellectual Property or other

rights associated with Nefecon and (ii) such Subsidiary does not conduct any Product Development and Commercialization Activities with respect to Nefecon; provided, that, (x) for the avoidance of doubt, no "Excluded Subsidiary" shall (A) own, license or otherwise control Nefecon or any Intellectual Property or other rights associated with Nefecon or (B) conduct any Product Development and Commercialization Activities with respect to Nefecon and (y) notwithstanding the foregoing or anything to the contrary set forth in this Agreement, no U.S. Loan Party as of the Closing Date shall at any time during the term of this Agreement constitute an "Excluded Subsidiary"; provided, further, that, any Subsidiary that would otherwise be classified as an "Excluded Subsidiary" pursuant to the terms and provisions of this definition shall not fail to be classified as an "Excluded Subsidiary" due to personnel whose employment or consulting agreements are with such Excluded Subsidiary conducting Product Development and Commercialization Activities with respect to Nefecon, on behalf of one or more Loan Parties.

"Existing Credit Agreement" means that certain Agreement for the Provision of Loan Facilities dated as of July 15, 2021, by and among Kreos Capital VI (UK) Limited and Kreos Capital 2020 Opportunity (UK) Limited, each as lender thereunder, the Borrower and the Guarantors, as amended.

"Extraordinary Receipts" means any cash received by or paid to or for the account of any Person not in the ordinary course of business, including, without limitation, tax refunds, pension plan reversions, proceeds of insurance (other than proceeds of business interruption insurance to the extent such proceeds constitute compensation for lost earnings), condemnation awards and similar payments, indemnity payments, any purchase price adjustments and any cash received in connection with the settlement or other resolution (including by judgment) of any litigation, arbitration or other dispute; provided, that, in no event shall "Extraordinary Receipts" include (a) the proceeds of any issuances, Permitted Transfers or Dispositions of Qualified Capital Stock of such Person, (b) the proceeds of any insurance, condemnation awards or similar payments, or indemnity payments, in each case, to the extent that such proceeds are received by such Person in respect of any actual or potential third-party claim against such Person and applied to pay (or reimburse such Person for its prior payment of) such claim and/or related costs and expenses, or (c) the proceeds of Permitted Transfers (including, without limitation, fees, milestones, upfront payments, royalties and any other payments received from Permitted Licenses).

"Extraordinary Receipts (Nefecon)" means any cash received by or paid to or for the account of any Person in respect of Nefecon or any Intellectual Property or other rights associated therewith and not in the ordinary course of business, including, without limitation, tax refunds, proceeds of insurance and similar payments, indemnity payments, any purchase price adjustments and any cash received in connection with the settlement or other resolution (including by judgment) of any litigation, arbitration or other dispute; provided, that, in no event shall "Extraordinary Receipts (Nefecon)" include (a) the proceeds of any insurance, condemnation awards or similar payments, or indemnity payments, in each case, to the extent that such proceeds are received by such Person in respect of any actual or potential third-party claim against such Person and applied to pay (or reimburse such Person for its prior payment of) such claim and/or related costs and expenses, or (b) the proceeds of Permitted Transfers (including, without limitation, fees, milestones, upfront payments, royalties and any other payments received from Permitted Licenses).

"Facilities" means, at any time, a collective reference to the facilities and real properties owned, leased or operated by any Loan Party or any Subsidiary.

"Facility Termination Date" means the date as of which all of the following shall have occurred: (a) all of the Commitments have terminated and (b) all Obligations have been paid in full in cash (other than contingent indemnification obligations for which no claim has been asserted).

"FATCA" means Sections 1471 through 1474 of the Internal Revenue Code as of the Closing Date (or any amended or successor version that is substantively comparable and not materially more onerous to

comply with), any current or future regulations thereunder, official interpretations thereof, any agreement entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among Governmental Authorities and implementing such Sections of the Internal Revenue Code.

"FDA" means the United States Food and Drug Administration and any successor entity.

"FDCA" means the U.S. Food, Drug and Cosmetic Act (or any successor thereto) and the rules, regulations, guidelines, guidance documents and compliance policy guides issued or promulgated thereunder.

"Federal Funds Rate" means, for any day, the rate per annum equal to the weighted average of the rates on overnight federal funds transactions with members of the Federal Reserve System on such day, as published by the Federal Reserve Bank of New York on the Business Day next succeeding such day; provided, that, if such day is not a Business Day, the Federal Funds Rate for such day shall be such rate on such transactions on the next preceding Business Day as so published on the next succeeding Business Day.

"Fee Letter" means that certain letter agreement dated as of the Closing Date among the Borrower, on the one hand, and the Lenders and/or one or more of their respective Affiliates, on the other hand.

"Flood Hazard Property" means any real property subject to a Mortgage that is in an area designated by the Federal Emergency Management Agency as having special flood or mudslide hazards.

"Foreign Loan Party" means any Loan Party that is not a U.S. Loan Party.

"Foreign Subsidiary" means any Subsidiary that is not a Domestic Subsidiary.

"FRB" means the Board of Governors of the Federal Reserve System of the United States.

"French Collateral" means Collateral governed by French law.

"French Securities Account Pledge Agreement" means the French law governed pledge over the financial securities account in respect of Calliditas Therapeutics France SAS, to be entered into between the Borrower and the Administrative Agent, subject to the terms of Section 7.21.

"Fund" means any Person (other than a natural Person) that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its activities.

"Funded Indebtedness" means, as to any Person at a particular time, without duplication, all of the following, whether or not included as indebtedness or liabilities in accordance with IFRS:

(a) all obligations, whether current or long-term, for borrowed money (including the Obligations) and all obligations of such Person evidenced by bonds, debentures, notes, loan agreements or other similar instruments;

(b) all purchase money Indebtedness;

(c) the principal portion of all obligations under conditional sale or other title retention agreements relating to property purchased by such Person or any Subsidiary thereof (other than

customary reservations or retentions of title under agreements with suppliers entered into in the ordinary course of business);

(d) all obligations arising under letters of credit (including standby and commercial), bankers' acceptances, bank guaranties, surety bonds and similar instruments;

(e) (i) all obligations in respect of the deferred purchase price of property or services (other than (x) ordinary course incentive or deferred compensation to directors, officers and employees of such Person and its Subsidiaries or (y) trade accounts payable in the ordinary course of business that remain unpaid for more than 90 days following the due date thereof (unless such obligations are being contested in good faith by appropriate proceedings diligently conducted)) and (ii) any Earn Out Obligations solely to the extent required to be reflected as a liability on a balance sheet prepared in accordance with IFRS;

(f) the Attributable Indebtedness of Capital Leases, [***] and Synthetic Leases;

(g) all obligations of such Person to purchase, redeem, retire, defease or otherwise make any payment in respect of any Disqualified Capital Stock in such Person or any other Person, valued, in the case of a redeemable preferred interest, at the greater of its voluntary or involuntary liquidation preference plus accrued and unpaid dividends;

(h) all Funded Indebtedness of others secured by (or for which the holder of such Funded Indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on, or payable out of the proceeds of production from, property owned or acquired by such Person, whether or not the obligations secured thereby have been assumed;

(i) all Guarantees with respect to Funded Indebtedness of the types specified in clauses (a) through (h) above of another Person; and

(j) all Funded Indebtedness of the types referred to in clauses (a) through (i) above of any partnership or joint venture (other than a joint venture that is itself a corporation or limited liability company) in which such Person is a general partner or joint venturer, except to the extent that Funded Indebtedness is expressly made non-recourse to such Person.

For purposes hereof, the amount of any direct obligation arising under letters of credit (including standby and commercial), bankers' acceptances, bank guaranties, surety bonds and similar instruments shall be the maximum amount available to be drawn thereunder.

"Governmental Authority" means any national, supranational, federal, state, county, provincial, local, municipal or other government or political subdivision thereof (including any Regulatory Agency), whether domestic or foreign, and any agency, authority, commission, ministry, instrumentality, regulatory body, court, tribunal, arbitrator, central bank or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to any such government (including any supra-national bodies such as the European Union or the European Central Bank).

"Guarantee" means, as to any Person, (a) any obligation, contingent or otherwise, of such Person guaranteeing or having the economic effect of guaranteeing any Indebtedness or other obligation payable or performable by another Person (the "primary obligor") in any manner, whether directly or indirectly, and including any obligation of such Person, direct or indirect, (i) to purchase or pay (or advance or supply funds for the purchase or payment of) such Indebtedness or other obligation, (ii) to purchase or lease property, securities or services for the purpose of assuring the obligee in respect of such Indebtedness or

other obligation of the payment or performance of such Indebtedness or other obligation, (iii) to maintain working capital, equity capital or any other financial statement condition or liquidity or level of income or cash flow of the primary obligor so as to enable the primary obligor to pay such Indebtedness or other obligation, or (iv) entered into for the purpose of assuring in any other manner the obligee in respect of such Indebtedness or other obligation of the payment or performance thereof or to protect such obligee against loss in respect thereof (in whole or in part), or (b) any Lien on any assets of such Person securing any Indebtedness or other obligation of any other Person, whether or not such Indebtedness or other obligation is assumed by such Person (or any right, contingent or otherwise, of any holder of such Indebtedness to obtain any such Lien). The amount of any Guarantee shall be deemed to be an amount equal to the stated or determinable amount of the related primary obligation, or portion thereof, in respect of which such Guarantee is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by the guaranteeing Person in good faith. The term "Guarantee" as a verb has a corresponding meaning.

"Guarantors" means (a) each Subsidiary identified as a "Guarantor" on the signature pages hereto and (b) each other Person that joins as a Guarantor pursuant to Section 7.12, together with their successors and permitted assigns; provided, that, no Excluded Subsidiary shall be a "Guarantor" under the Loan Documents.

"Guaranty" means the Guaranty made by the Guarantors in favor of the Secured Parties pursuant to Article IV.

"Hazardous Materials" means all explosive or radioactive substances or wastes and all hazardous or toxic substances, wastes or other pollutants, including petroleum or petroleum distillates, asbestos or asbestos-containing materials, polychlorinated biphenyls, radon gas, infectious or medical wastes and all other substances or wastes of any nature regulated pursuant to any Environmental Law.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996, as amended from time to time, and the rules and regulations promulgated thereunder from time to time and any equivalent Law in any jurisdiction other than the United States.

"IFRS" means international accounting standards within the meaning of IAS Regulation 1606/2002 to the extent applicable to the relevant financial statements delivered under or referred to in the Loan Documents, consistently applied and subject to Section 1.03(a).

"Immaterial Foreign Subsidiary" means at any time a Foreign Subsidiary that (a) as of the last day of the fiscal quarter of the Borrower most recently ended for which the Borrower was required to deliver financial statements pursuant to Section 7.01(a) or (b), did not have (together with its Subsidiaries) assets in excess of (i) [***] percent ([***]%) of the consolidated total assets of the Borrower and its Subsidiaries at the end of such fiscal quarter for such Immaterial Foreign Subsidiary (and its Subsidiaries) and (ii) [***]percent ([***]%) of the consolidated total assets of the Borrower and its Subsidiaries at the end of such fiscal quarter for all Immaterial Foreign Subsidiaries (and their respective Subsidiaries) in the aggregate; and (b) for the period of four fiscal quarters most recently ended for which the Borrower was required to deliver financial statements pursuant to Section 7.01(a) or (b), did not have (together with its Subsidiaries) Consolidated Revenues attributable to such Foreign Subsidiary for such period in excess of (i) [***] percent ([***]%) of Consolidated Revenues for such period for such Immaterial Foreign Subsidiary (and its Subsidiaries) and (ii) [***] percent ([***]%) of Consolidated Revenues for such period for all Immaterial Foreign Subsidiaries (and their respective Subsidiaries) in the aggregate; provided, that, no "Immaterial Foreign Subsidiary" shall (x) own, license or otherwise control Nefecon or any Intellectual Property or other rights associated with Nefecon or (y) conduct any Product Development and Commercialization Activities with respect to Nefecon; provided, further, that, any Subsidiary that would

otherwise be classified as an "Immaterial Foreign Subsidiary" pursuant to the terms and provisions of this definition shall not fail to be classified as an "Immaterial Foreign Subsidiary" due to personnel whose employment or consulting agreements are with such Immaterial Foreign Subsidiary conducting Product Development and Commercialization Activities with respect to Nefecon, on behalf of one or more Loan Parties.

"IND" means (a) (i) an investigational new drug application (as defined in the FDCA) that is required to be filed with the FDA before beginning clinical testing in human subjects, or any successor application or procedure; and (ii) any similar application or functional equivalent relating to any investigational new drug application applicable to or required by any country, jurisdiction or Governmental Authority other than the United States and (b) all supplements and amendments that may be filed with respect to the foregoing.

"Indebtedness" means, as to any Person at a particular time, without duplication, all of the following, whether or not included as indebtedness or liabilities in accordance with IFRS:

(a) all Funded Indebtedness;

(b) the Swap Termination Value of any Swap Contract;

(c) all Guarantees with respect to outstanding Indebtedness of the types specified in clauses (a) and (b) above of any other Person; and

(d) all Indebtedness of the types referred to in clauses (a) through (c) above of any partnership or joint venture (other than a joint venture that is itself a corporation or limited liability company) in which such Person or a Subsidiary thereof is a general partner or joint venturer, unless such Indebtedness is expressly made non-recourse to such Person or such Subsidiary.

For the avoidance of doubt, "Indebtedness" shall not include obligations or liabilities under any Permitted Equity Derivatives.

"Indemnified Taxes" has the meaning set forth in Section 3.01(a).

"Indemnitee" has the meaning set forth in Section 11.04(b).

"Indirect Lender" means any Person that is not a U.S. Person and either (a) directly holds equity interests in a Lender that is treated as a partnership or disregarded entity for United States federal income tax purposes or (b) directly holds equity interests in a U.S. Person that is treated as a partnership or disregarded entity for U.S. federal income tax purposes that, directly, or indirectly through entities each of which is treated as a partnership or disregarded entity for U.S. federal income tax purposes, holds equity interests in a Lender.

"Information" has the meaning set forth in Section 11.07.

"Infringement" and "Infringes" mean the infringement, misappropriation, or other violation of any Patents, Copyrights, Trademarks, know-how, trade secrets, confidential information, and/or other Intellectual Property.

"Intellectual Property" means all (a) Patents; (b) Trademarks and all applications, registrations and renewals thereof; (c) Copyrights and other works of authorship (registered or unregistered), and all applications, registrations and renewals thereof; (d) Regulatory Authorizations; (e) [reserved]; (f)

proprietary computer software, proprietary databases, domain registrations, pre-clinical and clinical data and documentation; (g) trade secrets and confidential information, whether patentable or unpatentable and whether or not reduced to practice, know-how, inventions, manufacturing processes and techniques, and research and development information; (h) [reserved]; (i) other intellectual property or similar proprietary rights; (j) copies and tangible embodiments of any of the foregoing (in whatever form or medium) within the custody or control of a relevant Person; (k) any and all improvements to any of the foregoing; and (l) all exclusive and nonexclusive licenses from third parties to use any of the foregoing intellectual property or rights to use any intellectual property owned or licensed by such third parties.

"Interest Payment Date" means (a) the last Business Day of each March, June, September and December and (b) the Maturity Date.

"Interest Rate" means a rate equal to nine percent (9.00%) per annum.

"Interim Financial Statements" means the unaudited consolidated financial statements of the Borrower and its Subsidiaries for the fiscal quarter ended September 30, 2023, including balance sheets and statements of operations, shareholders' equity and cash flows.

"Internal Revenue Code" means the United States Internal Revenue Code of 1986.

"Internal Revenue Service" means the United States Internal Revenue Service.

"Investment" means, as to any Person, any direct or indirect acquisition or investment by such Person, whether by means of (a) the purchase or other acquisition of Equity Interests of another Person, (b) a loan, advance or capital contribution to, Guarantee or assumption of debt of, or purchase or other acquisition of any other debt or equity participation or interest in, another Person, including any partnership or joint venture interest in such other Person and any arrangement pursuant to which the investor Guarantees Indebtedness of such other Person or (c) an Acquisition. For purposes of covenant compliance, the amount of any Investment shall be the amount actually invested, without adjustment for subsequent increases or decreases in the value of such Investment.

"Involuntary Disposition" means any loss of, damage to or destruction of, or any condemnation or other taking for public use of, any property of any Loan Party or any of its Subsidiaries.

"Joinder Agreement" means a joinder agreement substantially in the form of Exhibit C executed and delivered by a Subsidiary in accordance with the provisions of Section 7.12.

"Judgment Currency" has the meaning set forth in Section 11.20.

"Key Permits" means (a) all marketing authorizations issued by the FDA or EMA for Nefecon and (b) all other Permits relating to Nefecon, including all applicable Regulatory Authorizations, the loss of which could reasonably be expected to result, either individually or in the aggregate, in a material adverse effect on the commercialization of Nefecon in the United States.

"knowledge" means, with respect to any Loan Party or any Subsidiary, the knowledge of any Responsible Officer of such Loan Party or such Subsidiary, as the case may be.

"Laws" means, collectively, all international, foreign, federal, state and local statutes, treaties, rules, guidelines, regulations, ordinances, codes and administrative or judicial precedents or authorities, including the interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders, directed

duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority, in each case whether or not having the force of law.

"Legal Reservations" means:

(a) the principle that equitable remedies may be granted or refused at the discretion of a court and the limitation of enforcement by laws relating to insolvency, reorganization and other similar laws generally affecting the rights of creditors;

(b) the time barring of claims and defenses of set-off or counterclaim;

(c) similar principles, rights and defenses under the laws of any relevant jurisdiction;

(d) any limitation of recognition and application of foreign Laws as a result of order public;

(e) the making or the procuring of the appropriate registrations, filings, endorsements, notarization, stampings and/or notifications of the Swedish Collateral Documents and/or the Collateral in which Liens are granted thereunder; and

(f) any other matters which are set out as qualifications or reservations as to matters of law of general application in the LL Legal Opinion.

"Lenders" means each of the Persons identified as a "Lender" on the signature pages hereto, each other Person that becomes a "Lender" in accordance with this Agreement and their successors and assigns.

"Lending Office" means, as to any Lender, the office address of such Lender and, as appropriate, account of such Lender set forth on Schedule 11.02 or such other address or account as such Lender may from time to time notify the Borrower and the Administrative Agent.

"Lien" means any mortgage, pledge, hypothecation, assignment, deposit arrangement, encumbrance, lien (statutory or other), charge, or preference, priority or other security interest or preferential arrangement in the nature of a security interest of any kind or nature whatsoever (including any conditional sale or other title retention agreement, any easement, right of way or other encumbrance on title to real property, and any financing lease having substantially the same economic effect as any of the foregoing).

"LL Legal Opinion" has the meaning set forth in Section 5.01(b).

"Loan" means an extension of credit by a Lender to the Borrower under Article II in the form of a Term Loan.

"Loan Documents" means this Agreement, the Fee Letter, each Note, each Joinder Agreement, each Collateral Document and any other agreement, instrument or document designated by its terms as a "Loan Document".

"Loan Notice" means a notice of a Borrowing of Loans pursuant to Section 2.02(a), which shall be substantially in the form of Exhibit A.

"Loan Parties" means, collectively, the Borrower and each Guarantor.

"Make-Whole Amount" means, on any date of determination, with respect to any Loan that is repaid or required to be repaid, the amount, if any, by which (a) [***] exceeds (b) [***].

"Material Adverse Effect" means (a) a material adverse change in, or a material adverse effect upon, the business, assets, properties, liabilities (actual or contingent) or financial condition of the Borrower and its Subsidiaries (taken as a whole), (b) a material impairment of the rights and remedies, taken as a whole, of the Administrative Agent and the Lenders under the Loan Documents or a material impairment in the perfection or priority of the Administrative Agent's security interests in the Collateral (taken as a whole) (other than solely as a result of any sale, license or other disposition expressly permitted by this Agreement) or (c) a material impairment of the ability of the Loan Parties (taken as a whole) to perform their respective material obligations under Loan Documents to which they are a party.

"Material Contracts" means [***] all other contracts or agreements to which the Borrower or any Subsidiary is a party and the breach, nonperformance or cancellation of which, or the failure to renew could, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

"Material Indebtedness" has the meaning set forth in Section 9.01(e).

"Material Intellectual Property" means all items of Intellectual Property owned or licensed by any Loan Party that are, individually or in the aggregate, material to the commercialization of Nefecon.

"Material Regulatory Authorization" means any Regulatory Authorization where the failure to possess or maintain such Regulatory Authorization, or any restriction placed thereon, in either case, could reasonably be expected, either individually or in the aggregate, to result in (a) a material adverse effect on the commercialization of Nefecon or (b) a Material Adverse Effect.

"Material Subsidiary" means any Subsidiary that is not an Immaterial Foreign Subsidiary.

"Maturity Date" means December 31, 2027; provided, that, if such date is not a Business Day, the Maturity Date shall be the first Business Day immediately preceding such date.

"Maximum Rate" has the meaning set forth in Section 11.09.

"Moody's" means Moody's Investors Service, Inc. and any successor thereto.

"Mortgage" or "Mortgages" means, individually or collectively, as the context requires, each of the mortgages, deeds of trust or deeds to secure debt executed by a Loan Party that purport to grant to the Administrative Agent, for the benefit of the Secured Parties, a security interest in the fee interest of any Loan Party in real property (other than Excluded Property).

"Multiemployer Plan" means any employee benefit plan of the type described in Section 4001(a)(3) of ERISA, to which the Borrower or any ERISA Affiliate makes or is obligated to make contributions, or during the preceding five plan years, has made or been obligated to make contributions.

"Multiple Employer Plan" means a Plan which has two or more contributing sponsors (including the Borrower or any ERISA Affiliate) at least two of whom are not under common control, as such a plan is described in Section 4064 of ERISA.

"NDA" means a new drug application filed with the FDA pursuant to section 505(b) of the FDCA, along with all supplements and amendments thereto, and any similar application for marketing

authorization required by any country, jurisdiction or Governmental Authority other than the United States (including the FDA-equivalent in any other relevant jurisdiction).

"Nefecon" means the formulation of budesonide developed by or for the Borrower under the name "NEFECON®" for administration to patients with primary immunoglobulin A (IgA) nephropathy, and [***]. For the avoidance of doubt, "Nefecon" includes the formulation of budesonide for administration to patients with primary immunoglobulin A (IgA) nephropathy marketed in the United States under the trademark "TARPEYO®" and in other territories under other brand names or trademarks.

"Nefecon License" means any present or future outbound license of, or other grant of rights under, Intellectual Property relating to Nefecon entered into by the Borrower or any Subsidiary for purposes of Product Development and Commercialization Activities, including, but not limited to, any agreement related to any co-promotion, co-marketing or similar arrangement with respect to Nefecon.

"Net Cash Proceeds" means the aggregate cash or Cash Equivalents proceeds received by any Loan Party or any Subsidiary in respect of any Disposition (excluding, for the avoidance of doubt, any proceeds received in connection with any Permitted Transfers), Debt Issuance, Involuntary Disposition or Extraordinary Receipt, net of (a) reasonable direct costs incurred in connection therewith (including, without limitation, legal, accounting and investment banking fees, and sales commissions), (b) taxes paid or reasonably determined by the Borrower to be payable as a result thereof, and (c) in the case of any Disposition or Involuntary Disposition, the amount necessary to retire any Indebtedness secured by a Permitted Lien (ranking senior to any Lien of the Administrative Agent) on the related property; it being understood that "Net Cash Proceeds" shall include, without limitation, any cash or Cash Equivalents received upon the sale or other disposition of any non-cash consideration received by any Loan Party or any Subsidiary in any Disposition (excluding, for the avoidance of doubt, any proceeds received in connection with Permitted Transfers), Debt Issuance, Involuntary Disposition or Extraordinary Receipt.

"Non-Consenting Lender" means any Lender that does not approve any consent, waiver or amendment that (a) requires the approval of all Lenders or all affected Lenders in accordance with the terms of Section 11.01 and (b) has been approved by the Required Lenders.

"Not Otherwise Applied" means, with reference to any proceeds of any transaction or event that is proposed to be applied to a particular use or transaction, that such amount (a) was not required to prepay Loans pursuant to Section 2.03 and (b) has not previously been (and is not simultaneously being) applied to anything other than such particular use or transaction.

"Note" has the meaning set forth in Section 2.09.

"Obligations" means (a) all advances to, and debts, liabilities, obligations, covenants and duties of, any Loan Party arising under any Loan Document or otherwise with respect to any Loan and (b) all costs and expenses incurred in connection with enforcement and collection of the foregoing, including the fees, charges and disbursements of counsel, in each case, whether direct or indirect (including those acquired by assumption), absolute or contingent, due or to become due, now existing or hereafter arising and including interest and fees that accrue after the commencement by or against any Loan Party or any Affiliate thereof of any proceeding under any Debtor Relief Laws naming such Person as the debtor in such proceeding, regardless of whether such interest and fees are allowed claims in such proceeding.

"OFAC" means the Office of Foreign Assets Control of the United States Department of the Treasury.

"Organization Documents" means, (a) with respect to any corporation, the certificate or articles of incorporation and the bylaws (or equivalent or comparable constitutive documents with respect to any non-U.S. jurisdiction), (b) with respect to any limited liability company, the certificate or articles of formation or organization and operating agreement or limited liability company agreement (or equivalent or comparable documents with respect to any non-U.S. jurisdiction), and (c) with respect to any partnership, joint venture, trust or other form of business entity, the partnership, joint venture or other applicable agreement of formation or organization and any agreement, instrument, filing or notice with respect thereto filed in connection with its formation or organization with the applicable Governmental Authority in the jurisdiction of its formation or organization and, if applicable, any certificate or articles of formation or organization of such entity.

"Other Administrative Proceeding" means any administrative proceeding relating to a dispute involving a patent office or other relevant intellectual property registry which relates to validity, opposition, revocation, ownership or enforceability of the relevant Intellectual Property.

"Other Taxes" has the meaning set forth in Section 3.01(a).

"Outstanding Amount" means with respect to any Loans on any date, the aggregate outstanding principal amount thereof after giving effect to any borrowings and prepayments or repayments with respect to such Loans occurring on such date.

"Paragraph IV Certification" has the meaning specified in Section 6.17(c)(iii).

"Participant" has the meaning set forth in Section 11.06(e).

"Participant Register" has the meaning specified in Section 11.06(e).

"Participating Member States" means any member state of the European Union that adopts or has adopted the Euro as its lawful currency in accordance with legislation of the European Union relating to Economic and Monetary Union.

"Patents" means any patent rights of any kind, including any and all: patents (whether registered or not), patent applications or invention disclosures, as well as all divisions, continuations, continuations in-part, provisionals, continued prosecution applications, substitutions, reissues, reexaminations, inter partes review, renewals, extensions, adjustments, restorations, supplemental protection certificates and other additions in connection therewith, whether in or related to the United States or any foreign country or other jurisdiction, together with the right to claim the priority thereto and the right to sue for past infringement of any of the foregoing.

"PBGC" means the Pension Benefit Guaranty Corporation or any successor thereto.

"Pension Funding Rules" means the rules of the Internal Revenue Code and ERISA regarding minimum required contributions (including any installment payment thereof) to Pension Plans and set forth in Section 412, 430, 431, 432 and 436 of the Internal Revenue Code and Sections 302, 303, 304 and 305 of ERISA.

"Pension Plan" means any employee pension benefit plan (including a Multiple Employer Plan or a Multiemployer Plan) that is maintained or is contributed to by the Borrower and any ERISA Affiliate and is either covered by Title IV of ERISA or is subject to minimum funding standards under Section 412 of the Internal Revenue Code or any Swedish defined benefit pension plan or similar arrangement that

provides benefits on a defined benefit basis in the event of retirement or termination of employment that is not otherwise fully funded through insurance.

"Permits" means all Regulatory Authorizations, permits, licenses, registrations, certificates, accreditations, orders, approvals, authorizations, consents, waivers, franchises, variances and similar rights issued by or obtained from any Governmental Authority or any other Person, including, without limitation, those relating to Environmental Laws.

"Permitted Acquisition" means an Investment consisting of an Acquisition by a Loan Party; provided, that, (a) the property acquired (or the property of the Person acquired) in such Acquisition is used or useful in the same or a reasonably related or complementary line of business as the Borrower and its Subsidiaries were engaged in on the Closing Date (or any reasonable extensions or expansions thereof), (b) no Event of Default shall have occurred and be continuing or would result from such Acquisition, (c) the Administrative Agent shall have received all items in respect of the Equity Interests or property acquired in such Acquisition as and when required to be delivered by the terms of Section 7.12 and/or Section 7.14, (d) such Acquisition shall not be a "hostile" acquisition and shall have been approved by the Board of Directors and/or the shareholders (or equivalent) of the applicable Loan Party and the target of such Acquisition, (e) following written request by the Administrative Agent, the Borrower shall have delivered to the Administrative Agent *pro forma* financial statements for the Borrower and its Subsidiaries after giving effect to such Acquisition for the twelve month period ending as of the most recent fiscal quarter end in a form reasonably satisfactory to the Administrative Agent and (f) the representations and warranties made by the Loan Parties in each Loan Document shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) at and as if made as of the date of such Acquisition (after giving effect thereto) except to the extent any such representation and warranty expressly relates to an earlier date, in which case it shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) as of such earlier date.

"Permitted Convertible Bond Indebtedness" means Convertible Bond Indebtedness issued by the Borrower in an aggregate principal amount not to exceed [***] at any one time outstanding; provided, that, (a) such Convertible Bond Indebtedness shall be unsecured, (b) no Subsidiary shall Guarantee such Convertible Bond Indebtedness, (c) such Convertible Bond Indebtedness shall not mature, and no scheduled or mandatory principal payments, prepayments, cash settlements, repurchases, redemptions or sinking fund or like payments of such Convertible Bond Indebtedness shall be required at any time on or prior to the date that is one hundred and eighty-one days (181) days after the Maturity Date, other than (x) the settlement of conversions at the option of the holders thereof into Qualified Capital Stock plus cash, if any, in lieu of any fractional share, (y) any customary provisions granting the issuer thereof the right, but not the obligation, to redeem the same (it being understood that any exercise of such redemption right will be subject to Section 8.11), and (z) any customary upon a "change of control", "fundamental change" or similar provisions granting the holders of such Convertible Bond Indebtedness a right to require the repurchase of such Convertible Bond Indebtedness upon such event in circumstances that would also constitute a Change of Control under this Agreement, (d) such Convertible Bond Indebtedness shall (i) not include covenants and terms that are, taken as a whole, more restrictive on the Borrower and its Subsidiaries than the provisions of this Agreement (as determined by the Borrower in good faith) and (ii) [***], (e) such Convertible Bond Indebtedness shall include conversion, redemption and fundamental change provisions that are customary for convertible notes issued in public or "Rule 144A" offerings of convertible notes, as determined in good faith by the Borrower, (f) no Event of Default shall have occurred and be continuing at the time of incurrence of such Convertible Bond Indebtedness or could result therefrom, (g) such Convertible Bond Indebtedness shall include subordination provisions with respect to the Obligations on terms and conditions reasonably satisfactory to the Administrative Agent and (h) the Borrower shall have

delivered to the Administrative Agent a certificate of a Responsible Financial Officer of the Borrower certifying as to the foregoing clauses (a) through (f).

"Permitted Equity Derivative" means (a) any agreement or arrangement pursuant to which the Borrower acquires a bond hedge, call option, capped call option, forward, accelerated share repurchase or any similar derivative arrangement requiring the counterparty thereto to deliver to the Borrower Qualified Capital Stock of the Borrower, (b) any agreement or arrangement entered into concurrently with a transaction described in clause (a) pursuant to which, among other things, the Borrower issues to the counterparty thereto warrants to acquire Qualified Capital Stock of the Borrower, cash in lieu of delivering such Qualified Capital Stock or cash representing the termination value of such option, or a combination thereof upon settlement, exercise or early termination thereof, and (c) any share lending agreement or stock borrower facility with respect to the Borrower's Qualified Capital Stock on customary terms for any such agreement in connection with an issuance of Convertible Bond Indebtedness for an amount of Qualified Capital Stock of the Borrower no greater than the number of Qualified Capital Stock into which the related Permitted Convertible Bond Indebtedness may convert; provided, that, in all cases under clauses (a), (b), or (c), (x) such transaction is entered into by the Borrower in connection with any issuance or Permitted Refinancing of Permitted Convertible Bond Indebtedness (including in each case, without limitation, in connection with the exercise of any over-allotment or initial purchaser's (or initial purchasers') or underwriter's (or underwriters') option to purchase additional securities) and (y) the aggregate cash consideration paid to purchase (net of any cash consideration received) any Permitted Equity Derivatives shall not exceed the cash proceeds of the related Permitted Convertible Bond Indebtedness.

"Permitted Licenses" means (a) Permitted Nefecon Licenses, (b) Permitted Setanaxib Licenses, (c) [***].

"Permitted Liens" means, at any time, Liens in respect of property of any Loan Party or any of its Subsidiaries permitted to exist at such time pursuant to the terms of Section 8.01.

"Permitted Nefecon License" means (a) the Closing Date License Agreements and (b) any other Nefecon License entered into in the ordinary course of business; provided, that, [***].

"Permitted Refinancing" means, with respect to any Indebtedness, any refinancings, refundings, renewals or extensions thereof; provided, that, (i) the amount of such Indebtedness is not increased at the time of such refinancing, refunding, renewal or extension except by an amount equal to a reasonable premium or other reasonable amount paid, and fees and expenses reasonably incurred, in connection with such refinancing and by an amount equal to any existing commitments unutilized thereunder, (ii) the direct or any contingent obligor with respect thereto is not changed, as a result of or in connection with such refinancing, refunding, renewal or extension; (iii) such refinancing, refunding, renewing or extending Indebtedness has a later or equal final maturity and longer or equal weighted average life than the Indebtedness being refinanced, refunded, renewed or extended; (iv) if the Indebtedness being refinanced, refunded, renewed or extended is subordinated in right of payment to the Obligations, such refinancing, refunding, renewal or extension is subordinated in right of payment to the Obligations on terms, taken as a whole, as favorable in all material respects to the Lenders (including, if applicable, as to Collateral) as those contained in the documentation governing the Indebtedness being refinanced, refunded, renewed or extended; (v) if the Indebtedness being refinanced, refunded, renewed or extended is secured, such refinancing, refunding, renewal or extension is, if secured, subject to intercreditor arrangements on terms, taken as a whole, as favorable in all material respects to the Lenders (including as to the applicable Collateral) as those contained in the documentation governing the Indebtedness being refinanced, refunded, renewed or extended; (vi) the interest rate applicable to any such refinancing, refunding, renewing or extending Indebtedness does not exceed the then applicable market interest rate; and (vii) such refinancing, refunding, renewing or extending Indebtedness may not have guarantors, obligors or security in any case

more extensive than that which applied to the Indebtedness being refinanced, refunded, renewed or extended.

"Permitted Setanaxib License" means any Setanaxib License, including licenses granted to suppliers and subcontractors in the ordinary course of business; provided, that, with respect to each such Setanaxib License, [***].

"Permitted Transfers" has the meaning set forth in the definition of "Disposition".

"Person" means any natural person, corporation, limited liability company, trust, unincorporated organization, joint venture, association, company, partnership, Governmental Authority or any other legal entity, whether acting in an individual, fiduciary or other capacity.

"Personal Information" means (a) all information that could reveal the identity of any natural Person and (b) all other information regarding natural Persons the collection, use, or disclosure of which is subject to applicable Privacy Laws, including without limitation information regarding patient care or payment for patient care.

"PHSA" means the Public Health Service Act (or any successor thereto) and each Swedish Law and ordinance applicable to health services, in each case, as amended from time to time, and the rules, regulations, guidelines, guidance documents and compliance policy guides issued or promulgated thereunder.

"Plan" means any employee benefit plan within the meaning of Section 3(3) of ERISA (including a Pension Plan) or any Swedish employee benefit plan, in either case, maintained for employees of the Borrower or any ERISA Affiliate or any such Plan to which the Borrower or any ERISA Affiliate is required to contribute on behalf of any of its employees.

"Pledge Agreement" means that certain U.S. pledge agreement dated as of the Closing Date executed in favor of the Administrative Agent, for the benefit of the Secured Parties, by each of the Loan Parties, as amended or modified from time to time in accordance with the terms hereof.

"Privacy Laws" means all Laws applicable to the privacy or security of individually identifiable information of any patient or individual, including without limitation HIPAA, the EU General Data Protection Regulation (EU) 2016/679 (GDPR) and equivalent Laws in other jurisdictions.

"Product" means Nefecon (including those Nefecon products set forth on Schedule 1.01 (as supplemented from time to time in accordance with the terms of this Agreement)); provided, that, if the Loan Parties shall fail to comply with their obligations under this Agreement to give notice to the Administrative Agent and update Schedule 1.01 prior to the first commercial launch of any new Nefecon product, any such improperly undisclosed Product shall be deemed to be included in this definition.

"Product Agreement" means each agreement, license, document, instrument, interest (equity or otherwise) or the like under which one or more parties grants or receives any right, title or interest with respect to any Product Development and Commercialization Activities in respect of one or more Products specified therein or to exclude third parties from engaging in, or otherwise restricting any right, title or interest as to any Product Development and Commercialization Activities with respect thereto, including each contract or agreement with suppliers, manufacturers, pharmaceutical companies, distributors, clinical research organizations, hospitals, group purchasing organizations, wholesalers, pharmacies or any other Person related to any such entity, in each case, solely to the extent a counterparty to such Product Agreement is in direct privity with a Loan Party or a Subsidiary.

"Product Authorizations" means any and all approvals, licenses, notifications, registrations or authorizations of any Governmental Authority for the testing, manufacture, development, distribution, use, storage, import, export, transport, promotion, marketing, sale or commercialization of a Product in any country or jurisdiction, including without limitation registration and listing, INDs, NDAs, ANDAs and similar applications.

"Product Development and Commercialization Activities" means, with respect to any Product, any combination of research, development, manufacture, import, use, sale, licensing, importation, storage, labeling, marketing, promotion, supply, distribution, testing, packaging, purchasing or other commercialization activities, receipt of payment in respect of any of the foregoing, or like activities the purpose of which is to develop or commercially exploit such Product.

"Product Distributor" means any Person that, pursuant to a Product Agreement, is engaged in any commercialization activities with respect to the Products.

"Public Borrower Materials" has the meaning set forth in Section 7.02.

"Qualified Capital Stock" of any Person means any Equity Interests of such Person (other than, for the avoidance of doubt, any Convertible Bond Indebtedness) that are not Disqualified Capital Stock.

"Qualified Equity Issuance" means any issuance of the Borrower's Qualified Capital Stock occurring after the Closing Date and not more than three (3) months prior to the applicable Restricted Payment to be made in reliance on Section 8.06(e).

"Qualified Equity Issuance Proceeds" means the net cash proceeds received by the Borrower from any Qualified Equity Issuance to the extent such net cash proceeds are Not Otherwise Applied.

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"Real Property Security Documents" means with respect to the fee interest of any Loan Party in any real property:

(a) a fully executed and notarized Mortgage encumbering the fee interest of such Loan Party in such real property;

(b) if requested by the Administrative Agent in its sole discretion, maps or plats of an as-built survey of the sites of such real property certified to the Administrative Agent and the title insurance company issuing the policies referred to in clause (c) of this definition in a manner satisfactory to each of the Administrative Agent and such title insurance company, dated a date satisfactory to each of the Administrative Agent and such title insurance company by an independent professional licensed land surveyor, which maps or plats and the surveys on which they are based shall be sufficient to delete any standard printed survey exception contained in the applicable title policy and be made in accordance with the Minimum Standard Detail Requirements for Land Title Surveys jointly established and adopted by the American Land Title Association and the National Society of Professional Surveyors, Inc. in 2016 with items 2, 3, 4, 6(b), 7(a), 7(b)(1), 7(c), 8, 9, 10, 11, 13, 14, 16,17, 18 and 19 on Table A thereof completed;

(c) ALTA mortgagee title insurance policies issued by a title insurance company acceptable to the Administrative Agent with respect to such real property, assuring the Administrative Agent that the Mortgage covering such real property creates a valid and enforceable first priority mortgage lien on such real property, free and clear of all defects and encumbrances except Permitted Liens, which title insurance policies shall otherwise be in form and substance satisfactory to the Administrative Agent and shall include such endorsements as are requested by the Administrative Agent;

(d) (i) a completed "Life-of-Loan" Federal Emergency Management Agency Standard Flood Hazard Determination with respect to such real property (together with a notice about special flood hazard area status and flood disaster assistance duly executed by each Loan Party relating thereto) and (ii) if such real property is a Flood Hazard Property, (A) notices to (and confirmations of receipt by) such Loan Party as to the existence of a special flood hazard and, if applicable, the unavailability of flood hazard insurance under the National Flood Insurance Program and (B) evidence of applicable flood insurance, if available, in each case in such form, on such terms and in such amounts as required by The National Flood Insurance Reform Act of 1994 or as otherwise required by the Administrative Agent;

(e) if requested by the Administrative Agent in its sole discretion, an environmental assessment report as to such real property, in form and substance and from professional firms acceptable to the Administrative Agent;

(f) if requested by the Administrative Agent in its sole discretion, evidence reasonably satisfactory to the Administrative Agent that such real property, and the uses of such real property, are in compliance in all material respects with all applicable zoning laws (the evidence submitted as to which should include the zoning designation made for such real property, the permitted uses of such real property under such zoning designation and, if available, zoning requirements as to parking, lot size, ingress, egress and building setbacks); and

(g) if requested by the Administrative Agent in its sole discretion, an opinion of legal counsel to the Loan Party granting the Mortgage on such real property, addressed to the Administrative Agent and each Lender, in form and substance reasonably acceptable to the Administrative Agent.

"Recipient" means the Administrative Agent, any Lender, and any other recipient of any payment by or on account of any obligation of any Loan Party under any Loan Document.

"Register" has the meaning set forth in Section 11.06(c).

"Regulatory Agencies" means any Governmental Authority that is concerned with the use, control, safety, efficacy, reliability, manufacturing, marketing, distribution, sale or other Product Development and Commercialization Activities relating to any Product, including CMS, FDA, DEA, EMA, and all similar agencies in other jurisdictions, and includes Standard Bodies.

"Regulatory Authorizations" means all approvals, clearances, notifications, authorizations, orders, exemptions, registrations, certifications, licenses and permits granted by, submitted to or filed with any Regulatory Agencies, including all Product Authorizations.

"Related Parties" means, with respect to any Person, such Person's Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors, sub-advisors and representatives of such Person and of such Person's Affiliates.

"Reportable Event" means any of the events set forth in Section 4043(c) of ERISA, other than events for which the thirty-day notice period has been waived.

"Required Lenders" means, at any time, Lenders having Total Credit Exposures representing more than fifty percent (50%) of the Total Credit Exposures of all Lenders. The Total Credit Exposure of any Defaulting Lender shall be disregarded in determining Required Lenders at any time.

"Resolution Authority" means an EEA Resolution Authority or, with respect to any UK Financial Institution, a UK Resolution Authority.

"Responsible Financial Officer" means the chief executive officer, president or chief financial officer or any comparable officer of the Borrower or the chief executive officer or president of any Loan Party other than the Borrower. Any document delivered hereunder that is signed by a Responsible Financial Officer of a Loan Party shall be conclusively presumed to have been authorized by all necessary corporate, partnership and/or other action on the part of such Loan Party and such Responsible Financial Officer shall be conclusively presumed to have acted on behalf of such Loan Party.

"Responsible Officer" means the chief executive officer, president, chief financial officer, chief medical officer, chief scientific officer or general counsel of the Borrower or the chief executive officer or president of any Loan Party other than the Borrower and, solely for purposes of the delivery of certificates pursuant to Sections 5.01 or 7.12(b), the secretary or any assistant secretary of a Loan Party. Any document delivered hereunder that is signed by a Responsible Officer of a Loan Party shall be conclusively presumed to have been authorized by all necessary corporate, partnership and/or other action on the part of such Loan Party and such Responsible Officer shall be conclusively presumed to have acted on behalf of such Loan Party.

"Restricted" means, when referring to cash or Cash Equivalents of the Loan Parties, that such cash or Cash Equivalents (a) appear (or would be required to appear) as "restricted" on a consolidated balance sheet of the Borrower and its Subsidiaries as determined in accordance with IFRS (other than as a result of the Liens of the Administrative Agent for the benefit of the Secured Parties) or (b) are subject to any Lien in favor of any Person (other than bankers' liens and rights of setoff) other than the Administrative Agent for the benefit of the Secured Parties.

"Restricted Payment" means (a) any dividend or other distribution, direct or indirect, on account of any shares (or equivalent) of any class of Equity Interests of any Loan Party or any Subsidiary, now or hereafter outstanding, (b) any redemption, retirement, sinking fund or similar payment, purchase or other acquisition for value, direct or indirect, of any shares (or equivalent) of any class of Equity Interests of any Loan Party or any Subsidiary, now or hereafter outstanding, (c) any payment made to retire, or to obtain the surrender of, any outstanding warrants, options or other rights to acquire shares of any class of Equity Interests of any Loan Party or any Subsidiary, now or hereafter outstanding and (d) any payment made in cash to the holders of Convertible Bond Indebtedness in excess of the original principal (or notional) amount thereof, interest thereon and any fees due thereunder.

"S&P" means Standard & Poor's Financial Services LLC, a subsidiary of S&P Global, Inc., and any successor thereto.

"Safety Notice" means any product recall, field notification, safety alert, correction, withdrawal, warning, "dear doctor" letter, investigator notice, "serious adverse event" report, clinical hold, marketing suspension, removal from the market, material label change request or the like which could reasonably be expected, either individually or in the aggregate, to result in (a) a material adverse effect on the commercialization of Nefecon or (b) a Material Adverse Effect.

"Sale and Leaseback Transaction" means, with respect to any Loan Party or any Subsidiary, any arrangement, directly or indirectly, with any Person whereby the Loan Party or such Subsidiary shall sell or transfer any property used or useful in its business, whether now owned or hereafter acquired, and thereafter rent or lease such property or other property that it intends to use for substantially the same purpose or purposes as the property being sold or transferred.

"Sanction(s)" means any sanction administered or enforced by the United States government (including, without limitation, OFAC), the United Nations Security Council, the European Union, His Majesty's Treasury ("HMT") or other relevant sanctions authority.

"SEC" means the Securities and Exchange Commission, or any Governmental Authority succeeding to any of its principal functions.

"Secured Parties" means, collectively, the Administrative Agent, the Lenders, the Indemnitees and each co-agent or sub-agent appointed by the Administrative Agent from time to time pursuant to Section 10.05.

"Securities Act" means the Securities Act of 1933.

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"Security Agreement" means the security agreement dated as of the Closing Date executed in favor of the Administrative Agent, for the benefit of the Secured Parties, by each of the Loan Parties, as amended or modified from time to time in accordance with the terms hereof.

"Setanaxib" means the compound designated with the International Nonproprietary Name "setanaxib" currently being investigated inter alia in primary biliary cholangitis and squamous cell carcinoma of the head and neck, [***]; provided, that, for the avoidance of doubt, "Setanaxib" shall not include Nefecon or any Intellectual Property or other rights associated with Nefecon.

[***].

"Setanaxib License" means any present or future outbound license of, or other grant of rights under, Intellectual Property relating to Setanaxib entered into by the Borrower or any Subsidiary [***]; provided, that, no "Setanaxib License" shall include Nefecon or any Intellectual Property or other rights associated with Nefecon.

"Solvent" or "Solvency" means, with respect to any Person as of a particular date, that on such date (a) such Person is able to pay its debts and other liabilities, contingent obligations and other commitments as they mature in the ordinary course of business, (b) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person's ability to pay as such debts and liabilities mature in their ordinary course, (c) such Person is not engaged in a business or a transaction, and is not about to engage in a business or a transaction, for which such Person's property would constitute unreasonably small capital after giving due consideration to the prevailing practice in the industry in which such Person is engaged or is to engage, (d) the fair value of the property of such Person is greater than the total amount of liabilities, including, without limitation, contingent liabilities, of such Person and (e) the present fair salable value of the assets of such Person is not less than the amount that will be required to pay the probable

liability of such Person on its debts as they become absolute and matured. In computing the amount of contingent liabilities at any time, it is intended that such liabilities will be computed at the amount which, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

"*Soulte*" means, in relation to the enforcement of any relevant French Collateral occurring by way of appropriation (including pursuant to a *pacte commissoire* or any similar enforcement mechanism) or judicial foreclosure of the French Securities Account Pledge Agreement, the amount by which the value of the pledged assets appropriated or foreclosed pursuant to that enforcement of the relevant French Collateral exceeds the amount of obligations secured by the French Securities Account Pledge Agreement which is discharged as a result of that enforcement of the relevant French Collateral being carried out.

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"Specified Event of Default" means any Event of Default under Section 9.01(a), Section 9.01(f) or Section 9.01(g).

"Standard Bodies" means any of the organizations that create, sponsor or maintain safety, quality or other standards, including ISO, ANSI, CEN and SCC and the like.

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"Subsidiary" of a Person means a corporation, partnership, joint venture, limited liability company or other business entity of which a majority of the shares of Voting Stock is at the time beneficially owned, or the management of which is otherwise controlled, directly, or indirectly through one or more intermediaries, or both, by such Person. Unless otherwise specified, all references herein to a "Subsidiary" or to "Subsidiaries" shall refer to a Subsidiary or Subsidiaries of the Borrower.

"Swap Contract" means (a) any and all rate swap transactions, basis swaps, credit derivative transactions, forward rate transactions, commodity swaps, commodity options, forward commodity contracts, equity or equity index swaps or options, bond or bond price or bond index swaps or options or forward bond or forward bond price or forward bond index transactions, interest rate options, forward foreign exchange transactions, cap transactions, floor transactions, collar transactions, currency swap transactions, cross-currency rate swap transactions, currency options, spot contracts, or any other similar transactions or any combination of any of the foregoing (including any options to enter into any of the foregoing), whether or not any such transaction is governed by or subject to any master agreement, and (b) any and all transactions of any kind, and the related confirmations, which are subject to the terms and conditions of, or governed by, any form of master agreement published by the International Swaps and Derivatives Association, Inc., any International Foreign Exchange Master Agreement, or any other master agreement (any such master agreement, together with any related schedules, a "Master Agreement"), including any such obligations or liabilities under any Master Agreement; provided, that, "Swap Contract" shall not include any Permitted Equity Derivatives.

"Swap Termination Value" means, in respect of any one or more Swap Contracts, after taking into account the effect of any legally enforceable netting agreement relating to such Swap Contracts, (a) for any date on or after the date such Swap Contracts have been closed out and termination value(s) determined in accordance therewith, such termination value(s) and (b) for any date prior to the date referenced in clause (a), the amount(s) determined as the mark-to-market value(s) for such Swap Contracts, as determined based upon one or more mid-market or other readily available quotations provided by any recognized dealer in such Swap Contracts (which may include a Lender or any Affiliate of a Lender).

"Swedish Collateral Documents" means (a) a Swedish law governed share pledge agreement between the Borrower and the Administrative Agent regarding the shares in Nefecon AB (reg. no. 556604-9069), (b) a Swedish law governed trademark pledge agreement between the Borrower and the Administrative Agent regarding certain trademarks listed therein and (c) with respect to the Borrower or any Swedish Guarantor, such additional security documents as shall be required by the Administrative Agent in accordance with Section 7.14 and such other security documents as may be executed and delivered by the Borrower or any Swedish Guarantor pursuant to the terms of Section 7.14 or Section 7.21.

"Swedish Guarantor" has the meaning set forth in Section 1.06(e).

"Swedish Recipient" has the meaning set forth in Section 1.06(b).

"Synthetic Lease" means any synthetic lease, tax retention operating lease, off-balance sheet loan or similar off-balance sheet financing arrangement whereby the arrangement is considered borrowed money indebtedness for tax purposes but is classified as an operating lease or does not otherwise appear on a balance sheet under IFRS.

"Systems" means any device or combination thereof that contains data and Personal Information, including any physical and electronic data information storage services and systems and in particular those that use, access, store or disclose Personal Information.

"Targit License" means that certain License and Transfer Agreement dated June 28, 2011, between the Borrower and Kyowa Kirin Services Ltd., f/k/a Archimedes Development Ltd, as may be amended or otherwise modified from time to time in a manner not materially adverse to the Administrative Agent or any Lender.

"Term Facility" means, at any time, (a) on or prior to the Closing Date, the aggregate amount of the Commitments at such time and (b) thereafter, the aggregate principal amount of the Term Loans of all Lenders outstanding at such time.

"Term Loan" has the meaning set forth in Section 2.01.

"Test Date" means March 31, June 30, September 30 and December 31 of each calendar year.

"Third Party" means any Person other than the Borrower or any Subsidiary or Affiliate thereof.

"Threshold Amount" means [***].

"Total Credit Exposure" means, as to any Lender at any time, the unused Commitments of such Lender and the Outstanding Amount of all Loans of such Lender at such time.

"Trademarks" means any statutory or common law trademark, service mark, trade name, logo, symbol, trade dress, domain name, corporate name or other indicator of source or origin or identifies the goods and services of one provider from another, and all applications and registrations therefor, together with all of the goodwill associated therewith.

"Treasury Regulations" means the regulations, including temporary regulations, promulgated by the United States Treasury Department under the Internal Revenue Code, as such regulations may be amended from time to time (including the corresponding provisions of any future regulations).

"UK Financial Institution" means any BRRD Undertaking (as such term is defined under the PRA Rulebook (as amended form time to time) promulgated by the United Kingdom Prudential Regulation Authority) or any person falling within IFPRU 11.6 of the FCA Handbook (as amended from time to time) promulgated by the United Kingdom Financial Conduct Authority, which includes certain credit institutions and investment firms, and certain affiliates of such credit institutions or investment firms.

"UK Resolution Authority" means the Bank of England or any other public administrative authority having responsibility for the resolution of any UK Financial Institution.

"Uniform Commercial Code" means the Uniform Commercial Code as in effect in the State of New York; provided, that, if perfection or the effect of perfection or non-perfection or the priority of any security interest in any Collateral is governed by the Uniform Commercial Code as in effect in a jurisdiction other than the State of New York, "Uniform Commercial Code" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions hereof or of the other Loan Documents relating to such perfection, effect of perfection or non-perfection or priority.

"United States" and "U.S." mean the United States of America.

"Unrestricted Cash" means, at any time, cash and Cash Equivalents of the Loan Parties (without duplication) that are not Restricted at such time.

"U.S. Loan Party" means each Guarantor that is a Domestic Subsidiary.

"U.S. Person" means any "United States person" as defined in Section 7701(a)(30) of the Internal Revenue Code.

"Voting Stock" means, with respect to any Person, Equity Interests issued by such Person the holders of which are ordinarily, in the absence of contingencies, entitled to vote for the election of directors (or persons performing similar functions) of such Person, even though the right so to vote has been suspended by the happening of such a contingency.

"Wholly Owned Subsidiary" means any Person 100% of whose Equity Interests are at the time owned by the Borrower directly or indirectly through other Persons 100% of whose Equity Interests are at the time owned, directly or indirectly, by the Borrower. Unless otherwise specified, all references herein to a "Wholly Owned Subsidiary" or to "Wholly Owned Subsidiaries" shall refer to a Wholly Owned Subsidiary or Wholly Owned Subsidiaries of the Borrower.

"Withholding Agent" means any Loan Party, the Administrative Agent and any other Person required by applicable Law to withhold or deduct amounts from a payment made by or on account of any obligation of any Loan Party under any Loan Document.

"Work" means any work or subject matter that is subject to protection pursuant to Title 17 of the United States Code.

"Write-Down and Conversion Powers" means, (a) with respect to any EEA Resolution Authority, the write-down and conversion powers of such EEA Resolution Authority from time to time under the Bail-In Legislation for the applicable EEA Member Country, which write-down and conversion powers are described in the EU Bail-In Legislation Schedule, and (b) with respect to the United Kingdom, any powers of the applicable Resolution Authority under the Bail-In Legislation to cancel, reduce, modify or change the form of a liability of any UK Financial Institution or any contract or instrument under which that liability arises, to convert all or part of that liability into shares, securities or obligations of that person or any other

person, to provide that any such contract or instrument is to have effect as if a right had been exercised under it or to suspend any obligation in respect of that liability or any of the powers under that Bail-In Legislation that are related to or ancillary to any of those powers.

1.02 Other Interpretive Provisions.

With reference to this Agreement and each other Loan Document, unless otherwise specified herein or in such other Loan Document:

(a) The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." The word "will" shall be construed to have the same meaning and effect as the word "shall." Unless the context requires otherwise, (i) any definition of or reference to any agreement, instrument or other document (including the Loan Documents and any Organization Document) shall be construed as referring to such agreement, instrument or other document as from time to time amended, modified, extended, restated, replaced or supplemented from time to time (subject to any restrictions set forth herein or in any other Loan Document), (ii) any reference herein to any Person shall be construed to include such Person's successors and assigns, (iii) the words "hereto", "herein," "hereof" and "hereunder," and words of similar import when used in any Loan Document, shall be construed to refer to such Loan Document in its entirety and not to any particular provision thereof, (iv) all references in any Loan Document to Articles, Sections, Preliminary Statements, Exhibits and Schedules shall be construed to refer to Articles and Sections of, and Preliminary Statements, Exhibits and Schedules to, the Loan Document in which such references appear, (v) any reference to any law shall include all statutory and regulatory provisions consolidating, amending, replacing or interpreting such law and any reference to any law or regulation shall, unless otherwise specified, refer to such law or regulation as amended, modified, extended, restated, replaced or supplemented from time to time, and (vi) the words "asset" and "property" shall be construed to have the same meaning and effect and to refer to any and all real and personal property and tangible and intangible assets and properties, including cash, securities, accounts and contract rights.

(b) In the computation of periods of time from a specified date to a later specified date, the word "from" means "from and including;" the words "to" and "until" each mean "to but excluding;" and the word "through" means "to and including."

(c) Section headings herein and in the other Loan Documents are included for convenience of reference only and shall not affect the interpretation of this Agreement or any other Loan Document.

(d) Any reference herein or in any other Loan Document to a merger, transfer, consolidation, amalgamation, assignment, sale, disposition or transfer, or similar term, shall be deemed to apply to a division of or by a limited liability company, or an allocation of assets to a series of a limited liability company (or the unwinding of such a division or allocation), as if it were a merger, transfer, consolidation, amalgamation, assignment, sale, disposition or transfer, or similar term, as applicable, to, of or with a separate Person. Any division of a limited liability company shall constitute a separate Person hereunder (and each division of any limited liability company that is a Subsidiary, joint venture or any other like term shall also constitute such a Person or entity).

1.03 Accounting Terms.

(a) Generally. All accounting terms not specifically or completely defined herein shall be construed in conformity with, and all financial data (including financial ratios and other financial calculations) required to be submitted pursuant to this Agreement shall be prepared in conformity with, IFRS applied on a consistent basis, as in effect from time to time, applied in a manner consistent with that used in preparing the Audited Financial Statements, except as otherwise specifically prescribed herein. Notwithstanding the foregoing, for purposes of determining compliance with any covenant (including the computation of any financial covenant) contained herein, (i) Indebtedness of the Borrower and its Subsidiaries shall be deemed to be carried at one hundred percent (100%) of the outstanding principal amount thereof, and the effects of IFRS on financial liabilities to the contrary shall be disregarded, and (ii) all terms of an accounting or financial nature used herein shall be construed, and all computations of amounts and ratios referred to herein shall be made, without giving effect to any election under IFRS to value any Indebtedness of the Borrower or any Subsidiary at "fair value", as defined therein.

(b) Changes in IFRS. The Borrower shall provide a written summary of material changes in IFRS and in the consistent application thereof with each Compliance Certificate delivered in connection with the annual and quarterly financial statement required to be delivered in accordance with Section 7.01. If at any time any change in IFRS would affect the computation of any financial ratio or requirement set forth in any Loan Document, and either the Borrower or the Required Lenders shall so request, the Administrative Agent, the Lenders and the Borrower shall negotiate in good faith to amend such ratio or requirement to preserve the original intent thereof in light of such change in IFRS (subject to the approval of the Borrower and the Required Lenders); provided, that, until so amended, (i) such ratio or requirement shall continue to be computed in accordance with IFRS prior to such change therein, and (ii) the Borrower shall provide to the Administrative Agent and the Lenders financial statements and other documents reasonably requested by the Administrative Agent or the Required Lenders setting forth a reconciliation between calculations of such ratio or requirement made before and after giving effect to such change in IFRS.

(c) Calculations. For purposes of all calculations hereunder, the principal amount of Convertible Bond Indebtedness shall be the outstanding principal (or notional) amount thereof, valued at par.

(d) Consolidation of Variable Interest Rate Entities. All references herein to consolidated financial statements of the Borrower and its Subsidiaries or to the determination of any amount for the Borrower and its Subsidiaries on a consolidated basis or any similar reference shall, in each case, be deemed to include each variable interest entity that the Borrower is required to consolidate pursuant to IFRS as if such variable interest entity were a Subsidiary as defined herein.

1.04 Times of Day.

Unless otherwise specified, all references herein to times of day shall be references to Eastern time (daylight or standard, as applicable).

1.05 Currency Equivalents.

Wherever in this Agreement in connection with a Borrowing, a repayment or a prepayment of a Loan, an amount, such as a required minimum or multiple amount, is expressed in Dollars, but such Borrowing or Loan is denominated in Euro, such amount shall be the relevant Euro Equivalent of such

Dollar amount (rounded to the nearest unit of Euros, with 0.5 of a unit being rounded upward), as determined by the Administrative Agent.

1.06 Swedish Terms.

(a) Without prejudice to the generality of any provision of this Agreement, in this Agreement where it relates to a person established or incorporated in Sweden or governed by Swedish law or the context so requires, a reference to:

(i) a "composition", "assignment" or similar arrangement with any creditor includes a *företagsrekonstruktion, konkursförfarande,* or *ackordsuppgörelse* under the Swedish Bankruptcy Act (*konkurslagen (1987:672)*) or the Swedish Reorganisation Act (*lag om företagsrekonstruktion (2022:964)*) (as the case may be), and any write-down of debt in bankruptcy (*ackord i konkurs*) under the Swedish Bankruptcy Act (*Konkurslag (1987:672)*);

(ii) a "receiver" or "administrator" includes a *förvaltare, företagsrekonstruktör, likvidator* or *god man* under Swedish law;

(iii) a "guarantee" includes any "*garanti"* under Swedish law which is independent from the debt to which it relates and any *borgen* under Swedish law which is accessory to or dependent on the debt to which it relates;

(iv) a "merger" includes any fusion implemented in accordance with Chapter 23 of the Swedish Companies Act; and

(v) a "winding-up**"**, "administration" or "dissolution" includes a *frivillig likvidation*, or *tvångslikvidation* under Chapter 25 of the Swedish Companies Act.

(b) If any party incorporated in Sweden is required by this Agreement to hold an amount of money on trust for another party (the "Swedish Recipient"), then such requirement will be interpreted as an obligation on that person to act as agent for the Swedish Recipient and to hold such amount on a separate account and to promptly pay or transfer such amount to the Swedish Recipient.

(c) For the avoidance of doubt, any novation effected in accordance with this Agreement shall, in relation to any security governed by Swedish law, take effect as an assignment and assumption and transfer of such security interests. Each transfer and assignment shall include a proportionate part of the security created under the Collateral Documents governed by Swedish law.

(d) Notwithstanding any other provision of the Loan Documents, the release of any perfected security over any assets created pursuant to a Swedish Collateral Document or disposal of (including, without limitation, any conversion, set-off or forgiveness of indebtedness), payment or by way of merger of shares or assets which are subject to perfected security under a Swedish Collateral Document or transfer of any assets, property and/or interests subject to such perfected security, in each case, to the extent such security is governed by Swedish law, will be subject to the prior written consent of the Administrative Agent. Each Secured Party irrevocably authorizes the Administrative Agent to release such security governed by Swedish law without notification or further reference to the Secured Parties.

(e) Notwithstanding any other provision of the Loan Documents, the obligations and liabilities of any Guarantor incorporated under the laws of Sweden (a "Swedish Guarantor") under the Loan Documents to which it is a party shall be limited if (and only if) and to the extent required by (i) an application of the provisions of Chapter 17 (or its equivalent from time to time) of the Swedish Companies Act (*Aktiebolagslagen (2005:551)*) regulating distribution of assets (including profits and dividends and any other form of transfer of value (*värdeöverföring*) within the meaning of the Swedish Companies Act); (ii) prohibited loans, security and guarantees pursuant to Chapter 21, Section 1 to 3 of the Swedish Companies Act, or (iii) financial assistance within the meaning of Chapter 21, Section 5 (or its equivalents from time to time) of the Swedish Companies Act and it is agreed that the obligations and liabilities of each Swedish Guarantor under any Loan Document to which it is a party shall apply only to the maximum extent permitted by the aforementioned provisions of the Swedish Companies Act and each Swedish Guarantor's obligations and liabilities shall be limited in accordance herewith.

1.07 Reporting Obligations.

Notwithstanding anything to the contrary herein or in any other Loan Document (including any reporting obligations set forth in Article VII), in respect of its undertakings under this Agreement and the other Loan Documents, the Borrower shall only be required to supply documents, details or information to the extent that the Borrower, by supplying such documents, details or information, would not breach any applicable mandatory laws or regulations or any undertaking made to any exchange on which the Borrower's shares or other securities are listed; provided, that, the Borrower has taken reasonable steps in order to overcome any such breach (for example, by entering into non-disclosure agreements or insider lists).

ARTICLE II

THE COMMITMENTS

2.01 Commitments. Subject to the terms and conditions set forth herein and in reliance upon the representations and warranties of the Loan Parties set forth herein, each Lender severally and not jointly agrees to make a single loan (each such loan, a "Term Loan") to the Borrower, in Euros, on the Closing Date in an aggregate amount not to exceed such Lender's Commitment. The Borrowing on the Closing Date shall consist of Term Loans made simultaneously by the Lenders in accordance with their respective Commitments. Borrowings repaid or prepaid may not be reborrowed.

2.02 Borrowings.

(a) The Borrowing on the Closing Date shall be made upon the Borrower's irrevocable notice (in the form of a written Loan Notice, appropriately completed and signed by a Responsible Financial Officer of the Borrower) to the Administrative Agent, which must be given not later than 9:00 a.m. on the date three (3) Business Days prior to the Closing Date. The Loan Notice shall specify (i) the requested date of the Borrowing (which shall be a Business Day) and (ii) the principal amount of Loans to be borrowed.

(b) Following receipt of the Loan Notice, the Administrative Agent shall promptly notify each Lender of the amount of its Applicable Percentage of the applicable Loans. Each Lender shall make the amount of its Loan available to the Administrative Agent in immediately available funds at the Administrative Agent's Office not later than 1:00 p.m. on the Business Day specified in the Loan Notice. Upon satisfaction of the applicable conditions set forth in Section 5.02 and Section 5.01, the Administrative Agent shall make all funds so received available to the

Borrower in like funds as received by the Administrative Agent by wire transfer of such funds in accordance with instructions provided to (and acceptable to) the Administrative Agent by the Borrower.

2.03 Prepayments.

(a) Voluntary Prepayments. Subject to the payment of any repayment premium as required under Section 2.03(d), the exit fee required under Section 2.07(b) and any other fees or amounts payable hereunder at such time, the Borrower may, upon written notice from the Borrower to the Administrative Agent, voluntarily prepay the Loans, in Euros, in whole or in part; provided, that, (i) such notice must be received not later than 11:00 a.m. three (3) Business Days prior to the date of prepayment and (ii) any such prepayment shall be in a principal amount of €[***] or a whole multiple of €[***] in excess thereof (or, if less, the entire principal amount thereof then outstanding). Each such notice shall specify the date and amount of such prepayment. If such notice is given by the Borrower, the Borrower shall make such prepayment and the payment amount specified in such notice shall be due and payable on the date specified therein; provided, that, if such notice expressly states that it is conditioned upon the effectiveness of other credit facilities or the closing of a specified transaction, such notice may be revoked by the Borrower (by notice in writing to the Administrative Agent on or prior to the specified effective date) if such condition is not satisfied. Any prepayment pursuant to this Section 2.03(a) shall be accompanied by (x) all accrued interest on the principal amount of the Loans prepaid, (y) the repayment premium required under Section 2.03(d) and the exit fee required under Section 2.07(b) and (z) all fees, costs, expenses, indemnities and other amounts due and payable hereunder at the time of prepayment. The principal component of each such prepayment of the Loans shall be applied to the principal repayment installments thereof under Section 2.05 as elected by the Borrower in writing (or, if not so elected in the direct order of maturity). Each such prepayment shall be applied to the Loans of the Lenders in accordance with their respective Applicable Percentages in respect of the Term Facility.

(b) Mandatory Prepayments of Loans.

(i) Dispositions and Involuntary Dispositions. The Borrower shall promptly (and, in any event, within five (5) Business Days) prepay the Loans, in Euros, in an aggregate amount equal to [***]% of the Net Cash Proceeds of all Dispositions and Involuntary Dispositions received by any Loan Party or any Subsidiary to the extent (x) such Net Cash Proceeds are not invested or otherwise used to purchase Eligible Assets within [***] of the date of such Disposition or Involuntary Disposition and (y) after deducting all such investments and applications in respect of Eligible Assets during such [***] period, the aggregate Net Cash Proceeds of all Dispositions and Involuntary Dispositions received by the Loan Parties and their Subsidiaries in the then current fiscal year exceeds [***] in the aggregate. Any prepayment pursuant to this clause (i) shall be applied as set forth in clause (iv) below.

(ii) Extraordinary Receipts.

(A) The Borrower shall promptly (and, in any event, within five (5) Business Days) upon the receipt by any Loan Party or any Subsidiary of the Net Cash Proceeds of any Extraordinary Receipt (other than any Extraordinary Receipt (Nefecon)), prepay the Loans, in Euros, in an aggregate amount equal to [***]% of such Net Cash Proceeds to the extent that (x) such Net Cash Proceeds are not invested or otherwise used to purchase Eligible Assets within [***] of the

date of such Extraordinary Receipt and (y) after deducting all such investments and applications in respect of Eligible Assets during such [***] period, the aggregate Net Cash Proceeds of all Extraordinary Receipts received by the Loan Parties and their Subsidiaries in the then current fiscal year exceeds [***] in the aggregate.

(B) The Borrower shall promptly (and, in any event, within five (5) Business Days) upon the receipt by any Loan Party or any Subsidiary of the Net Cash Proceeds of any Extraordinary Receipt (Nefecon), prepay the Loans, in Euros, in an aggregate amount equal to [***]% of such Net Cash Proceeds.

Any prepayment pursuant to this clause (ii) shall be applied as set forth in clause (iv) below.

(iii) Debt Issuance. The Borrower shall promptly (and, in any event, within three (3) Business Days) upon the receipt by any Loan Party or any Subsidiary of the Net Cash Proceeds of any Debt Issuance, prepay the Loans, in Euros, in an aggregate amount equal to [***]% of such Net Cash Proceeds. Any prepayment pursuant to this clause (iii) shall be applied as set forth in clause (iv) below.

(iv) Application of Mandatory Prepayments. All payments under this Section 2.03(b) shall be applied first to all fees (other than, for the avoidance of doubt, the exit fee required under Section 2.07(b)), costs, expenses, indemnities and other amounts due and payable hereunder, then proportionately (based on the relation of such amounts to the total amount of the relevant payment under this Section 2.03(b)) to the payment or prepayment (as applicable) of the following amounts of the Obligations: default interest, if any, repayment premium required by Section 2.03(d) and the exit fee required by Section 2.07(b), accrued interest and principal. The principal component of each such prepayment of the Loans shall be applied to the principal repayment installments thereof under Section 2.05 as elected by the Borrower in writing (or, if not so elected in the direct order of maturity). Each such prepayment shall be applied to the Loans of the Lenders in accordance with their respective Applicable Percentages in respect of the Term Facility.

(c) Change of Control. Upon the occurrence of a Change of Control, the Borrower shall, at the direction of the Required Lenders, and may, at its option upon five (5) Business Days prior written notice from the Borrower to the Administrative Agent, prepay the Outstanding Amount of the Loans, together with all accrued and unpaid interest thereon plus the repayment premium required by Section 2.03(d) (if applicable) and the exit fee required by Section 2.07(b) plus all other Obligations (other than contingent indemnification obligations for which no claim has been asserted), in each case, in Euros. Each such direction or notice shall specify the date and amount of such prepayment. If such direction or notice is given, the Borrower shall make such prepayment and the payment amount specified in such direction or notice shall be due and payable on the date specified therein. Each prepayment under this Section 2.03(c) shall be applied to the Loans of the Lenders in accordance with their respective Applicable Percentages.

(d) Repayment Premiums. Notwithstanding anything to the contrary in this Agreement or any other Loan Document, if all or any portion of the principal amount of any Loans are repaid or prepaid, or required to be repaid or prepaid, at any time on or prior to the [***]anniversary of the Closing Date, pursuant to this Section 2.03, Article IX or otherwise, then, in all such cases, the Borrower shall pay to the Administrative Agent, for the respective ratable accounts of the Lenders, on the date on which such repayment is paid or prepaid or required to be

paid or prepaid, in addition to the other Obligations so repaid or required to be repaid or prepaid, a repayment premium in an amount equal to the Make-Whole Amount with respect to such repayment or prepayment.

2.04 Termination of Commitments. The Commitments will be automatically and permanently reduced to zero upon the Borrowing on the Closing Date pursuant to Section 2.01.

2.05 Repayment of Loans. The Borrower shall repay the outstanding principal amount of the Loans, in Euros, in installments on the dates set forth below, in each case, in the respective amounts set forth in the table below (which amounts shall be reduced as a result of the application of prepayments in accordance with the order of priority set forth in Section 2.03(a) and Section 2.03(b)(iv)), unless accelerated sooner pursuant to Section 9.02:

Payment Dates	Principal Amortization Payment
December 31, 2026	€[***]
March 31, 2027	€[***]
June 30, 2027	€[***]
September 30, 2027	€[***]
Maturity Date	Outstanding Principal Balance of Loans

provided, however, that, (x) notwithstanding anything to the contrary set forth in this Agreement, the final principal repayment installment of the Loans shall be repaid on the Maturity Date and in any event shall be in an amount equal to the aggregate principal amount of all Loans outstanding on such date, together with all accrued and unpaid interest thereon and all other outstanding Obligations, and (y) if any principal repayment installment to be repaid by the Borrower shall come due on a day other than a Business Day, such principal repayment installment shall be due on the first Business Day immediately preceding such day.

2.06 Interest.

(a) Pre-Default Rate. Subject to the provisions of clause (b) and clause (c) below, each Loan shall bear interest on the outstanding principal amount thereof (for the avoidance of doubt, based on the stated principal amount thereof without reducing such amount by any applicable original issue discount) from the applicable borrowing date thereof at a rate per annum equal to the Interest Rate.

(b) Default Rate. (i) Upon the occurrence and during the existence of any Event of Default, all outstanding Obligations shall thereafter bear interest at an interest rate per annum at all times equal to the Interest Rate plus [***] per annum (the "Default Rate"), to the fullest extent permitted by applicable Laws and (ii) accrued and unpaid interest on past due amounts (including interest on past due interest) shall be due and payable in cash on demand.

(c) Interest Generally. Interest on each Loan shall be due and payable in arrears on each Interest Payment Date and at such other times as may be specified herein. All interest shall be due and payable in cash. Interest hereunder shall be due and payable in accordance with the terms hereof before and after judgment, and before and after the commencement of any proceeding under any Debtor Relief Law. Each determination of an interest rate by the Administrative Agent pursuant to any provision of this Agreement shall be determinative in the absence of manifest error.

2.07 Fees.

(a) Fee Letter. The Borrower shall pay to the Administrative Agent, the Lenders and their respective Affiliates for their own respective accounts fees and original issue discount in the amounts and at the times specified in the Fee Letter. Such fees and original issue discount shall be fully earned when paid and shall be non-refundable for any reason whatsoever.

(b) Exit Fees. Upon the prepayment or repayment of all or any portion of the principal amount of the Loans (or upon the date any such prepayment or repayment is required to be paid), whether pursuant to Section 2.03, Section 2.05, Section 9.02 or otherwise, the Borrower shall pay to the Lenders, for their respective ratable accounts, on the date on which such prepayment or repayment is paid or required to be paid, as the case may be, in addition to the other Obligations so prepaid, repaid or required to be prepaid or repaid, an exit fee in an amount equal to the Applicable Exit Fee Percentage of the principal amount of the Loans prepaid, repaid or required to be prepaid or repaid, as the case may be, on such date.

2.08 Computation of Interest.

All computations of interest shall be made on the basis of a 360-day year and actual days elapsed. Interest shall accrue on each Loan for the day on which such Loan is made, and shall not accrue on a Loan, or any portion thereof, for the day on which such Loan or such portion is paid.

2.09 Evidence of Debt.

The Loans made by each Lender shall be evidenced by one or more accounts or records maintained by such Lender in the ordinary course of business. The accounts or records maintained by each Lender shall be conclusive absent manifest error of the amount of Loans made by the Lenders to the Borrower and the interest and payments thereon. Any failure to so record or any error in doing so shall not, however, limit or otherwise affect the obligation of the Borrower hereunder to pay any amount owing with respect to the Obligations. Upon the request of any Lender made through the Administrative Agent, the Borrower shall execute and deliver to such Lender a promissory note, which shall evidence such Lender's Loans in addition to such accounts or records. Each such promissory note shall be in the form of Exhibit B (a "Note"). Each Lender may attach schedules to its Note and endorse thereon the date, amount and maturity of its Loans and payments with respect thereto.

2.10 Payments Generally.

(a) General. All payments to be made by the Borrower shall be made free and clear of and without condition or deduction for any counterclaim, defense, recoupment or setoff. Subject to Section 9.03, all payments of principal, interest, repayment premiums and fees on the Loans and all other Obligations payable by any Loan Party under the Loan Documents shall be due, without any presentment thereof, directly to the Lenders, at the respective Lending Offices of the Lenders; provided, that, if at the time of any such payment a Lender is a Defaulting Lender, such Defaulting Lender's *pro rata* share of such payment shall be made directly to the Administrative Agent. The Loan Parties will make such payments in Euros, in immediately available funds not later than 2:00 p.m. on the date due, marked for attention as indicated, or in such other manner or to such other account in any United States bank as the Lenders may from time to time direct in writing. Without limiting the generality of the foregoing, the Lenders may require that any payments due under this Agreement be made in the United States. If, for any reason, the Borrower is prohibited by any Law from making any required payment hereunder in Euros, the Borrower shall make such payment in Dollars in the Dollar Equivalent of the Euro payment amount. All payments received by the

Lenders after 2:00 p.m. shall be deemed received on the next succeeding Business Day and any applicable interest or fee shall continue to accrue. If any payment to be made by the Borrower shall come due on a day other than a Business Day, payment shall be made on the next following Business Day, and such extension of time shall be reflected in computing interest.

(b) Obligations of Lenders Several. The obligations of the Lenders hereunder to make the Loans and to make payments pursuant to Section 11.04(c) are several and not joint. The failure of any Lender to make any Loan or to make any payment under Section 11.04(c) on any date required hereunder shall not relieve any other Lender of its corresponding obligation to do so on such date, and no Lender shall be responsible for the failure of any other Lender to so make a Loan or to make its payment under Section 11.04(c).

(c) Funding Source. Nothing herein shall be deemed to obligate any Lender to obtain the funds for the making of any Loan in any particular place or manner or to constitute a representation by any Lender that it has obtained or will obtain the funds for the making of any Loan in any particular place or manner.

2.11 Sharing of Payments by Lenders.

If any Lender shall, by exercising any right of setoff or otherwise, obtain payment in respect of any principal of or interest on its Loans or repayment premium or exit fee in connection therewith resulting in such Lender's receiving payment of a proportion of the aggregate amount of the Loans and accrued interest thereon and repayment premium or exit fee in connection therewith greater than its *pro rata* share thereof as provided herein, then the Lender shall (a) notify the Administrative Agent of such fact and (b) purchase (for cash at face value) participations in the Loans of the other Lenders pursuant to documentation satisfactory to the Administrative Agent, or make such other adjustments as shall be equitable, so that the benefit of all such payments shall be shared by the Lenders ratably in accordance with the aggregate amount of principal of, accrued interest on and repayment premium or exit fee in connection with their respective Loans and other amounts owing them; provided, that:

(i) if any such participations are purchased and all or any portion of the payment giving rise thereto is recovered, such participations shall be rescinded and the purchase price restored to the extent of such recovery, without interest; and

(ii) the provisions of this Section 2.11 shall not be construed to apply to (x) any payment made by or on behalf of the Borrower pursuant to and in accordance with the express terms of this Agreement (including the application of funds arising from the existence of a Defaulting Lender) or (y) any payment obtained by a Lender as consideration for the assignment of or sale of a participation in any of its Loans to any assignee or participant, other than an assignment to the Borrower or any Subsidiary (as to which the provisions of this Section 2.11 shall apply).

Each Loan Party consents to the foregoing and agrees, to the extent it may effectively do so under applicable Law, that any Lender acquiring a participation pursuant to the foregoing arrangements may exercise against such Loan Party rights of setoff and counterclaim with respect to such participation as fully as if such Lender were a direct creditor of such Loan Party in the amount of such participation.

2.12 Defaulting Lenders.

(a) Adjustments. Notwithstanding anything to the contrary contained in this Agreement, if any Lender becomes a Defaulting Lender, then, until such time as that Lender is no longer a Defaulting Lender, to the extent permitted by applicable Law:

(i) Waivers and Amendment. The Defaulting Lender's right to approve or disapprove any amendment, waiver or consent with respect to this Agreement shall be restricted as set forth in Section 11.01.

(ii) Reallocation of Payments. Any payment of principal, interest, fees or other amounts received by the Administrative Agent for the account of that Defaulting Lender (whether voluntary or mandatory, at maturity, pursuant to Article IX or otherwise, and including any amounts made available to the Administrative Agent by that Defaulting Lender pursuant to Section 11.08), shall be applied at such time or times as may be determined by the Administrative Agent as follows: first, to the payment of any amounts owing by that Defaulting Lender to the Administrative Agent hereunder; second, as the Borrower may request (so long as no Default or Event of Default exists), to the funding of any Loan in respect of which that Defaulting Lender has failed to fund its portion thereof as required by this Agreement, as determined by the Administrative Agent; third, if so determined by the Administrative Agent and the Borrower, to be held in a non-interest bearing deposit account and released in order to satisfy obligations of that Defaulting Lender to fund Loans under this Agreement; fourth, to the payment of any amounts owing to the Lenders as a result of any judgment of a court of competent jurisdiction obtained by any Lender against that Defaulting Lender as a result of that Defaulting Lender's breach of its obligations under this Agreement; fifth, so long as no Default or Event of Default exists, to the payment of any amounts owing to the Borrower as a result of any judgment of a court of competent jurisdiction obtained by the Borrower against that Defaulting Lender as a result of that Defaulting Lender's breach of its obligations under this Agreement; and sixth, to that Defaulting Lender or as otherwise directed by a court of competent jurisdiction; provided, that, if (x) such payment is a payment of the principal amount of any Loans in respect of which that Defaulting Lender has not fully funded its appropriate share and (y) such Loans were made at a time when the conditions set forth in Section 5.02 were satisfied or waived, such payment shall be applied solely to pay the Loans of all non-Defaulting Lenders on a pro rata basis prior to being applied to the payment of any Loans of that Defaulting Lender. Any payments, prepayments or other amounts paid or payable to a Defaulting Lender that are applied (or held) to pay amounts owed by a Defaulting Lender pursuant to this Section 2.12(a)(ii) shall be deemed paid to and redirected by that Defaulting Lender, and each Lender irrevocably consents hereto.

(b) Defaulting Lender Cure. If the Borrower and the Administrative Agent agree in writing in their sole discretion that a Defaulting Lender should no longer be deemed to be a Defaulting Lender, the Administrative Agent will so notify the parties hereto, whereupon as of the effective date specified in such notice and subject to any conditions set forth therein, that Lender will cease to be a Defaulting Lender; provided, that, no adjustments will be made retroactively with respect to fees accrued or payments made by or on behalf of the Borrower while that Lender was a Defaulting Lender; provided, further, that, except to the extent otherwise expressly agreed by the affected parties, no change hereunder from Defaulting Lender to Lender will constitute a waiver or release of any claim of any party hereunder arising from that Lender having been a Defaulting Lender.

ARTICLE III

TAXES, INCREASED COSTS AND YIELD PROTECTION

3.01 Taxes.

(a) All payments of principal and interest on the Loans and all other amounts payable hereunder shall be made free and clear of and without deduction for any present or future income, excise, stamp, documentary, property or franchise taxes and other taxes, fees, duties, levies, assessments, withholdings or other charges of any nature whatsoever (including interest and penalties thereon) imposed by any taxing authority, except as required by applicable law. If any withholding or deduction of any present or future income, excise, stamp, documentary, property or franchise taxes and other taxes, fees, duties, levies, assessments, withholdings or other charges of any nature whatsoever (including interest and penalties thereon) imposed by any taxing authority from any payment by or on account of any obligation of any Loan Party hereunder is required pursuant to any applicable law, then (i) the applicable Withholding Agent shall be entitled to make such withholding or deduction and shall pay directly to the relevant Governmental Authority the full amount required to be so withheld or deducted, (ii) the applicable Withholding Agent shall promptly forward to the Administrative Agent an official receipt or other documentation satisfactory to the Administrative Agent evidencing such payment to such Governmental Authority and (iii) the sum payable by the applicable Loan Party shall be increased by such additional amount or amounts as is necessary to ensure that the net amount actually received by the applicable Recipient will equal the full amount such Recipient would have received had no such withholding or deduction for present or future income, excise, stamp, documentary, property or franchise taxes and other taxes, fees, duties, levies, assessments, withholdings or other charges of any nature whatsoever (including interest and penalties thereon) imposed by any taxing authority (including such withholdings or deductions applicable to additional sums payable under this Section 3.01) been required, excluding (w) taxes attributable to a Recipient's failure to comply with Section 3.01(c) or (d), (x) taxes imposed on or measured by net income (however denominated), franchise taxes, and branch profits taxes, in each case, (i) imposed by the jurisdiction under which a Recipient is organized, has its principal office, or, in the case of any Lender, has its applicable Lending Office, or has any present or former connection (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document), (y) in the case of a Lender, U.S. federal withholding taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Loan or Commitment pursuant to a Law in effect on the date on which (i) such Lender acquires such interest in the Loan or Commitment (other than pursuant to an assignment request by the Borrower pursuant to Section 11.13) or (ii) such Lender changes its Lending Office, except in each case to the extent that, pursuant to this Section 3.01, amounts with respect to such taxes were payable either to such Lender's assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its Lending Office and (z) withholding tax imposed under FATCA (all non-excluded items being called "Indemnified Taxes"). Notwithstanding anything to the contrary in the preceding sentence, Indemnified Taxes shall include any withholding tax imposed at any time on payments made by or on behalf of a Foreign Loan Party to any Recipient hereunder or under any other Loan Document. Further, the Loan Parties agree to pay any and all present or future stamp, court or documentary, intangible, recording, filing or similar taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to any of the Loan Documents, other than taxes imposed as a result of a present or former connection between a

Recipient and the jurisdiction imposing such tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document) (all such taxes hereinafter referred to as "Other Taxes").

(b) If, due to a change in Sections 871(h) or 881(c) of the Internal Revenue Code (or any successor provisions) after the date a Person becomes an Indirect Lender under this Agreement, any withholding is required to be made by a Lender or any Affiliate thereof to such Indirect Lender attributable to payments made by any Loan Party hereunder, such Loan Party shall pay to such Lender such additional amount or amounts as is necessary to ensure that the net amount actually received by any Indirect Lender will equal the full amount such Lender would have received had no such withholding or deduction been required; provided, that, in the event additional amounts are due in respect of an Indirect Lender, immediately before such Indirect Lender transfers a direct or indirect interest in a Lender to a transferee and withholding is required to be made by a Lender or any Affiliate to such transferee Indirect Lender attributable to payments to be made by any Loan Party hereunder, a Loan Party shall be required to pay additional amounts pursuant to this Section 3.01 in an amount not exceeding the additional amounts payable prior to the transfer by the transferor Indirect Lender; provided, further, that, no such additional amounts shall be payable by a Loan Party to the extent such withholding could have been avoided by any Indirect Lender and each entity in the chain of ownership between such Indirect Lender and the Lender providing Internal Revenue Service Forms W-9, W-8ECI, W-8BEN, W-8BEN-E or W-8IMY (as applicable) or any successor forms thereto, to the Lender or other entity in the chain of ownership between such Indirect Lender and the Lender, as applicable.

(c) The Loan Parties shall indemnify each Recipient, within ten (10) days after written demand therefor, for the full amount of any Indemnified Taxes and Other Taxes (including Indemnified Taxes and Other Taxes imposed on or attributable to amounts payable under this Section 3.01) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes or Other Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to the Borrower by a Lender (with a copy to the Administrative Agent), or by the Administrative Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error.

(d) Any Lender that is entitled to an exemption from or reduction of withholding tax with respect to payments made under any Loan Document shall deliver to the Borrower and the Administrative Agent, at the time or times reasonably requested by the Borrower or the Administrative Agent, such properly completed and executed documentation reasonably requested by the Borrower or the Administrative Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by the Borrower or the Administrative Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by the Borrower or the Administrative Agent as will enable the Borrower or the Administrative Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements, including FATCA. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation shall not be required if in the Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender. Solely

for purposes of this clause (d), FATCA shall include any amendments made to FATCA after the date of this Agreement.

(e) Each Lender agrees that if any form or certification it previously delivered pursuant to this Section 3.01 expires or becomes obsolete or inaccurate in any respect, it shall promptly update such form or certification or promptly notify the Administrative Agent and the Borrower of its inability to do so.

(f) If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any taxes as to which it has been indemnified pursuant to this Section 3.01 (including by the payment of additional amounts pursuant to this Section 3.01), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under this Section 3.01 with respect to the taxes giving rise to such refund), net of all out-of-pocket expenses (including taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this clause (f) (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this clause (f), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this clause (f) the payment of which would place the indemnified party in a less favorable net after-tax position than the indemnified party would have been in if the tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such tax had never been paid. This paragraph shall not be construed to require any indemnified party to make available its tax returns (or any other information relating to its taxes that it deems confidential) to the indemnifying party or any other Person.

(g) Each Lender shall severally indemnify the Administrative Agent, within ten (10) days after demand therefor, for (i) any Indemnified Taxes or Other Taxes attributable to such Lender (but only to the extent that the Loan Parties have not already indemnified the Administrative Agent for such Indemnified Taxes or Other Taxes and without limiting the obligation of the Loan Parties to do so), (ii) any taxes attributable to such Lender's failure to comply with the provisions of Section 11.06(e) relating to the maintenance of a Participant Register and (iii) any taxes that are excluded from the definition of Indemnified Taxes attributable to such Lender, in each case, that are payable or paid by the Administrative Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to any Lender by the Administrative Agent shall be conclusive absent manifest error. Each Lender hereby authorizes the Administrative Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by the Administrative Agent to the Lender from any other source against any amount due to the Administrative Agent under this clause (g).

3.02 Increased Costs.

(a) Increased Costs Generally. If any Change in Law shall:

(i) impose, modify or deem applicable any reserve, special deposit, compulsory loan, insurance charge or similar requirement against assets of, deposits with or for the account of, or credit extended or participated in by, any Lender;

(ii) subject any Recipient to any taxes (other than (A) Indemnified Taxes and Other Taxes that are covered by Section 3.01(a) and (B) taxes that are excluded from the definition of Indemnified Taxes in Section 3.01(a)) on its loans, loan principal, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto; or

(iii) impose on any Lender or the applicable interbank market any other condition, cost or expense (other than taxes) affecting this Agreement;

and the result of any of the foregoing shall be to increase the cost to such Lender of making or maintaining any Loan (or of maintaining its obligation to make any Loan), then, upon written demand of such Lender, the Borrower will pay to such Lender, as the case may be, such additional amount or amounts as will compensate such Lender, as the case may be, for such additional costs incurred or reduction suffered.

(b) Capital Requirements. If any Lender determines that any Change in Law affecting such Lender or any Lending Office of such Lender or such Lender's holding company, if any, regarding capital or liquidity requirements has or would have the effect of reducing the rate of return on such Lender's capital or on the capital of such Lender's holding company, if any, as a consequence of this Agreement, the Commitments of such Lender or the Loans made by such Lender to a level below that which such Lender or such Lender's holding company could have achieved but for such Change in Law (taking into consideration such Lender's policies and the policies of such Lender's holding company with respect to capital adequacy), then from time to time the Borrower will pay to such Lender, as the case may be, such additional amount or amounts as will compensate such Lender or such Lender's holding company for any such reduction suffered.

(c) Certificates for Reimbursement. A certificate of a Lender setting forth the amount or amounts necessary to compensate such Lender or its holding company, as the case may be, as specified in clause (a) or (b) of this Section 3.02 and delivered to the Borrower shall be conclusive absent manifest error. The Borrower shall pay such Lender the amount shown as due on any such certificate within ten (10) days after receipt thereof.

(d) Delay in Requests. Failure or delay on the part of any Lender to demand compensation pursuant to the foregoing provisions of this Section 3.02 shall not constitute a waiver of such Lender's right to demand such compensation, provided, that, the Borrower shall not be required to compensate a Lender pursuant to the foregoing provisions of this Section 3.02 for any increased costs incurred or reductions suffered more than nine (9) months prior to the date that such Lender notifies the Borrower of the Change in Law giving rise to such increased costs or reductions and of such Lender's intention to claim compensation therefor (except that, if the Change in Law giving rise to such increased costs or reductions is retroactive, then the nine-month period referred to above shall be extended to include the period of retroactive effect thereof).

3.03 Mitigation Obligations; Replacement of Lenders.

(a) Designation of a Different Lending Office. If any Lender requests compensation under Section 3.02 or requires the Borrower to pay any Indemnified Taxes or additional amounts to any Lender or any Governmental Authority for the account of any Lender pursuant to Section 3.01 or if any Lender gives a notice pursuant to Section 3.02, then at the request of the Borrower such Lender shall, as applicable, use reasonable efforts to designate a different Lending Office for funding or booking its Loans hereunder or to assign its rights and obligations hereunder to another of its offices, branches or affiliates, if, in the judgment of such Lender, such designation or

assignment (i) would eliminate or reduce amounts payable pursuant to Section 3.01 or 3.02, as the case may be, in the future, or eliminate the need for the notice pursuant to Section 3.04, as applicable, and (ii) in each case, would not subject such Lender, as the case may be, to any unreimbursed cost or expense and would not otherwise be disadvantageous to such Lender. The Borrower hereby agrees to pay all reasonable costs and expenses incurred by any Lender in connection with any such designation or assignment.

(b) Replacement of Lenders. If any Lender requests compensation under Section 3.02, or if the Borrower is required to pay any Indemnified Taxes or additional amounts to any Lender or any Governmental Authority for the account of any Lender pursuant to Section 3.01 and, in each case, such Lender has declined or is unable to designate a different Lending Office in accordance with Section 3.03(a), the Borrower may replace such Lender in accordance with Section 11.13.

3.04 Illegality.

If any Lender determines that any Law has made it unlawful, or that any Governmental Authority has asserted that it is unlawful, for any Lender or its Lending Office to perform any of its obligations hereunder or to make, maintain or fund or charge interest with respect to any Loan, or any Governmental Authority has imposed material restrictions on the authority of such Lender to purchase or sell, or to take deposits of, Dollars in the applicable interbank market, then, on notice thereof by such Lender to the Borrower through the Administrative Agent, any obligation of such Lender to issue, make, maintain, fund or charge interest with respect to any such Loan or to make any such Loan shall be suspended until such Lender notifies the Administrative Agent and the Borrower that the circumstances giving rise to such determination no longer exist. Upon receipt of such notice, the Borrower shall, upon demand from such Lender (with a copy to the Administrative Agent), prepay the Loans of such Lender immediately.

3.05 Survival.

All of the Borrower's obligations under this Article III shall survive termination of the Commitments and the Loan Documents, repayment of all Obligations and resignation of the Administrative Agent.

ARTICLE IV

GUARANTY

4.01 The Guaranty.

Each of the Guarantors hereby jointly and severally guarantees to each Secured Party and the Administrative Agent as hereinafter provided, as primary obligor and not as surety, the prompt payment of the Obligations in full when due (whether at stated maturity, as a mandatory prepayment, by acceleration or otherwise) strictly in accordance with the terms thereof. The Guarantors hereby further agree that if any of the Obligations are not paid in full when due (whether at stated maturity, as a mandatory prepayment, by acceleration or otherwise), the Guarantors will, jointly and severally, promptly pay the same, without any demand or notice whatsoever, and that in the case of any extension of time of payment or renewal of any of the Obligations, the same will be promptly paid in full when due (whether at extended maturity, as a mandatory prepayment, by acceleration or otherwise) in accordance with the terms of such extension or renewal.

Notwithstanding any provision to the contrary contained herein or in any other of the Loan Documents, the obligations of each Guarantor under this Agreement and the other Loan Documents shall

be limited to an aggregate amount equal to the largest amount that would not render such obligations subject to avoidance under the Debtor Relief Laws or any comparable provisions of any applicable state law.

4.02 Obligations Unconditional.

The obligations of the Guarantors under Section 4.01 are joint and several, absolute and unconditional, irrespective of the value, genuineness, validity, regularity or enforceability of any of the Loan Documents, or any other agreement or instrument referred to therein, or any substitution, release, impairment or exchange of any other guarantee of or security for any of the Obligations, and, to the fullest extent permitted by applicable law, irrespective of any law or regulation or other circumstance whatsoever which might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor, it being the intent of this Section 4.02 that the obligations of the Guarantors hereunder shall be absolute and unconditional under any and all circumstances. Each Guarantor agrees that such Guarantor shall have no right of subrogation, indemnity, reimbursement or contribution against the Borrower or any other Guarantor for amounts paid under this Article IV until such time as the Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been paid in full and the Commitments have expired or terminated. Without limiting the generality of the foregoing, it is agreed that, to the fullest extent permitted by law, the occurrence of any one or more of the following shall not alter or impair the liability of any Guarantor hereunder, which shall remain absolute and unconditional as described above:

(a) at any time or from time to time, without notice to any Guarantor, the time for any performance of or compliance with any of the Obligations shall be extended, or such performance or compliance shall be waived;

(b) any of the acts mentioned in any of the provisions of any of the Loan Documents, or any other agreement or instrument referred to in the Loan Documents shall be done or omitted;

(c) the maturity of any of the Obligations shall be accelerated, or any of the Obligations shall be modified, supplemented or amended in any respect, or any right under any of the Loan Documents, or any other agreement or instrument referred to in the Loan Documents shall be waived or any other guarantee of any of the Obligations or any security therefor shall be released, impaired or exchanged in whole or in part or otherwise dealt with;

(d) any Lien granted to, or in favor of, any Secured Party as security for any of the Obligations shall fail to attach or be perfected; or

(e) any of the Obligations shall be determined to be void or voidable (including, without limitation, for the benefit of any creditor of any Guarantor) or shall be subordinated to the claims of any Person (including, without limitation, any creditor of any Guarantor).

With respect to its obligations hereunder, each Guarantor hereby expressly waives diligence, presentment, demand of payment, protest and all notices whatsoever, and any requirement that the Secured Parties exhaust any right, power or remedy or proceed against any Person under any of the Loan Documents, or any other agreement or instrument referred to in the Loan Documents, or against any other Person under any other guarantee of, or security for, any of the Obligations.

4.03 Reinstatement.

The obligations of the Guarantors under this Article IV shall be automatically reinstated if and to the extent that for any reason any payment by or on behalf of any Person in respect of the Obligations is

rescinded or must be otherwise restored by any Secured Party, whether as a result of any proceedings in bankruptcy or reorganization or otherwise, and each Guarantor agrees that it will indemnify the Secured Parties on demand for all reasonable costs and expenses (including, without limitation, the fees, charges and disbursements of counsel) incurred by the Secured Parties in connection with such rescission or restoration, including any such costs and expenses incurred in defending against any claim alleging that such payment constituted a preference, fraudulent transfer or similar payment under any bankruptcy, insolvency or similar law.

4.04 Certain Additional Waivers.

Each Guarantor agrees that such Guarantor shall have no right of recourse to security for the Obligations, except through the exercise of rights of subrogation pursuant to Section 4.02 and through the exercise of rights of contribution pursuant to Section 4.06.

4.05 Remedies.

The Guarantors agree that, to the fullest extent permitted by law, as between the Guarantors, on the one hand, and the Secured Parties, on the other hand, the Obligations may be declared to be forthwith due and payable as provided in Section 9.02 (and shall be deemed to have become automatically due and payable in the circumstances provided in said Section 9.02) for purposes of Section 4.01 notwithstanding any stay, injunction or other prohibition preventing such declaration (or preventing the Obligations from becoming automatically due and payable) as against any other Person and that, in the event of such declaration (or the Obligations being deemed to have become automatically due and payable), the Obligations (whether or not due and payable by any other Person) shall forthwith become due and payable by the Guarantors for purposes of Section 4.01. The Guarantors acknowledge and agree that their obligations hereunder are secured in accordance with the terms of the Collateral Documents and that the Secured Parties may exercise their remedies thereunder in accordance with the terms thereof.

4.06 Rights of Contribution.

The Guarantors agree among themselves that, in connection with payments made hereunder, each Guarantor shall have contribution rights against the other Guarantors as permitted under applicable law. Such contribution rights shall be subordinate and subject in right of payment to the obligations of such Guarantors under the Loan Documents and no Guarantor shall exercise such rights of contribution until all Obligations (other than contingent indemnification obligations for which no claim has been asserted) have been paid in full and the Commitments have terminated.

4.07 Guarantee of Payment; Continuing Guarantee.

The guarantee in this Article IV is a guaranty of payment and not of collection, is a continuing guarantee, and shall apply to all Obligations whenever arising.

ARTICLE V

CONDITIONS PRECEDENT TO BORROWINGS

5.01 Conditions of Initial Borrowing.

This Agreement shall become effective upon and the obligation of each Lender to make Loans to be advanced on the Closing Date is subject to satisfaction of the following conditions precedent:

(a) Loan Documents. Receipt by the Administrative Agent of executed counterparts of this Agreement and the other Loan Documents (to the extent applicable), each properly executed by a Responsible Officer of the signing Loan Party and each other party to such Loan Documents, in each case in form and substance satisfactory to the Administrative Agent.

(b) Opinions of Counsel. Receipt by the Administrative Agent of a legal opinion of Cooley LLP, as U.S. counsel to the Loan Parties, and a legal opinion of Linklaters (the "LL Legal Opinion"), Swedish counsel to the Administrative Agent, addressed to the Administrative Agent and each Lender, dated as of the Closing Date, and in form and substance satisfactory to the Administrative Agent.

(c) Financial Statements; Due Diligence. The Administrative Agent shall have received the Audited Financial Statements, the Interim Financial Statements and such other reports, statements and due diligence items as the Administrative Agent or any Lender shall request; provided, that, it is understood and agreed that the Audited Financial Statements and Interim Financial Statements have been delivered to the Administrative Agent prior to the Closing Date.

(d) No Material Adverse Change. There shall not have occurred since December 31, 2022 any event or condition that has had or could reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect.

(e) Litigation. There shall not exist any action, suit, investigation or proceeding pending or, to the knowledge of any Loan Party, threatened in any court or before an arbitrator or Governmental Authority that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

(f) Organization Documents, Resolutions, Etc. Receipt by the Administrative Agent of the following, each of which shall be originals or facsimiles (followed promptly by originals), in form and substance satisfactory to the Administrative Agent:

(i) copies of the Organization Documents of each Loan Party certified to be true and complete as of a recent date by the appropriate Governmental Authority of the state or other jurisdiction of its incorporation or organization, where applicable, and certified by a secretary, assistant secretary or other Responsible Officer of such Loan Party to be true and correct as of the Closing Date;

(ii) such certificates of resolutions or other action, incumbency certificates and/or other certificates of Responsible Officers of each Loan Party as the Administrative Agent may require evidencing the identity, authority and capacity of each Responsible Officer thereof and each Responsible Financial Officer thereof authorized to act as a Responsible Officer or a Responsible Financial Officer in connection with this Agreement and the other Loan Documents to which such Loan Party is a party; and

(iii) such documents and certifications as the Administrative Agent may reasonably require to evidence that each Loan Party is duly organized or formed, and is validly existing, in good standing and qualified to engage in business in its state of organization or formation (to the extent relevant under applicable law).

(g) Perfection and Priority of Liens. Receipt by the Administrative Agent of the following:

(i) searches of Uniform Commercial Code filings or equivalent foreign filings in the jurisdiction of formation of each Loan Party or where a filing would need to be made in order to perfect the Administrative Agent's security interest in the Collateral, copies of the financing statements on file in such jurisdictions and evidence that no Liens exist other than Permitted Liens (or Liens to be terminated on the Closing Date in connection with the transactions contemplated hereby);

(ii) Uniform Commercial Code financing statements for each appropriate jurisdiction as is necessary, in the Administrative Agent's reasonable discretion, to perfect the Administrative Agent's security interest in the Collateral;

(iii) subject to Section 7.21, all certificates evidencing any certificated Equity Interests pledged to the Administrative Agent pursuant to the Pledge Agreement, together with duly executed in blank and undated stock powers attached thereto;

(iv) searches of ownership of, and Liens on, the Intellectual Property of each Loan Party in the appropriate governmental offices; and

(v) duly executed notices of grant of security interest as are necessary, in the Administrative Agent's sole discretion, to perfect the Administrative Agent's security interest in the Intellectual Property of the Loan Parties.

(h) Real Property Collateral. Receipt by the Administrative Agent of Real Property Security Documents with respect to the fee interest of any Loan Party in each real property identified on Schedule 6.20(a) (other than Excluded Property) (if any).

(i) Evidence of Insurance. Receipt by the Administrative Agent of insurance certificates of the Loan Parties evidencing liability and casualty insurance meeting the requirements set forth in the Loan Documents, including, but not limited to, subject to Section 7.21, naming the Administrative Agent as additional insured (in the case of liability insurance) or lender's loss payee (in the case of casualty and property insurance) on behalf of the Secured Parties.

(j) Closing Certificate. Receipt by the Administrative Agent of a certificate signed by a Responsible Financial Officer of the Borrower certifying (i) that the conditions specified in Sections 5.01(d), (e) and (l) and Sections 5.02(a) and (b) have been satisfied, (ii) that the Borrower and its Subsidiaries (after giving effect to the transactions contemplated hereby and the incurrence of Indebtedness related thereto) are Solvent on a consolidated basis and (iii) that neither the Borrower nor any Subsidiary as of the Closing Date has outstanding any Disqualified Capital Stock.

(k) Existing Credit Agreement. All Indebtedness under the Existing Credit Agreement shall be repaid in full and all security interests related thereto shall be terminated substantially concurrently with the funding of the Loan on the Closing Date.

(l) Governmental and Third Party Approvals. The Borrower and its Subsidiaries shall have received all required governmental, shareholder and third party consents and approvals, in each case, to the extent necessary or required to enter into the transactions contemplated by this Agreement and the other Loan Documents and the other transactions contemplated hereby and all applicable waiting periods shall have expired without any action being taken by any Person that could reasonably be expected to restrain, prevent or impose any material adverse conditions on the Borrower or any of its Subsidiaries or such other transactions or that could seek to threaten any of

the foregoing, and no law or regulation shall be applicable which could reasonably be expected to have such effect.

(m) Letter of Direction. Receipt by the Administrative Agent of a satisfactory letter of direction containing funds flow information with respect to the proceeds of the Loans to be made on the Closing Date.

(n) Fees. Receipt by Athyrium, the Administrative Agent and the Lenders of any fees or original issue discount required to be paid on or before the Closing Date pursuant to this Agreement and/or the Fee Letter (which may be paid by deductions from the Borrowing on the Closing Date).

(o) Attorney Costs; Due Diligence Expenses. The Borrower shall have paid all reasonable and documented fees, charges and disbursements of counsel to the Administrative Agent and all due diligence expenses of Athyrium and the Lenders, in each case, incurred prior to or on the Closing Date.

(p) Other. Receipt by the Administrative Agent and the Lenders of such other documents, instruments, agreements and information as reasonably requested by the Administrative Agent or any Lender in advance of the Closing Date, including, but not limited to, information regarding litigation, tax, accounting, labor, insurance, pension liabilities (actual or contingent), real estate leases, material contracts, license agreements, debt agreements, property ownership, environmental matters, contingent liabilities, commercial trends, pipeline indications and associated clinical data, competitive landscape, regulatory exclusivity, Material Intellectual Property and management of the Borrower and its Subsidiaries.

Without limiting the generality of the provisions of the last paragraph of Section 10.03, for purposes of determining compliance with the conditions specified in this Section 5.01, each Lender that has signed this Agreement shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless the Administrative Agent shall have received written notice from such Lender prior to the proposed Closing Date specifying its objection thereto.

5.02 Conditions to all Borrowings.

The obligation of each Lender to honor any Loan Notice is subject to the following conditions precedent:

(a) The representations and warranties of the Borrower and each other Loan Party contained in Article VI or any other Loan Document, shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) on and as of the date of such Borrowing, except to the extent that such representations and warranties specifically refer to an earlier date, in which case they shall be true and correct in all material respects (and in all respects if any such representation or warranty is already qualified by materiality or reference to Material Adverse Effect) as of such earlier date, and except that for purposes of this Section 5.02, the representations and warranties contained in clauses (a) and (b) of Section 6.05 shall be deemed to refer to the most recent statements furnished pursuant to clauses (a) and (b), respectively, of Section 7.01.

(b) No Default or Event of Default shall exist or would result from such proposed Borrowing or from the application of the proceeds thereof.

(c) The Administrative Agent shall have received a Loan Notice in accordance with the requirements hereof.

Each Loan Notice submitted by the Borrower shall be deemed to be a representation and warranty that the conditions specified in Sections 5.02(a) and (b) have been satisfied on and as of the date of the applicable Borrowing.

ARTICLE VI

REPRESENTATIONS AND WARRANTIES

The Loan Parties represent and warrant to the Administrative Agent and the Lenders that:

6.01 Existence, Qualification and Power.

Each Loan Party and each of its Subsidiaries (a) is duly organized or formed, validly existing and in good standing under the Laws of the jurisdiction of its incorporation or organization, (b) has all requisite power and authority and all requisite governmental licenses, authorizations, consents and approvals to (i) own or lease its assets and carry on its business and (ii) execute, deliver and perform its obligations under the Loan Documents to which it is a party, and (c) is duly qualified and is licensed and in good standing under the Laws of each jurisdiction where its ownership, lease or operation of properties or the conduct of its business requires such qualification or license; except in each case referred to in clause (b)(i) or (c), to the extent that failure to do so could not reasonably be expected to have a Material Adverse Effect.

6.02 Authorization; No Contravention.

The execution, delivery and performance by each Loan Party of each Loan Document to which such Person is party have been duly authorized by all necessary corporate or other organizational action, and do not (a) contravene the terms of any of such Person's Organization Documents, (b) conflict with or result in any breach or contravention of, or the creation of any Lien under, or require any payment to be made under (i) any Contractual Obligation to which such Person is a party or affecting such Person or the properties of such Person or any of its Subsidiaries or (ii) any order, injunction, writ or decree of any Governmental Authority or any arbitral award to which such Person or its property is subject, or (c) violate, in any material respect, any Law (including, without limitation, Regulation U or Regulation X issued by the FRB), except with respect to any conflict, breach or contravention or payment (but not creation of Liens) referred to in clause (b)(i) to the extent that such conflict, breach, contravention or payment could not reasonably be expected to have a Material Adverse Effect.

6.03 Governmental Authorization; Other Consents.

No approval, consent, exemption, authorization, or other action by, or notice to, or filing with, any Governmental Authority or any other Person is necessary or required in connection with the execution, delivery or performance by, or enforcement against, any Loan Party of this Agreement or any other Loan Document other than (a) those that have already been obtained and are in full force and effect and (b) filings to perfect the Liens created by the Collateral Documents.

6.04 Binding Effect.

Each Loan Document has been duly executed and delivered by each Loan Party that is party thereto. Each Loan Document constitutes a legal, valid and binding obligation of each Loan Party that is party

thereto, enforceable against each such Loan Party in accordance with its terms, subject to applicable Debtor Relief Laws or other Laws affecting creditors' rights generally and subject to general principles of equity.

6.05 Financial Statements; No Material Adverse Effect.

(a) The Audited Financial Statements (i) were prepared in accordance with IFRS consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the financial condition of the Borrower and its Subsidiaries as of the date thereof and their results of operations for the period covered thereby in accordance with IFRS consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, and (iii) show all material indebtedness and other liabilities, direct or contingent, of the Borrower and its Subsidiaries as of the date thereof, including material liabilities for taxes, commitments and Indebtedness.

(b) The Interim Financial Statements (i) were prepared in accordance with IFRS consistently applied throughout the period covered thereby, except as otherwise expressly noted therein, (ii) fairly present in all material respects the financial condition of the Borrower and its Subsidiaries as of the date thereof and their results of operations for the period covered thereby, subject, in the case of clauses (i) and (ii), to the absence of footnotes and to normal year-end audit adjustments, and (iii) show all material indebtedness and other liabilities, direct or contingent, of the Borrower and its Subsidiaries as of the date thereof, including material liabilities for taxes, material commitments and Indebtedness.

(c) From the date of the Audited Financial Statements to and including the Closing Date, there has been no Disposition, or any Involuntary Disposition, of any material part of the business or property of any Loan Party or any Subsidiary, and no purchase by any of them of any business or property (including any Equity Interests of any other Person) material to any Loan Party or any Subsidiary (taken as a whole), in each case, which is not reflected in the foregoing financial statements or in the notes thereto and has not otherwise been disclosed in writing to the Lenders on or prior to the Closing Date.

(d) Since the date of the Audited Financial Statements, there has been no event or circumstance, either individually or in the aggregate, that has had or could reasonably be expected to have a Material Adverse Effect.

6.06 Litigation.

There are no actions, suits, proceedings, claims or disputes pending or, to the knowledge of the Loan Parties after due and diligent investigation, threatened or contemplated, at law, in equity, in arbitration or before any Governmental Authority, by or against any Loan Party or any of its Subsidiaries or against any of their properties or revenues that (a) purport to affect or pertain to this Agreement or any other Loan Document, or any of the transactions contemplated hereby or (b) either individually or in the aggregate, could reasonably be expected to have a Material Adverse Effect.

6.07 No Default.

(a) Neither any Loan Party nor any Subsidiary is in default under or with respect to any Contractual Obligation that could reasonably be expected to have a Material Adverse Effect.

(b) No Default has occurred and is continuing.

6.08 Ownership of Property; Liens.

Each Loan Party and its Subsidiaries has good record and marketable title in fee simple to, or valid leasehold interests in, all real property necessary or used in the ordinary conduct of its business, except for such defects in title as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The property of each Loan Party and its Subsidiaries is subject to no Liens, other than Permitted Liens.

6.09 Environmental Compliance.

Except as could not reasonably be expected to have a Material Adverse Effect:

(a) Each of the Facilities and all operations at the Facilities are in compliance with all applicable Environmental Laws, and there is no violation of any Environmental Law with respect to the Facilities or the Businesses, and there are no conditions relating to the Facilities or the Businesses that could give rise to liability under any applicable Environmental Laws.

(b) None of the Facilities contains, or has previously contained any Hazardous Materials at, on or under the Facilities in amounts or concentrations that constitute or constituted a violation of, or could give rise to liability under, Environmental Laws.

(c) Neither any Loan Party nor any Subsidiary has received any written or verbal notice of, or inquiry from any Governmental Authority regarding, any violation, alleged violation, non-compliance, liability or potential liability regarding environmental matters or compliance with Environmental Laws with regard to any of the Facilities or the Businesses, nor does any Responsible Officer of any Loan Party have knowledge or reason to believe that any such notice will be received or is being threatened.

(d) Hazardous Materials have not been transported or disposed of from the Facilities, or generated, treated, stored or disposed of at, on or under any of the Facilities or any other location, in each case, by or on behalf of any Loan Party or any Subsidiary in violation of, or in a manner that would be reasonably likely to give rise to liability under, any applicable Environmental Law.

(e) No judicial proceeding or governmental or administrative action is pending or, to the knowledge of the Loan Parties, threatened, under any Environmental Law to which any Loan Party or any Subsidiary is or will be named as a party, nor are there any consent decrees or other decrees, consent orders, administrative orders or other orders, or other administrative or judicial requirements outstanding under any Environmental Law with respect to any Loan Party, any Subsidiary, the Facilities or the Businesses.

(f) There has been no release or threat of release of Hazardous Materials at or from the Facilities, or arising from or related to the operations (including, without limitation, disposal) of any Loan Party or any Subsidiary in connection with the Facilities or otherwise in connection with the Businesses, in violation of or in amounts or in a manner that could give rise to liability under Environmental Laws.

6.10 Insurance.

(a) The properties of the Loan Parties and their Subsidiaries are insured with financially sound and reputable insurance companies not Affiliates of such Persons, in such amounts, with such deductibles and covering such risks as are customarily carried by companies

engaged in similar businesses and owning similar properties in localities where the applicable Loan Party or the applicable Subsidiary operates. The insurance coverage of the Loan Parties and their Subsidiaries as in effect on the Closing Date is outlined as to carrier, policy number, expiration date, type, amount and deductibles on Schedule 6.10.

(b) Each Loan Party and each of their respective Subsidiaries maintains, if available, fully paid flood hazard insurance on all real property that is located in a special flood hazard area and that constitutes Collateral, on such terms and in such amounts as required by The National Flood Insurance Reform Act of 1994 or as otherwise reasonably required by the Administrative Agent.

6.11 Taxes.

The Loan Parties and their respective Subsidiaries have filed all federal, state and other tax returns and reports required to be filed, except to the extent that failure to do so could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The Loan Parties and their respective Subsidiaries have paid all federal, state and other material taxes, assessments, fees and other governmental charges levied or imposed upon them or their properties, income or assets otherwise due and payable, except (x) those which are being contested in good faith by appropriate proceedings diligently conducted and for which adequate reserves have been provided in accordance with IFRS or (y) to the extent that failure to do so could not reasonably be expected to result in a Material Adverse Effect. There is no proposed tax assessment against any Loan Party or any Subsidiary that would, if made, have a Material Adverse Effect.

6.12 ERISA Compliance.

(a) Each Plan is in compliance in all material respects with the applicable provisions of ERISA, the Internal Revenue Code and other federal or state laws and all applicable Swedish pension and social security Laws. Each Pension Plan that is intended to be a qualified plan under Section 401(a) of the Internal Revenue Code has received a favorable determination letter from the Internal Revenue Service to the effect that the form of such Plan is qualified under Section 401(a) of the Internal Revenue Code and the trust related thereto has been determined by the Internal Revenue Service to be exempt from federal income tax under Section 501(a) of the Internal Revenue Code or an application for such a letter is currently being processed by the Internal Revenue Service. To the best knowledge of the Loan Parties, nothing has occurred that would prevent, or cause the loss of, such tax-qualified status.

(b) There are no pending or, to the best knowledge of the Loan Parties, threatened claims, actions or lawsuits, or action by any Governmental Authority, with respect to any Plan that could reasonably be expected to have a Material Adverse Effect. There has been no prohibited transaction or violation of the fiduciary responsibility rules with respect to any Plan that has resulted or could reasonably be expected to result in a Material Adverse Effect.

(c) (i) No ERISA Event has occurred and neither the Borrower nor any ERISA Affiliate has knowledge of any fact, event or circumstance that could reasonably be expected to constitute or result in an ERISA Event with respect to any Pension Plan, (ii) the Borrower and each ERISA Affiliate has met all applicable requirements under the Pension Funding Rules in respect of each Pension Plan, and no waiver of the minimum funding standards under the Pension Funding Rules has been applied for or obtained, (iii) as of the most recent valuation date for any Pension Plan, the funding target attainment percentage (as defined in Section 430(d)(2) of the Internal Revenue Code) is sixty percent (60%) or higher and neither the Borrower nor any ERISA Affiliate

knows of any facts or circumstances that could reasonably be expected to cause the funding target attainment percentage for any such plan to drop below sixty percent (60%) as of the most recent valuation date, (iv) neither the Borrower nor any ERISA Affiliate has incurred any liability to the PBGC other than for the payment of premiums, and there are no premium payments which have become due that are unpaid, (v) neither the Borrower nor any ERISA Affiliate has engaged in a transaction that could be subject to Section 4069 or Section 4212(c) of ERISA, and (vi) no Pension Plan has been terminated by the plan administrator thereof nor by the PBGC, and no event or circumstance has occurred or exists that could reasonably be expected to cause the PBGC to institute proceedings under Title IV of ERISA to terminate any Pension Plan.

6.13 Subsidiaries and Capitalization.

(a) Set forth on Schedule 6.13(a) is a complete and accurate list as of the Closing Date of each Subsidiary, together with (i) jurisdiction of organization, (ii) number of shares of each class of Equity Interests outstanding, (iii) number and percentage of outstanding shares of each class owned (directly or indirectly) by any Loan Party or any Subsidiary, (iv) number and effect, if exercised, of all outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto and (v) identification of each Subsidiary that is an Excluded Subsidiary and/or an Immaterial Foreign Subsidiary. The outstanding Equity Interests of each Subsidiary are validly issued, fully paid and non-assessable.

(b) As of the Closing Date, except as described on Schedule 6.13(b), there are no outstanding commitments or other obligations of the Borrower or any Subsidiary to issue, and no rights of any Person to acquire, any shares of any Equity Interests of the Borrower or any of its Subsidiaries. All issued and outstanding Equity Interests of the Borrower and each of its Subsidiaries is duly authorized and validly issued, fully paid and non-assessable and such Equity Interests were issued in compliance with all applicable Laws.

6.14 Margin Regulations; Investment Company Act.

(a) The Borrower is not engaged and will not engage, principally or as one of its important activities, in the business of purchasing or carrying margin stock (within the meaning of Regulation U issued by the FRB), or extending credit for the purpose of purchasing or carrying margin stock. Following the application of the proceeds of each Borrowing, not more than 25% of the value of the assets (either of the Borrower only or of the Borrower and its Subsidiaries on a consolidated basis) subject to the provisions of Section 8.01 or Section 8.05 or subject to any restriction contained in any agreement or instrument between the Borrower and any Lender or any Affiliate of any Lender relating to Indebtedness and within the scope of Section 9.01(e) will be margin stock.

(b) None of any Loan Party or any Subsidiary is or is required to be registered as an "investment company" under the Investment Company Act of 1940.

6.15 Disclosure.

Each Loan Party has disclosed to the Administrative Agent and the Lenders all agreements, instruments and corporate or other restrictions to which it or any of its Subsidiaries is subject, and all other matters known to it, that, either individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect. No report, financial statement, certificate or other written information furnished by or on behalf of any Loan Party to the Administrative Agent or any Lender in connection with the transactions contemplated hereby and the negotiation of this Agreement or delivered hereunder or under

any other Loan Document (in each case, as modified or supplemented by other information so furnished and, when taken as a whole) contains any material misstatement of fact or omits to state any fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, that, with respect to financial projections, estimates, budgets or other forward-looking information, the Loan Parties represent only that such information was prepared in good faith based upon assumptions believed by the applicable Loan Party to be reasonable at the time such information was prepared (it being understood that such information is as to future events and is not to be viewed as facts, is subject to significant uncertainties and contingencies, many of which are beyond the control of the Borrower and its Subsidiaries, that no assurance can be given that any particular projection, estimate or forecast will be realized and that actual results during the period or periods covered by any such projections, estimates, budgets or forecasts may differ significantly from the projected results and such differences may be material).

6.16 Compliance with Laws.

Each Loan Party and each Subsidiary is in compliance with the requirements of all Laws and all orders, writs, injunctions and decrees applicable to it or to its properties, except in such instances in which (a) such requirement of Law or order, writ, injunction or decree is being contested in good faith by appropriate proceedings diligently conducted or (b) the failure to comply therewith could not reasonably be expected to have a Material Adverse Effect.

6.17 Intellectual Property; Licenses, Etc.

(a) Schedule 6.17(a) sets forth a complete and accurate list of all (i) Patents (including any Patent applications and letters patent), (ii) registered Trademarks (including domain names) and any pending registrations for Trademarks, (iii) any other registered Intellectual Property (including any copyright registrations or applications for registration), and (iv) any other items of Material Intellectual Property, in each case of the foregoing clauses (i) through (iv), that is (A) owned by any Loan Party or (B) is owned by any Subsidiary that is not a Loan Party and covers or is related to the commercialization of Nefecon. For each item of Intellectual Property listed on Schedule 6.17(a), the Loan Parties have, where relevant, indicated on such schedule the owner of record, jurisdiction of application and/or registration, the application numbers, the registration or patent numbers or patent application numbers, and the date of application and/or registration. Schedule 6.17(a) also sets forth a complete and accurate list as of the Closing Date of all license agreements (inbound or outbound) of any of the foregoing items of Intellectual Property.

(b) [Reserved].

(c) With respect to all Material Intellectual Property listed or required to be listed on Schedule 6.17(a), except as could not reasonably be expected to result, either individually or in the aggregate, in a material adverse effect on the commercialization of Nefecon:

(i) each Loan Party and its respective Subsidiaries, as applicable, owns or has a valid license to such Material Intellectual Property free and clear of any and all Liens other than Permitted Liens;

(ii) each Loan Party, as applicable, has taken commercially reasonable actions to maintain and protect such Material Intellectual Property;

(iii) except for rejections issued by a Governmental Authority in the ordinary course of prosecuting Patent or Trademark applications, (A) there is no proceeding

challenging the validity or enforceability of any such Material Intellectual Property, (B) none of the Loan Parties nor any of their respective Subsidiaries is involved in any such proceeding with any Person, (C) none of the Material Intellectual Property is the subject of any Other Administrative Proceeding, and (D) no Person has made any certification pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, including but not limited to any such certification pursuant to 21 U.S.C. §355(b)(2)(A)(iv) or 21 U.S.C. §355(j)(2)(A)(vii)(IV), or any reasonably similar or equivalent certification or notice in the United States or any other jurisdiction or any associated litigation (a "Paragraph IV Certification"), asserting the non-infringement, invalidity, or unenforceability of any Patent constituting Material Intellectual Property owned by or licensed to any Loan Party or any Subsidiary;

(iv) (A) such Material Intellectual Property is valid, enforceable, and subsisting and (B) no event has occurred, and nothing has been done or omitted to have been done, that would affect the validity or enforceability of such Material Intellectual Property and all such Intellectual Property is in full force and effect and has not lapsed, or been forfeited or cancelled or abandoned (except for routine abandonments associated with patent prosecution) and there are no delinquent unpaid maintenance, renewal or other fees payable or owing by such Loan Party or Subsidiary for any such Material Intellectual Property;

(v) each Loan Party, and its respective Subsidiaries, as applicable, is the sole and exclusive owner of all right, title and interest in and to all such Material Intellectual Property that is owned by it;

(vi) to the extent any such Intellectual Property was authored, developed, conceived or created, in whole or in part, for or on behalf of any Loan Party or any Subsidiary by any Person, then such Loan Party or Subsidiary has entered into a written agreement with such Person in which such Person has assigned all right, title and interest in and to such Intellectual Property to such Loan Party or Subsidiary; and

(vii) no such Material Intellectual Property is subject to any license grant, covenant not to sue, or similar arrangement, in each case, by any Loan Party or Subsidiary, except for (x) license grants between the Loan Parties and (y) those license grants disclosed on Schedule 6.17(c).

(d) To the knowledge of the Loan Parties, no Third Party is committing any act of Infringement of any Intellectual Property listed or required to be listed on Schedule 6.17(a).

(e) With respect to each license agreement listed or required to be listed on Schedule 6.17(a), except as could not reasonably be expected to result, either individually or in the aggregate, in a material adverse effect on the commercialization of Nefecon, such license agreement (i) is in full force and effect and is binding upon and enforceable against each Loan Party (or each Loan Party's respective Subsidiaries, as applicable) party thereto and, to the knowledge of the Borrower, all other parties thereto in accordance with its terms, (ii) has not been amended or otherwise modified in a manner materially adverse to the Administrative Agent or any Lender, and (iii) to the knowledge of the Borrower has not suffered a material default or breach thereunder. Except as could not reasonably be expected to result, either individually or in the aggregate, in a material adverse effect on the commercialization of Nefecon, none of the Loan Parties nor any of their respective Subsidiaries, to the knowledge of the Borrower, has taken or omitted to take any action that would permit any other Person party to any such license agreement to have, and to the

knowledge of the Loan Parties, no such Person otherwise has, any defenses, counterclaims or rights of setoff thereunder. Except for Patents co-owned by the Borrower, the Borrower and its Subsidiaries are not utilizing any Intellectual Property licensed to the Borrower or any of its Subsidiaries under the Targit License Agreement.

(f) (i) None of the Loan Parties nor any of their respective Subsidiaries nor, to the knowledge of the Borrower, any licensees of any Intellectual Property owned by any Loan Party or any Subsidiary has received written notice from any Third Party alleging that the conduct of its business (including any research, development, manufacture, import, use, sale, storage, labeling, marketing, promotion, supply, distribution, testing, packaging, purchasing or other commercialization activities, receipt of payment in respect of any of the foregoing, or like activities the purpose of which is to develop or commercially exploit any Product) Infringes any Intellectual Property of that Third Party, and (ii) to the knowledge of the Borrower, the conduct of the business of the Loan Parties and any of their Subsidiaries and any licensees of any Intellectual Property owned by any Loan Party or any Subsidiary (including any research, development, manufacture, import, use, sale, storage, labeling, marketing, promotion, supply, distribution, testing, packaging, purchasing or other commercialization activities, receipt of payment in respect of any of the foregoing, or like activities the purpose of which is to develop or commercially exploit any Product) does not Infringe any Intellectual Property of any Third Party.

(g) Neither any Loan Party nor any Subsidiary has made any assignment or agreement in conflict with the security interest in any Material Intellectual Property of any Loan Party under the Collateral Documents and no license agreement with respect to any such Material Intellectual Property conflicts with the security interest granted to the Administrative Agent, on behalf of the Secured Parties, pursuant to the terms of the Collateral Documents. The exercise by the Administrative Agent or the Secured Parties of any right or protection set forth in the Loan Documents will not constitute a breach or violation of, or otherwise affect the enforceability or approval of, any licenses associated with any Material Intellectual Property owned or licensed by any Loan Party or any Subsidiary; provided, that, in each case, no representation or warranty is made with respect to the Closing Date License Agreements to the extent any applicable conflicts or violations are customary with industry practice for similar license agreements in each applicable jurisdiction.

6.18 Solvency.

The Borrower and its Subsidiaries, on a consolidated basis, are Solvent.

6.19 Perfection of Security Interests in the Collateral.

The Collateral Documents (subject, in the case of the Swedish Collateral Documents, to the Legal Reservations) create valid security interests in, and Liens on, the Collateral purported to be covered thereby, which security interests and Liens will be, upon the timely and proper filings, deliveries, notations and other actions contemplated in the Collateral Documents or this Agreement perfected security interests and Liens (to the extent that such security interests and Liens can be perfected by such filings, deliveries, notations and other actions), prior to all other Liens other than Permitted Liens.

6.20 Business Locations.

Set forth on Schedule 6.20(a) is a list of all real property that is owned or leased by the Loan Parties as of the Closing Date (with (x) a description of each real property that is Excluded Property and (y) a designation of whether such real property is owned or leased). Set forth on Schedule 6.20(b) is the taxpayer

identification number and organizational identification number of each Loan Party as of the Closing Date. The exact legal name and state of organization of (a) the Borrower is as set forth on the signature pages hereto and (b) each Guarantor is (i) as set forth on the signature pages hereto, (ii) as set forth on the signature pages to the Joinder Agreement pursuant to which such Guarantor became a party hereto or (iii) as may be otherwise disclosed by the Loan Parties to the Administrative Agent in accordance with Section 8.12(c). Except as set forth on Schedule 6.20(c), no Loan Party has during the five years preceding the Closing Date, (i) changed its legal name, (ii) changed its state of organization, or (iii) been party to a merger, consolidation or other change in structure.

6.21 Sanctions Concerns; Anti-Corruption Laws; PATRIOT Act.

(a) Sanctions Concerns. No Loan Party, nor any Subsidiary, nor, to the knowledge of the Loan Parties and their Subsidiaries, any director, officer, employee, agent, affiliate or representative thereof, is an individual or entity that is, or is owned or controlled by one or more individuals or entities that are (i) currently the subject or target of any Sanctions, (ii) included on OFAC's List of Specially Designated Nationals or HMT's Consolidated List of Financial Sanctions Targets, or any similar list enforced by any other relevant sanctions authority or (iii) located, organized or resident in a Designated Jurisdiction. The Borrower and its Subsidiaries have conducted their businesses in compliance with all applicable Sanctions and have instituted and maintained policies and procedures designed to promote and achieve compliance with such Sanctions.

(b) Anti-Corruption Laws. The Loan Parties and their Subsidiaries have conducted their business in compliance with the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar anti-corruption legislation in other jurisdictions, and have instituted and maintained policies and procedures designed to promote and achieve compliance with such laws.

(c) PATRIOT Act. To the extent applicable, each Loan Party and each Subsidiary is in compliance, in all material respects, with (i) the Trading with the Enemy Act, as amended, and each of the foreign assets control regulations of the United States Treasury Department (31 CFR, Subtitle B, Chapter V, as amended) and any other enabling legislation or executive order relating thereto and (ii) the PATRIOT Act.

6.22 Material Contracts.

Set forth on Schedule 6.22 is a complete and accurate list of all Material Contracts of the Borrower and its Subsidiaries as of the Closing Date, and all amendments and modifications thereto as of the Closing Date. Each Material Contract (a) is in full force and effect and is binding upon and enforceable against the Borrower and its Subsidiaries party thereto and, to the knowledge of the Borrower, all other parties thereto in accordance with its terms, and (b) is not currently subject to any breach or default by the Borrower or any Subsidiary or, to the knowledge of the Borrower, any other party thereto, in each case, to the extent that such breach or default could (individually or in the aggregate) reasonably be expected to result in a Material Adverse Effect. None of the Borrower nor any of its Subsidiaries has taken or failed to take any action that would permit any other Person party to any Material Contract to have, and, to the knowledge of the Borrower, no such Person otherwise has, any defenses, counterclaims or rights of setoff thereunder, in each case, to the extent that such action or failure to take such action could (individually or in the aggregate) reasonably be expected to result in a Material Adverse Effect. None of the Material Contracts are non-assignable by their terms (other than those certain agreements separately noted in Schedule 6.22 as being non-assignable) or as a matter of law, or prevent the granting of a security interest therein.

6.23 Compliance of Products.

(a) Except where the failure to do so could not reasonably be expected to result, either individually or in the aggregate, in (x) a material adverse effect on the commercialization of Nefecon or (y) a Material Adverse Effect:

(i) the Borrower and its Subsidiaries, either directly or through its Product Distributors, have obtained all Regulatory Authorizations necessary for compliance with all Laws and all such Regulatory Authorizations are in full force and effect;

(ii) all Regulatory Authorizations held by the Loan Parties and their respective Subsidiaries and Product Distributors are (A) legally and beneficially owned exclusively by one of the Loan Parties or their respective Subsidiaries or Product Distributors, free and clear of all Liens other than Permitted Liens, and (B) validly granted by and/or registered and on file with the applicable Regulatory Agency, in compliance with all filing and maintenance requirements (including any fee requirements) thereof, and are in good standing, valid and enforceable with the applicable Regulatory Agency; and

(iii) all required notices, registrations and listings, supplemental applications or notifications, reports (including reports of adverse experiences) and other required filings with respect to the Products have been filed with the FDA, the DEA, the EMA, and all other applicable Regulatory Agencies when due.

(b) Except where the failure to do so could not reasonably be expected to result in the termination or material restriction of a Material Regulatory Authorization, all applications, notifications, submissions, information, claims, reports and statistics and other data and conclusions derived therefrom, utilized as the basis for or submitted in connection with any and all requests for a Regulatory Authorization from the FDA, EMA, or other Regulatory Agency relating to the Borrower or any Subsidiary or any of their respective business operations and Products, when submitted to the FDA, EMA, or other Regulatory Agency were true, complete and correct in all material respects as of the date of submission (including any necessary or required updates, changes, corrections or modifications to such applications, submissions, information and data that have been submitted to the FDA, EMA, or other Regulatory Agency). The Regulatory Authorizations issued by the FDA, EMA, and other Regulatory Agencies for Nefecon are valid and supported by proper research, design, testing, analysis and disclosure, except where the failure to do so could not reasonably be expected to result, either individually or in the aggregate, in (x) a material adverse effect on the commercialization of Nefecon or (y) a Material Adverse Effect. There has been no material untrue statement of fact and/or no fraudulent statement made by the Loan Parties or their respective Subsidiaries or, to the knowledge of the Loan Parties, Product Distributors (as relating to Products), or any of their respective agents or representatives to the FDA, the DEA, the EMA, or any other Regulatory Agency, and there has been no failure to disclose any material fact required to be disclosed, commission of an act, making of a statement, or failure to make a statement to the FDA, the DEA, the EMA, or any other Regulatory Agency that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Regulation 46191 (September 10, 1991).

(c) Except as could not reasonably be expected to result in a material adverse effect, either individually or in the aggregate, on the commercialization of Nefecon:

(i) Nefecon, as well as the business of the Loan Parties and their respective Subsidiaries and, to the knowledge of the Borrower, Product Distributors (as relating to Products), materially comply with (A) all applicable Laws, rules, regulations, orders, injunctions and decrees of the FDA, the DEA, the EMA, and any other applicable Regulatory Agency, including, without limitation, all applicable requirements of the FDCA, the PHSA, the Controlled Substances Act, similar state Laws, and similar Laws of any country, jurisdiction or Governmental Authority other than the United States, and (B) all applicable Product Authorizations, Regulatory Authorizations, and all other Permits;

(ii) None of the Loan Parties, their respective Subsidiaries nor their respective Product Distributors or suppliers have received and do not otherwise have knowledge of: any inspection reports, warning letters, untitled letters or similar documents with respect to Nefecon or the manufacture, processing, packing, distribution, or holding thereof, as well as the business of the Loan Parties and their respective Subsidiaries or relevant Product Distributors, from any Regulatory Agency that assert lack of compliance with any applicable Laws, rules, regulations, orders, injunctions, or decrees;

(iii) None of the Loan Parties, their respective Subsidiaries nor, to the knowledge of the Borrower, their respective Product Distributors or suppliers have received any written notice of, and does not otherwise have knowledge of, any pending regulatory enforcement action, investigation or inquiry (other than non-material routine or periodic inspections or reviews) against the Loan Parties, any of their respective Subsidiaries or any of their respective Product Distributors or suppliers with respect to Nefecon, and, to the knowledge of the Borrower, there is no basis for any adverse regulatory action against the Loan Parties or their respective Subsidiaries or, to the knowledge of the Borrower, their respective Product Distributors or suppliers with respect to the Products; and

(iv) Without limiting the foregoing, (A) to the knowledge of the Borrower, no Product Distributor or supplier of any Loan Party or any Subsidiary has received, during [***] prior to the Closing Date, any Form FDA 483 from the FDA asserting a lack of compliance with respect to Nefecon or Product Development and Commercialization Activities therefor, (B) to the knowledge of the Borrower (1) there have been no Safety Notices conducted, undertaken or issued by any Person, whether or not at the request, demand or order of any Regulatory Agency or otherwise, with respect to Nefecon, (2) no Safety Notice has been requested, demanded or ordered by any Regulatory Agency, and, to the knowledge of the Borrower, there is no basis for the issuance of any Safety Notice by any Person with respect to Nefecon, and (C) the Loan Parties have not received any written notice of, and do not otherwise have knowledge of, any criminal, injunctive, seizure, detention or civil penalty actions that have at any time been commenced or threatened in writing by any Regulatory Agency with respect to or in connection with Nefecon, or any consent decrees (including plea agreements) which relate to Nefecon, and, to the knowledge of the Borrower, there is no basis for the commencement of any criminal injunctive, seizure, detention or civil penalty actions by any Regulatory Agency relating to Nefecon or for the issuance of any consent decrees. None of the Loan Parties or their respective Subsidiaries nor, to the knowledge of the Borrower, any of their respective Product Distributors or suppliers is employing or utilizing the services of any individual who is associated with the commercialization of Nefecon and has been convicted of any crime or engaged in any conduct for which debarment or temporary suspension under any applicable Law, rule or regulation is warranted.

(d) Except as could not reasonably be expected to result, either individually or in the aggregate, in a material adverse effect on the commercialization of Nefecon, none of the Loan Parties or their respective Subsidiaries nor, to the knowledge of the Borrower, any Product Distributors (as relating to Products) has received any communication from any Regulatory Agency regarding, and there are no facts or circumstances that are likely to give rise to, (i) any material adverse change in any applicable Regulatory Authorization, or any failure to materially comply with any Laws or any term or requirement of any applicable Regulatory Authorization or (ii) any revocation, withdrawal, suspension, cancellation, material limitation, termination or material modification of any applicable Regulatory Authorization.

(e) Except as could not reasonably be expected, either individually or in the aggregate, to result in a material adverse effect on the commercialization of Nefecon, all studies, tests, preclinical trials and clinical trials conducted by or on behalf of or for the benefit of any Loan Party or any of its respective Subsidiaries with respect to any Product have been conducted in material compliance with applicable Laws, including cGCPs. No Loan Party nor any of their respective Subsidiaries has received any notice from the FDA, EMA, or any other Regulatory Agency alleging any material non-compliance with applicable Laws, including cGCPs or otherwise terminating or suspending any clinical trial conducted by or on behalf of or for the benefit of such Loan Party or Subsidiary with respect to any Product. All results of such studies, tests and trials, and all other material information related to such studies, tests and trials, have been made available to the Administrative Agent. The summaries and descriptions of any of the foregoing provided to the Administrative Agent are accurate and contain no material omissions. None of the Loan Parties, their respective Subsidiaries, or, to the knowledge of the Borrower, any of their respective Product Distributors, licensees, licensors or third party services providers or consultants, has received from the FDA, EMA, or other applicable Regulatory Agency any notices or correspondence requiring the termination, suspension, material modification or clinical hold of any studies, tests or clinical trials in any material respect with respect to or in connection with the Products.

(f) Except as could not reasonably be expected, either individually or in the aggregate, to result in a material adverse effect on the commercialization of Nefecon:

(i) (A) all design, manufacturing, storage, distribution, packaging, labeling, sale, recordkeeping and other activities by the Loan Parties, their respective Subsidiaries and their respective Product Distributors and suppliers relating to the Products have been conducted, and are currently being conducted, in compliance with applicable Laws and the requirements of all applicable Regulatory Agencies, including, without limitation, cGMPs, adverse event reporting requirements, and state and federal requirements relating to the handling of controlled substances and (B) none of the Loan Parties or their respective Subsidiaries, or, to the knowledge of the Borrower, any of their respective Product Distributors and suppliers has received written notice or has knowledge of a threat of commencement of action by any Governmental Authority to initiate any action against the Borrower or any Subsidiary, any action to enjoin the Borrower or any Subsidiary, its officers, directors, employees, shareholders, or its agents and Affiliates, from conducting its business at any facility owned or used by it or for any material civil penalty, injunction, seizure or criminal action;

(ii) no Product in the inventory of the Loan Parties or their respective Subsidiaries or, to the knowledge of the Borrower, of any Product Distributor is adulterated or misbranded;

(iii) all labels and labeling (including package inserts) and product information are in material compliance with applicable FDA, EMA, and other Regulatory Agency requirements, and the Products are in material compliance with all classification, registration, listing, marking, tracking, reporting, recordkeeping and audit requirements of the FDA, the DEA, the EMA, and any other Regulatory Agency;

(iv) no Product is an article prohibited from introduction into interstate commerce under the provisions of Sections 404, 505 or 512 of the FDCA.

(g) Except as could not reasonably be expected, either individually or in the aggregate, to result in a material adverse effect on the commercialization of Nefecon, all manufacturing facilities used to manufacture any Product owned or operated by the Loan Parties and their respective Subsidiaries and, to the knowledge of the Borrower, of any Product Distributor (as relating to Products): (x) are and have been operated in material compliance with cGMPs and all other applicable Laws, and (y) all such facilities are operated in material compliance with the Controlled Substances Act, applicable DEA regulations, and other applicable federal and state Laws. No Form 483, warning letter, or untitled letter has been issued, and no other allegation of any material non-compliance with cGMPs has been made with respect to any such facility.

(h) The Loan Parties have made available to the Administrative Agent all material adverse event reports and material communications to or from the FDA, EMA, and other relevant Regulatory Agencies, including material inspection reports, warning letters, untitled letters, and material reports, studies and other correspondence, other than opinions of counsel that are attorney-client privileged, with respect to regulatory matters relating to the Loan Parties and their respective Subsidiaries, the conduct of their business, the operation of any manufacturing Facilities owned or operated by the Loan Parties and their respective Subsidiaries, and the Products, in each case, to the extent that the events or circumstances underlying such report or communication either had a Material Adverse Effect or could reasonably be expected to have a Material Adverse Effect.

(i) Except as could not reasonably be expected, either individually or in the aggregate, to result in a material adverse effect on the commercialization of Nefecon, there have been no significant failures in the manufacturing of any Product such that the amount of such Product successfully manufactured by or on behalf of the Borrower or any Subsidiary in accordance with all specifications thereof and the Regulatory Authorizations related thereto in any month have been insufficient to meet all obligations associated with Product Development and Commercialization Activities associated with such Product.

(j) Except as could not reasonably be expected, either individually or in the aggregate, to result in a material adverse effect on the commercialization of Nefecon, none of the Products is currently, and have not for the past [***] been, the subject of any claim or allegation, formal or informal, that any Product, or its use, is defective or has resulted in or proximately caused any injury to any Person or property.

(k) No Loan Party nor any of their respective Subsidiaries or, to the knowledge of the Borrower, any relevant Product Distributor engaged in Product Development and Commercialization Activities has received any material notice from the United States Department of Justice, any U.S. Attorney, any State Attorney General, or other similar federal, state, or foreign Governmental Authority alleging any violation of the Federal Anti-kickback Statute, the Federal False Claims Act, the Foreign Corrupt Practices Act, any federal Law, or state or foreign Law. No Loan Party nor any of their respective Subsidiaries has knowledge of any conduct that reasonably could be interpreted as a material violation of any such Law.

(l) The transactions contemplated by the Loan Documents will not (i) constitute a breach or violation of, or otherwise materially affect, the enforceability or approval of any Material Regulatory Authorization relating to Nefecon or (ii) impair the Loan Parties' ownership of or rights under (or the license or other right to use, as the case may be) any Material Regulatory Authorizations relating to the Nefecon in any material manner.

(m) The exercise by the Administrative Agent or the Secured Parties of any right or protection set forth in the Loan Documents will not (i) constitute a breach or violation of, or otherwise materially affect, the enforceability or approval of any Material Regulatory Authorization relating to Nefecon or (ii) impair the Loan Parties' ownership of or rights under (or the license or other right to use, as the case may be) any Material Regulatory Authorizations relating to the Nefecon in any material manner, in each case, assuming that the Administrative Agent or the Secured Parties in exercising such rights either (x) perform all required acts or (y) do not cause the Loan Parties and their Subsidiaries to cease performing all required acts, in each case, to maintain all required approvals, authorizations, licenses, permits, and the like with all applicable Governmental Authorities.

(n) Except as could not reasonably be expected, either individually or in the aggregate, to result in a material adverse effect on the commercialization of Nefecon, no Loan Party nor any of their respective Subsidiaries or any Product Distributor on behalf of any Loan Party or Subsidiary has ever been terminated from any federal or state government or private healthcare reimbursement program or otherwise had its rights to receive payments from any government or private healthcare reimbursement program adversely affected as a result of any investigation of wrongdoing or enforcement action, whether by any Governmental Authority or other Third Party.

(o) Except as could not reasonably be expected, either individually or in the aggregate, to result in a material adverse effect on the commercialization of Nefecon, the Loan Parties and their respective Subsidiaries, and to the knowledge of the Borrower, all relevant Product Distributors, are in compliance with Section 6002 of the Affordable Care Act and similar state Laws regarding the reporting of certain payments to physicians and hospitals.

(p) (i) The Loan Parties and their respective Subsidiaries are in compliance in all material respects with the privacy and security requirements of HIPAA or similar Laws of any country, jurisdiction or Governmental Authority other than the United States, (ii) neither any Loan Parties nor any of Subsidiary has received any written communication from any Governmental Authority that alleges non-compliance with HIPAA or similar Laws of any country, jurisdiction or Governmental Authority other than the United States, and (iii) no breach or violation has occurred, to the knowledge of the Borrower, with respect to any unsecured protected health information maintained by or for the Loan Parties or any of their respective Subsidiaries that is subject to the notification requirements of 45 C.F.R. §§ 164.406 or 164.408(b), similar state Laws, or similar Laws of any country, jurisdiction or Governmental Authority other than the United States, and no information security or privacy breach event has occurred that would require notification under any applicable Laws.

(q) No Loan Party nor any of their respective Subsidiaries nor, to the Borrower's knowledge, any individual who is an officer, director, manager, employee, shareholder, agent or managing agent of any Loan Party or any of their respective Subsidiaries, has been convicted of, charged with or, to the Borrower's knowledge, investigated for any federal or state health program-related offense or any other offense related to healthcare or been terminated, excluded or suspended from participation in any such program; or, to the Borrower's knowledge, has been convicted of, charged with or investigated for a violation of Laws related to fraud, theft, embezzlement, breach

of fiduciary responsibility, financial misconduct, obstruction of an investigation or controlled substances, or has been subject to any judgment, stipulation, order or decree of, or criminal or civil fine or penalty imposed by, any Regulatory Agency related to fraud, theft, embezzlement, breach of fiduciary responsibility, financial misconduct, obstruction of an investigation or controlled substances. No Loan Party nor any of their respective Subsidiaries nor, to the Borrower's knowledge, any individual who is an officer, director, employee, shareholder, agent or managing agent of any Loan Party or any of their respective Subsidiaries has been convicted of any crime or engaged in any conduct that has resulted or would reasonably be expected to result in a debarment or exclusion (i) under 21 U.S.C. Section 335a, or (ii) any similar applicable Law. No debarment proceedings or investigations in respect of the business of any Loan Party or any of their respective Subsidiaries are pending or, to the Borrower's knowledge, threatened against any Loan Party or any of their respective Subsidiaries or any individual who is an officer, director, manager, employee, shareholder, agent or managing agent of any Loan Party or any of their respective Subsidiaries.

(r) As of the Closing Date, all Products are listed on Schedule 1.01.

6.24 Labor Matters.

There are no existing or threatened strikes, lockouts or other labor disputes involving the Borrower or any Subsidiary that, either individually or in the aggregate, could reasonably be expected to have a Material Adverse Effect. Except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, hours worked by and payment made to employees of the Borrower and its Subsidiaries are not in violation of the Fair Labor Standards Act or any other applicable law, rule or regulation dealing with such matters.

6.25 Affected Financial Institution.

Neither any Loan Party nor any Subsidiary is an Affected Financial Institution.

6.26 Regulation H.

No owned real property subject to a Mortgage is a Flood Hazard Property unless the Administrative Agent shall have received the following: (a) the applicable Loan Party's written acknowledgment of receipt of written notification from the Administrative Agent (i) as to the fact that such Mortgaged property is a Flood Hazard Property and (ii) as to whether the community in which each such Flood Hazard Property is located is participating in the National Flood Insurance Program, (b) copies of insurance policies or certificates of insurance of the applicable Loan Party evidencing flood insurance reasonably satisfactory to the Administrative Agent and naming the Administrative Agent as loss payee on behalf of the Lenders and (c) such other flood hazard determination forms, notices and confirmations thereof as requested by the Administrative Agent. All flood hazard insurance policies required hereunder have been obtained and remain in full force and effect, and the premiums thereon have been paid in full.

6.27 Compliance with Privacy Laws.

To the extent that any Loan Party or any Subsidiary has access to any individually identifiable information of any individual, the Loan Parties and their respective Subsidiaries are in material compliance with all applicable Privacy Laws, and maintain information security processes that (a) include safeguards for the security, privacy, confidentiality, and integrity of transactions and confidential or proprietary data or individually identifiable health information used, disclosed, or accessed by the Loan Parties and their respective Subsidiaries, and (b) are designed to protect against unauthorized access to the Systems and data

of the Loan Parties and their respective Subsidiaries, and the Systems of any third person service providers that have access to the data or Systems of the Loan Parties and their respective Subsidiaries, in compliance with applicable Privacy Laws, and (c) have been in compliance with all applicable Privacy Laws in all material respects. Neither any Loan Party nor any Subsidiary has received written notice, nor to the knowledge of the Borrower, oral notice, of any claim that such Loan Party or Subsidiary or any of their respective contractors or employees, have suffered a breach of Personal Information as defined under applicable Law or is not in compliance with applicable Laws relating to the collection, use or disclosure of Personal Information, except to the extent any such breach or non-compliance: (i) did not require and is not likely to require such Loan Party or such Subsidiary to provide notification in accordance with applicable Law to affected customers, patients or other impacted individuals, or to any Governmental Authority, (ii) could not be reasonably likely, either individually or in the aggregate, to have a Material Adverse Effect, and (iii) has not resulted in or is not reasonably likely to result in any claim or notice from any Governmental Authority alleging a breach of Personal Information or non-compliance with Law or referencing the investigation of any such breach of Personal Information or non-compliance with Law.

6.28 Representations as to Foreign Loan Parties.

With respect to each Foreign Loan Party, that:

(a) Such Foreign Loan Party is subject to civil and commercial Laws with respect to its obligations under this Agreement and the other Loan Documents to which it is a party (collectively as to such Foreign Loan Party, the "Applicable Foreign Loan Party Documents"), and the execution, delivery and performance by such Foreign Loan Party of the Applicable Foreign Loan Party Documents constitute and will constitute private and commercial acts and not public or governmental acts. Neither such Foreign Loan Party nor any of its property has any immunity from jurisdiction of any court or from any legal process (whether through service or notice, attachment prior to judgment, attachment in aid of execution, execution or otherwise) under the laws of the jurisdiction in which such Foreign Loan Party is organized and existing in respect of its obligations under the Applicable Foreign Loan Party Documents.

(b) The Applicable Foreign Loan Party Documents are in proper legal form under the Laws of the jurisdiction in which such Foreign Loan Party is organized and existing for the enforcement thereof against such Foreign Loan Party under the Laws of such jurisdiction, and to ensure the legality, validity, enforceability, priority or admissibility in evidence of the Applicable Foreign Loan Party Documents. It is not necessary to ensure the legality, validity, enforceability, priority or admissibility in evidence of the Applicable Foreign Loan Party Documents that the Applicable Foreign Loan Party Documents be filed, registered or recorded with, or executed or notarized before, any court or other authority in the jurisdiction in which such Foreign Loan Party is organized and existing or that any registration charge or stamp or similar tax be paid on or in respect of the Applicable Foreign Loan Party Documents or any other document, except for (i) any such filing, registration, recording, execution or notarization as has been made or is not required to be made until the Applicable Foreign Loan Party Document or any other document is sought to be enforced and (ii) any charge or tax as has been timely paid.

(c) There is no tax, levy, impost, duty, fee, assessment or other governmental charge, or any deduction or withholding, imposed by any Governmental Authority in or of the jurisdiction in which such Foreign Loan Party is organized and existing either (i) on or by virtue of the execution or delivery of the Applicable Foreign Loan Party Documents or (ii) on any payment to

be made by such Foreign Loan Party pursuant to the Applicable Foreign Loan Party Documents, except as has been disclosed to the Administrative Agent.

(d) The execution, delivery and performance of the Applicable Foreign Loan Party Documents executed by such Foreign Loan Party are, under applicable foreign exchange control regulations of the jurisdiction in which such Foreign Loan Party is organized and existing, not subject to any notification or authorization except (i) such as have been made or obtained or (ii) such as cannot be made or obtained until a later date (provided that any notification or authorization described in clause (ii) shall be made or obtained as soon as is reasonably practicable).

(e) The choice of law of the State of New York as the governing law of certain of the Loan Documents will be recognized and enforced in such Foreign Loan Party's jurisdiction of incorporation and any judgment obtained in New York in relation to a Loan Document will be recognized and enforced in such Foreign Loan Party's jurisdiction of incorporation.

(f) Under the Laws of the jurisdiction in which such Foreign Loan Party is incorporated it is not necessary that the Loan Documents be filed, recorded or enrolled with any court or other authority in that jurisdiction or that any stamp, registration or similar tax be paid on or in relation to the Loan Documents or the transactions contemplated by the Loan Documents.

ARTICLE VII

AFFIRMATIVE COVENANTS

So long as any Lender shall have any Commitment hereunder, any Loan or other Obligation hereunder shall remain unpaid or unsatisfied (other than contingent indemnification obligations for which no claim has been asserted), the Loan Parties shall and shall cause each Subsidiary to:

7.01 Financial Statements.

Deliver to the Administrative Agent for further distribution to each Lender, in a form reasonably satisfactory to the Administrative Agent (provided that financial statements that conform with IFRS and any required SEC or other similar reporting rules binding on the Borrower shall be deemed satisfactory):

(a) within [***] days after the end of each fiscal year of the Borrower, a consolidated balance sheet of the Borrower and its Subsidiaries as at the end of such fiscal year, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for such fiscal year, setting forth in each case in comparative form the figures for the previous fiscal year, all in reasonable detail and prepared in accordance with IFRS, audited and accompanied by a report and opinion of Ernst & Young LLP (or EY Sweden) or another independent certified public accountant of nationally recognized standing reasonably acceptable to the Administrative Agent, which report and opinion shall be prepared in accordance with IFRS and shall not be subject to any "going concern" or like qualification or exception (other than a qualification for going concern resulting solely from the impending maturity of Indebtedness under this Agreement) or any qualification or exception as to the scope of such audit; and

(b) within [***] days after the end of each of the first three fiscal quarters of each fiscal year of the Borrower, a consolidated balance sheet of the Borrower and its Subsidiaries as at

the end of such fiscal quarter, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for such fiscal quarter and for the portion of the Borrower's fiscal year then ended, setting forth in each case in comparative form the figures for the corresponding fiscal quarter of the previous fiscal year and the corresponding portion of the previous fiscal year, all in reasonable detail and certified by a Responsible Financial Officer of the Borrower as fairly presenting in all material respects the financial condition, results of operations, shareholders' equity and cash flows of the Borrower and its Subsidiaries in accordance with IFRS, subject only to normal year-end audit adjustments and the absence of footnotes.

7.02 Certificates; Other Information.

Deliver to the Administrative Agent for further distribution to each Lender:

(a) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b), a duly completed Compliance Certificate signed by the chief executive officer, chief financial officer, treasurer or controller of the Borrower (in each case, which is a Responsible Financial Officer of the Borrower), which shall include (among other things required by the Loan Documents) (i) a certification as to compliance with the covenants set forth in Section 8.16 and Section 8.17, (ii) information regarding the amount of all Dispositions, Involuntary Dispositions, Debt Issuances, and Extraordinary Receipts that occurred during the period covered by such financial statements, in each case, solely to the extent the Net Cash Proceeds of such Dispositions, Involuntary Dispositions, Debt Issuances, and Extraordinary Receipts exceed [***] on an individual basis, (iii) information regarding any material changes in accounting policies or financial reporting practices by the Borrower or any Subsidiary during the reporting period covered by such Compliance Certificate, (iv) (A) a list of any new Material Contract entered into by the Borrower or any Subsidiary during the reporting period covered by such Compliance Certificate and (B) a list of any Material Contracts amended in any material respect or terminated during the reporting period covered by such Compliance Certificate and (v) a list of any fee owned real property subject to a Mortgage that is or has become a Flood Hazard Property during the reporting period covered by such Compliance Certificate.

(b) within [***] days after the commencement of each fiscal year of the Borrower, an annual business plan and budget of the Borrower and its Subsidiaries for the then current fiscal year containing projections for each quarter of such fiscal year, in form and substance reasonably satisfactory to the Administrative Agent;

(c) promptly after the same are available, copies of each annual report, proxy or financial statement or other report or communication sent to the equityholders of any Loan Party, and copies of all annual, regular, periodic and special reports and registration statements which a Loan Party may file or be required to file with the SEC under Section 13 or 15(d) of the Securities Exchange Act of 1934, and not otherwise required to be delivered to the Administrative Agent pursuant hereto;

(d) not more than [***] Business Days after their approval, copies of the minutes of each meeting of the Board of Directors of the Borrower; provided, that, it is understood and agreed that the Borrower may redact or withhold any information included in such materials if (i) such information may (in the reasonable determination of the Borrower upon advice of counsel), (A) be subject to the attorney-client or similar privilege or (B) constitute attorney work product, (ii) such Board of Directors or any executive officer of the Borrower deems (in its good faith determination) such information to constitute trade secrets or proprietary information or (iii) the disclosure thereof is prohibited by any applicable Law;

(e) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b), copies of any material statement or material report furnished to the holders of Permitted Convertible Bond Indebtedness during such period pursuant to the terms of the applicable indenture, loan or credit or similar governing agreement and not otherwise required to be furnished to the Administrative Agent under this Agreement, excluding, for the avoidance of doubt, any required periodic reporting or compliance certificates;

(f) promptly, and in any event within [***] Business Days after receipt thereof by any Loan Party or any Subsidiary, (i) copies of each notice or other correspondence received from the SEC (or comparable national agency in any applicable non-U.S. jurisdiction) concerning any investigation or possible investigation or other inquiry by such agency regarding financial or other operational results of any Loan Party or any Subsidiary and (ii) copies of any material written correspondence or any other material written communication from the FDA or any other regulatory body;

(g) promptly, such additional information regarding the business, financial or corporate affairs of any Loan Party or any Subsidiary, or compliance with the terms of the Loan Documents, as the Administrative Agent or any Lender may from time to time request;

(h) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b), a certificate of a Responsible Officer of the Borrower (i) listing (A) all applications by any Loan Party, if any, for Copyrights, Patents or Trademarks made since the date of the prior certificate (or, in the case of the first such certificate, the Closing Date), (B) all issuances of registrations or letters on existing applications by any Loan Party for Copyrights, Patents and Trademarks received since the date of the prior certificate (or, in the case of the first such certificate, the Closing Date), (C) any Nefecon License entered into by any Loan Party since the date of the prior certificate (or, in the case of the first such certificate, the Closing Date) and (D) such supplements to Schedule 6.17(a) as are necessary to cause such schedule to be true and complete as of the date of such certificate, (ii) attaching the insurance binder or other evidence of insurance for any insurance coverage of any Loan Party or any Subsidiary that was renewed, replaced or modified in any material respect during the period covered by such financial statements (provided that changes solely with respect to the policy period or renewal thereof or premium therefor shall not be deemed material) and (iii) an updated Schedule 1.01 as of the date of such certificate listing thereon any Product then manufactured, sold, developed, tested or marketed by any Loan Party to the extent such Product was not previously listed on Schedule 1.01 (which shall include a brief description of such Product, plus copies of all Regulatory Authorizations relating to such new Product and/or the Borrower's or such Subsidiary's manufacture, sale, development, testing or marketing thereof issued or outstanding as of the date of such notice);

(i) promptly, and in any event within five (5) Business Days after the Borrower or any Subsidiary or Product Distributor (as relating to Products) obtains any new or additional Regulatory Authorizations material to the commercialization of Nefecon from the FDA (or parallel state or local authorities), or foreign counterparts of the FDA (or parallel state or local authorities), with respect to any Product which has previously been disclosed to the Administrative Agent, the Loan Parties shall promptly give written notice to the Administrative Agent of such new or additional Regulatory Authorizations along with a copy thereof;

(j) promptly, and in any event within five (5) Business Days after receipt thereof by any Loan Party or any Subsidiary, copies of all subpoenas, requests for information and other notices regarding any active or potential investigation of, or claim or litigation against, any Loan Party or any Subsidiary or Product Distributor by any Governmental Authority, and the findings of

any inspections of any manufacturing facilities of any Loan Party, any Subsidiary or any Third Party suppliers or Product Distributors of any Loan Party or any Subsidiary by any Governmental Authority (including any Form 483s and warning letters); and

(k) concurrently with the delivery of the financial statements referred to in Sections 7.01(a) and (b), copies of each material report or notice received in respect of any Material Contract or its performance during the applicable period, including any such report or notice relating to the calculation of any amount owing to the Borrower or any Subsidiary under or in connection with any Material Contract (in each case, subject to the confidentiality obligations set forth in such Material Contracts).

Documents required to be delivered pursuant to Section 7.01(a) or (b) or Section 7.02 may be delivered electronically and if so delivered, shall be deemed to have been delivered (any such electronic delivery, a "Deemed Delivery") on the date (i) on which the Borrower posts such documents, or provides a link thereto on the Borrower's website on the Internet at the website address listed on Schedule 11.02, or (ii) on which such documents are posted on the Borrower's behalf on an Internet or intranet website (including EDGAR), if any, to which each Lender and the Administrative Agent have access (whether a commercial, third-party website or whether sponsored by the Administrative Agent) (it being understood and agreed that, prior to the posting of any such documents to any website (other than EDGAR) under this clause (ii) for the first time during the term of this Agreement, the Borrower shall identify such website to the Administrative Agent, in writing, together with a statement that it intends to use such website for Deemed Delivery under this Agreement). The Administrative Agent shall have no obligation to request the delivery of or to maintain paper copies of the documents referred to above, and in any event shall have no responsibility to monitor compliance by the Borrower with any such request for delivery by a Lender, and each Lender shall be solely responsible for requesting delivery to it or maintaining its copies of such documents.

The Borrower hereby acknowledges that certain of the Lenders may have personnel who do not wish to receive material non-public information with respect to the Borrower or its Affiliates, or the respective securities of any of the foregoing, and who may be engaged in investment and other market-related activities with respect to such Persons' securities. The Borrower hereby agrees that if requested by the Administrative Agent it will, (x) in good faith, identify that portion of the materials and/or information provided by, or to be provided by, or on behalf of the Borrower hereunder that does not constitute material non-public information with respect to the Borrower or its Affiliates or their respective securities (the "Public Borrower Materials") and (y) clearly and conspicuously mark all Public Borrower Materials "PUBLIC" which, at a minimum, shall mean that the word "PUBLIC" shall appear prominently on the first page thereof (it being understood that by marking Public Borrower Materials "PUBLIC," the Borrower shall be deemed to have authorized the Administrative Agent, any Affiliate thereof and the Lenders to treat such Public Borrower Materials as not containing any material non-public information (although it may be sensitive and proprietary) with respect to the Borrower or its securities for purposes of United States federal and state securities laws (provided, however, that to the extent such Public Borrower Materials constitute Information, they shall be treated as set forth in Section 11.07)).

7.03 Notices. Promptly after any Responsible Officer of the Borrower obtains knowledge of any of the following (but in any event within five (5) Business Days after such Responsible Officer obtains such knowledge) notify the Administrative Agent (for further distribution to each Lender) of:

(a) the occurrence of any Default.

(b) any matter that has resulted or could reasonably be expected to result in a Material Adverse Effect.

(c) the occurrence of any ERISA Event.

(d) any litigation, arbitration or governmental investigation or proceeding not previously disclosed in any public filing or otherwise by the Loan Parties which has been instituted (or, in each case, any material development with respect thereto) or, to the knowledge of the Borrower, is threatened in writing, with respect to any Product or against any Loan Party or any Subsidiary or to which any of the properties of any thereof is subject, in each case, which could reasonably be expected to result in a Material Adverse Effect.

Each notice pursuant to this Section 7.03(a) through (d) shall be accompanied by a statement of a Responsible Officer of the Borrower setting forth details of the occurrence referred to therein and stating what action the applicable Loan Party has taken and proposes to take with respect thereto. Each notice pursuant to Section 7.03(a) shall describe with particularity any and all provisions of this Agreement and any other Loan Document that have been breached.

7.04 Payment of Obligations.

Pay and discharge, as the same shall become due and payable, (a) prior to the date on which penalties attach thereto, all tax liabilities, assessments and governmental charges or levies upon it or its properties or assets, unless the same are being contested in good faith by appropriate proceedings diligently conducted and adequate reserves in accordance with IFRS are being maintained by the Loan Party or such Subsidiary, (b) all lawful claims which, if unpaid, would by law become a Lien upon its property (other than Permitted Liens), and (c) all Indebtedness, as and when due and payable, but subject to any subordination provisions contained in any instrument or agreement evidencing such Indebtedness, except, in each case, to the extent that the failure to do so could not reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

7.05 Preservation of Existence, Etc.

(a) Preserve, renew and maintain in full force and effect its legal existence under the Laws of the jurisdiction of its organization except in a transaction permitted by Section 8.04 or Section 8.05, except (other than with respect to the Borrowers or any U.S. Loan Party) where the failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(b) Preserve, renew and maintain in full force and effect its good standing under the Laws of the jurisdiction of its organization, except to the extent the failure to do so could not reasonably be expected to have a Material Adverse Effect.

(c) Take all commercially reasonable action to maintain all rights, privileges, permits, licenses and franchises necessary or desirable in the normal conduct of its business, except to the extent that the failure to do so could not reasonably be expected to have a Material Adverse Effect.

7.06 Maintenance of Properties.

(a) Maintain, preserve and protect all of its material properties and equipment necessary in the operation of its business in good working order and condition, ordinary wear and tear excepted except where the failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(b) Make all necessary repairs thereto and renewals and replacements thereof, except where the failure to do so could not reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect.

(c) Use the standard of care typical in the industry in the operation and maintenance of its Facilities.

7.07 Maintenance of Insurance.

(a) Maintain with financially sound and reputable insurance companies not Affiliates of the Borrower, insurance with respect to its properties and business against loss or damage of the kinds customarily insured against by Persons engaged in the same or similar business, of such types and in such amounts as are customarily carried under similar circumstances by such other Persons.

(b) Without limiting the foregoing, (i) maintain, if available, fully paid flood hazard insurance on all fee owned real property that is located in a special flood hazard area and that constitutes Collateral, on such terms and in such amounts as required by The National Flood Insurance Reform Act of 1994 or as otherwise reasonably required by the Administrative Agent, (ii) upon written request, furnish to the Administrative Agent evidence of the renewal (and payment of renewal premiums therefor) of all such policies prior to the expiration or lapse thereof, and (iii) upon written request, furnish to the Administrative Agent prompt written notice of any redesignation of any such improved real property into or out of a special flood hazard area.

(c) Cause the Administrative Agent and its successors and/or assigns to be named as lender's loss payee or mortgagee as its interest may appear, and/or additional insured with respect to any such insurance providing liability coverage or coverage in respect of any Collateral (excluding any business operations insurance policies, director and officer insurance policies, and cyber-security risk insurance policies), and use commercially reasonable efforts to cause each provider of any such insurance to agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Administrative Agent, that it will give the Administrative Agent thirty (30) days (or such lesser amount as the Administrative Agent may agree) prior written notice before any such policy or policies shall be adversely altered or canceled.

7.08 Compliance with Laws.

Comply with the requirements of all Laws and all orders, writs, injunctions and decrees applicable to it or to its business or property, except in such instances in which (a) such requirement of Law or order, writ, injunction or decree is being contested in good faith by appropriate proceedings diligently conducted, or (b) the failure to comply therewith could not reasonably be expected to have a Material Adverse Effect.

7.09 Books and Records.

(a) Maintain proper books of record and account, in which full, true and correct entries in conformity with IFRS consistently applied shall be made of all financial transactions and matters involving the assets and business of such Loan Party or such Subsidiary, as the case may be.

(b) Maintain such books of record and account in material conformity with all applicable requirements of any Governmental Authority having regulatory jurisdiction over such Loan Party or such Subsidiary, as the case may be.

7.10 Inspection Rights.

Permit representatives of the Administrative Agent, Athyrium and each Lender to visit and inspect any of its properties, to examine its corporate, financial and operating records, and make copies thereof or abstracts therefrom, and to discuss its affairs, finances and accounts with its officers, independent public accountants, and, with good cause shown, its directors, all at the expense of the Borrower and at such reasonable times during normal business hours and as often as may be desired, upon reasonable advance notice to the Borrower; provided, however, so long as no Event of Default exists, the Administrative Agent and each Lender (collectively) may make no more than one such visit and inspection (excluding any such visits and inspections during the continuance of an Event of Default) per fiscal year; provided, further, however, when an Event of Default exists, the Administrative Agent or any Lender (or any of their respective representatives) may do any of the foregoing at the expense of the Borrower at any time during normal business hours and without advance notice. Notwithstanding anything to the contrary in this Section 7.10, neither the Borrower nor any Subsidiary will be required to disclose or permit the inspection or discussion of, any document, information or other matter (i) that constitutes trade secrets or proprietary information, (ii) in respect of which disclosure to the Administrative Agent or any Lender (or their representatives or contractors) is prohibited by (x) Law or (y) fiduciary duty or any binding agreement, (iii) that is subject to attorney client or similar privilege or constitutes attorney work product or (iv) in respect of which the Borrower or any Subsidiary owes confidentiality obligations to any third party (provided such confidentiality obligations were not entered into in contemplation of the requirements of this Section 7.10); provided, that, in the case of binding agreements with respect to clause (ii)(y) or (iv), the Borrower or the applicable Subsidiary shall use commercially reasonable efforts to obtain waivers and, in the cases of clauses (ii)(y), (iii) and (iv) shall notify the Administrative Agent as to the scope of the information that is not being provided under the applicable exception.

7.11 Use of Proceeds.

Use the proceeds of the Loans (a) to refinance all Indebtedness (including related fees and expenses) of the Borrower and its Subsidiaries under the Existing Credit Agreement, (b) to support the commercialization of Nefecon, (c) to fund research and development activities and business development activities, (d) to pay fees and expenses in connection with this Agreement and the other Loan Documents and (e) for other general corporate purposes; provided, that, in no event shall the proceeds of the Loans be used in contravention of any Law or any Loan Document.

7.12 Additional Subsidiaries.

Within thirty (30) days (or such longer time period which is necessary, in the good faith judgment of the Borrower in consultation with the Administrative Agent, in order not to violate any applicable financial assistance rules (which for any Subsidiary incorporated in Sweden shall be ninety (90) days)) (or such later date reasonably acceptable to the Administrative Agent) after the acquisition or formation of any Subsidiary (it being understood that any Excluded Subsidiary ceasing to be an Excluded Subsidiary but remaining a Subsidiary shall be deemed to be the acquisition of a Subsidiary for purposes of this Section):

(a) notify the Administrative Agent thereof in writing, together with the (i) jurisdiction of organization, (ii) number of shares of each class of Equity Interests outstanding, (iii) number and percentage of outstanding shares of each class owned (directly or indirectly) by the Borrower or any Subsidiary and (iv) number and effect, if exercised, of all outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto; and

(b) cause such Subsidiary (other than any Excluded Subsidiary) to (i) become a Guarantor by executing and delivering to the Administrative Agent a Joinder Agreement or such other documents as the Administrative Agent shall reasonably request for such purpose, and (ii) deliver to the Administrative Agent documents of the types referred to in Sections 5.01(f) and (g)

and favorable opinions of counsel to such Person (which shall cover, among other things, the legality, validity, binding effect and enforceability of the documentation referred to in clause (i)), all in form and substance reasonably satisfactory to the Administrative Agent.

7.13 ERISA Compliance.

Do, and cause each of its ERISA Affiliates to do, each of the following: (a) maintain each Plan in compliance in all material respects with the applicable provisions of ERISA, the Internal Revenue Code and other federal or state law, (b) cause each Plan that is qualified under Section 401(a) of the Internal Revenue Code to maintain such qualification, and (c) make all required contributions to any Plan subject to Section 412, Section 430 or Section 431 of the Internal Revenue Code.

7.14 Pledged Assets.

(a) Equity Interests. Cause one hundred percent (100%) of the issued and outstanding Equity Interests of each Subsidiary directly owned by a Loan Party to be subject at all times to a first priority, perfected Lien in favor of the Administrative Agent, for the benefit of the Secured Parties, pursuant to the terms and conditions of the Collateral Documents, together with opinions of counsel and any filings and deliveries necessary in connection therewith to perfect the security interests therein, all in form and substance satisfactory to the Administrative Agent.

(b) Other Property. Cause all property (other than Excluded Property) of each Loan Party to be subject at all times to first priority (subject to Permitted Liens), perfected and, in the case of fee simple ownership of real property, title insured Liens in favor of the Administrative Agent to secure the Obligations pursuant to the Collateral Documents or, with respect to any such property acquired subsequent to the Closing Date, such other additional security documents as the Administrative Agent shall request and, in connection with the foregoing, deliver to the Administrative Agent such other documentation as the Administrative Agent may request including filings and deliveries necessary to perfect such Liens, Organization Documents, resolutions, Real Property Security Documents, and favorable opinions of counsel to such Person, all in form and substance reasonably satisfactory to the Administrative Agent; provided, that, notwithstanding anything to the contrary set forth herein, it is understood and agreed that, with respect to Collateral Access Agreements, the Loan Parties shall only be required to use commercially reasonable efforts to obtain or otherwise enter into such Collateral Access Agreements with applicable third parties.

7.15 Compliance with Material Contracts.

Comply in all respects with each Material Contract of such Person, except as could not, individually or in the aggregate, reasonably be expected to have (a) a material adverse effect on any Product Development and Commercialization Activities or (b) a Material Adverse Effect.

7.16 Deposit Accounts.

(a) Within thirty (30) days after the acquisition or establishment of any Deposit Account (other than an Excluded Account) by any Loan Party, provide written notice thereof to the Administrative Agent.

(b) Subject to Section 7.21, cause all Deposit Accounts of the Loan Parties (other than Excluded Accounts) maintained in the United States at all times to be subject to Account Control Agreements, in each case in form and substance satisfactory to the Administrative Agent (it being understood that the Loan Parties shall have sixty (60) days to comply with this Section 7.16(b)

solely with respect to any Deposit Account (other than Excluded Accounts) acquired or established after the Closing Date (such period to be measured from the date of acquisition or establishment)).

7.17 Products and Permits.

Either directly or through its Product Distributors, as applicable, obtain, maintain and preserve, comply with in all material respects, and take all necessary action to timely renew all Permits and accreditations which are necessary or material with respect to any Product Development and Commercialization Activities associated with any Product or to the conduct of the business of the Borrower and its Subsidiaries, and promptly provide evidence of the same to the Administrative Agent.

7.18 Consent of Licensors.

Promptly after entering into or becoming bound by any Material Contract after the Closing Date: (a) provide written notice to the Administrative Agent of the material terms of such Material Contract with a description of its anticipated and projected impact on the business and financial condition of the Borrower and its Subsidiaries and (b) in good faith take such commercially reasonable actions as the Administrative Agent may request to obtain the consent of, or waiver by, any Person whose consent or waiver is necessary for the Administrative Agent to be granted and perfect a valid security interest in such Material Contract and to fully exercise its rights under any of the Loan Documents with respect to such Material Contract, including in the event of a disposition or liquidation of the rights, assets or property that is the subject of such Material Contract.

7.19 Anti-Corruption Laws.

Conduct its business in compliance with the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other similar anti-corruption legislation in other jurisdictions and maintain policies and procedures designed to promote and achieve compliance with such laws.

7.20 Maintenance of Regulatory Authorizations, Contracts, Intellectual Property, Etc.

(a) With respect to the Products, (i) maintain, either directly or through its Product Distributors, as applicable, in full force and effect all Regulatory Authorizations, contract rights, authorizations or other rights necessary or material for the operations of the business of the Borrower and its Subsidiaries and relevant Product Distributors, and comply with the terms and conditions applicable to the foregoing excluding the maintenance of the Regulatory Authorizations that in the commercially reasonable business judgment of the Loan Parties are not necessary or material for the conduct of the business of the Borrower and its Subsidiaries; (ii) promptly notify the Administrative Agent of any Safety Notice conducted, to be undertaken or issued, by such Loan Party, its respective Subsidiaries or its respective Product Distributors or suppliers whether or not at the request, demand or order of any Governmental Authority or otherwise with respect to any Product or manufacturing facility owned or operated by any Loan Party or their respective Subsidiaries or any Product Distributor (as relating to Products), or any basis for undertaking or issuing any such action or item, in each case, that could reasonably be expected to have a material effect on any Product Development and Commercialization Activities; (iii) design, manufacture, store, transport, label, sell, market, and distribute all Products in compliance with applicable Laws, including without limitation, cGMPs, the FDCA, the PHSA, the Controlled Substances Act, except where the failure to do so could not reasonably be expected to have a material adverse effect on any Product Development and Commercialization Activities; (iv) conduct all studies, tests and preclinical and clinical trials relating to the Products in accordance with all cGCPs, and other applicable Laws, except where the failure to do so could not reasonably be expected to have a

material effect on any Product Development and Commercialization Activities; and (v) operate all manufacturing Facilities where Product Development and Commercialization Activities are conducted in material compliance with applicable Laws, including without limitation, cGMPs, the Controlled Substances Act, except where the failure to do so could not reasonably be expected to have a material adverse effect on any Product Development and Commercialization Activities.

(b) (i) Maintain in full force and effect or pursue the prosecution of, as the case may be, and pay all costs and expenses relating to, all Material Intellectual Property owned or controlled by such Loan Party or its respective Subsidiaries and all Material Contracts excluding the maintenance of Material Intellectual Property that in the commercially reasonable business judgment of the relevant Loan Party is not necessary or material for the conduct of the business of any Loan Party or any Subsidiary or to Product Development and Commercialization Activities with respect to any Product; (ii) promptly notify the Administrative Agent of any Infringement or other violation by any Person of Material Intellectual Property owned or controlled by such Loan Party or its respective Subsidiaries; (iii) use commercially reasonable efforts to pursue, enforce, and maintain in full force and effect legal protection for all Material Intellectual Property, including Patents, developed or controlled by such Loan Party or any of its respective Subsidiaries; and (iv) promptly notify the Administrative Agent of any claim by any Person that the conduct of such Loan Party's or such Subsidiary's business (including any research, development, manufacture, import, use, sale, storage, labeling, marketing, promotion, supply, distribution, testing, packaging, purchasing or other commercialization activities, receipt of payment in respect of any of the foregoing, or like activities the purpose of which is to develop or commercially exploit any Product) or the conduct of any Product Development or Commercialization Activities by any Product Distributor, Infringes any Intellectual Property of that Person and, if requested by the Administrative Agent, use commercially reasonable efforts to resolve such claim.

(c) Furnish to the Administrative Agent prompt written notice of the following:

(i) any notice that the FDA or any other Governmental Authority is limiting, suspending or revoking any Regulatory Authorization applicable to any Product, changing the market classification or labeling of or otherwise materially restricting any Product or considering any of the foregoing;

(ii) any Loan Party or any Subsidiary becoming subject to any administrative or regulatory action, any FDA or EMA inspection or any non-routine inspection by any other Person, receipt of inspectional observations (e.g., on FDA Form 483), warning letter, or notice of violation letter, or any Product being seized, withdrawn, recalled, detained, or subject to a suspension of manufacturing, or the commencement of any proceedings in the United States or any other jurisdiction seeking the withdrawal, recall, suspension, import detention, or seizure of any Product are pending or threatened against any Loan Party or any Subsidiary or any relevant Product Distributor;

(iii) any written recommendation (together with a copy thereof) from any Governmental Authority that any Loan Party or any Subsidiary, or any obligor to which any Loan Party or any Subsidiary provides Products or services, or any Product Distributor, should have its licensure, provider or supplier number, or accreditation suspended, revoked, or limited in any way, or any penalties or sanctions imposed; or

(iv) any notice relating to a Paragraph IV Certification concerning any Product and asserting the non-infringement, invalidity or unenforceability of any Patent owned by or licensed to any Loan Party or any Subsidiary or any associated litigation.

7.21 Post-Closing Obligations.

Within the time periods set forth on Schedule 7.21 (or such longer periods as the Administrative Agent may agree in its sole discretion), deliver to the Administrative Agent such documents, instruments, certificates or agreements set forth on Schedule 7.21, in each case in form and substance reasonably satisfactory to the Administrative Agent.

ARTICLE VIII

NEGATIVE COVENANTS

So long as any Lender shall have any Commitment hereunder, any Loan or other Obligation hereunder shall remain unpaid or unsatisfied (other than contingent indemnification obligations for which no claim has been asserted), no Loan Party shall, nor shall it permit any Subsidiary to, directly or indirectly:

8.01 Liens.

Create, incur, assume or suffer to exist any Lien upon any of its property, assets or revenues, whether now owned or hereafter acquired, other than the following:

(a) Liens pursuant to any Loan Document;

(b) Liens existing on the Closing Date and listed on Schedule 8.01 and any renewals or extensions thereof; provided, that, (i) the property covered thereby is not changed (other than the proceeds or products thereof and after-acquired property that is affixed to or incorporated into property covered by such Lien), (ii) the amount secured or benefited thereby is not increased, (iii) the direct or any contingent obligor with respect thereto is not changed, and (iv) any renewal or extension of the obligations secured or benefited thereby is permitted by Section 8.03(b);

(c) Liens (other than Liens imposed under ERISA) for taxes, assessments or governmental charges or levies not yet delinquent or which are being contested in good faith and by appropriate proceedings diligently conducted, if adequate reserves with respect thereto are maintained on the books of the applicable Person in accordance with IFRS;

(d) statutory Liens of landlords and Liens of carriers, warehousemen, mechanics, materialmen and suppliers and other Liens imposed by law or pursuant to customary reservations or retentions of title arising in the ordinary course of business; provided, that, such Liens secure only amounts (i) not yet due and payable or (ii) if due and payable, are unfiled and no other action has been taken to enforce the same or are being contested in good faith by appropriate proceedings for which adequate reserves determined in accordance with IFRS have been established or (iii) with respect to which the failure to make payment could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect;

(e) pledges or deposits in the ordinary course of business in connection with workers' compensation, unemployment insurance and other social security legislation, other than any Lien imposed by ERISA;

(f) deposits to secure the performance of bids, trade contracts and leases (other than Indebtedness), statutory obligations, surety and appeal bonds, indemnity and performance bonds and other obligations of a like nature incurred in the ordinary course of business;

(g) easements, rights-of-way, restrictions and other similar encumbrances and title deficiencies affecting real property which, in the aggregate, are not substantial in amount, and which do not in any case materially detract from the value of the property subject thereto or materially interfere with the ordinary conduct of the business of the applicable Person;

(h) Liens securing judgments for the payment of money (or appeal or other surety bonds relating to such judgments) not constituting an Event of Default under Section 9.01(h);

(i) Liens securing Indebtedness permitted under Section 8.03(e); provided, that: (i) such Liens do not at any time encumber any property other than the property financed by such Indebtedness, (ii) the Indebtedness secured thereby does not exceed the cost (negotiated on an arm's length basis) of the property being acquired on the date of acquisition and (iii) such Liens attach to such property concurrently with or within one hundred and eighty (180) days after the acquisition thereof;

(j) (i) licenses, sublicenses, leases or subleases (other than relating to intellectual property) granted to others in the ordinary course of business not interfering in any material respect with the business of any Loan Party or any Subsidiary and (ii) Permitted Licenses;

(k) any interest of title of a lessor under, and Liens arising from Uniform Commercial Code financing statements (or equivalent filings, registrations or agreements in foreign jurisdictions) relating to, leases permitted by this Agreement;

(l) Liens arising in the ordinary course of business by virtue of any contractual, statutory or common law provision relating to banker's Liens, rights of set off or similar rights and remedies covering deposit or securities accounts (including funds or other assets credited thereto) or other funds maintained with a depository institution or securities intermediary, in each case incurred in the ordinary course of business;

(m) Liens of a collection bank arising under Section 4-210 of the Uniform Commercial Code on items in the course of collection;

(n) Liens of sellers of goods to the Borrower and any of its Subsidiaries arising under Article 2 of the Uniform Commercial Code or similar provisions of applicable law in the ordinary course of business, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses;

(o) Liens in favor of customs and revenue authorities arising as a matter of law, in the ordinary course of business, to secure payment of customs duties in connection with the importation of goods;

(p) Liens arising from precautionary Uniform Commercial Code financing statements or similar filings under applicable law regarding operating leases entered into by the Borrower or any Subsidiary in the ordinary course of business; and

(q) other Liens securing Indebtedness or other obligations not exceeding [***] in the aggregate at any one time outstanding;

provided, that, no Lien otherwise permitted under this Section 8.01(a)-(q) (other than Permitted Nefecon Licenses) shall apply to Nefecon or any Intellectual Property or other rights associated with Nefecon.

8.02 Investments.

Make any Investments, except:

(a) Investments held by the Borrower or any Subsidiary in the form of cash or Cash Equivalents;

(b) Investments (i) existing as of the Closing Date and set forth in Schedule 8.02 and (ii) Investments by the Borrower and its Subsidiaries consisting of the ownership of Equity Interests in their respective Subsidiaries outstanding on the Closing Date;

(c) (i) Investments in any Person that is a Loan Party, (ii) Investments by any Excluded Subsidiary in any other Excluded Subsidiary (other than [***]), (iii) Investments by Loan Parties in Excluded Subsidiaries (other than [***]); provided, that, [***], (iv) [***] and (v) Investments by Loan Parties in Excluded Subsidiaries (other than [***]) to the extent, in the good faith judgment of the Borrower necessary to remediate, rectify or otherwise prevent any "thin capitalization" or similar obligation under applicable Law in the jurisdiction of organization or formation of such Excluded Subsidiary;

(d) Permitted Acquisitions;

(e) Investments consisting of extensions of credit in the nature of accounts receivable or notes receivable arising from the grant of trade credit in the ordinary course of business, and Investments received in satisfaction or partial satisfaction thereof from financially troubled account debtors to the extent reasonably necessary in order to prevent or limit loss;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business and (ii) loans to employees, officers or directors relating to the purchase of Qualified Capital Stock of the Borrower pursuant to employee stock purchase plans approved by the Borrower's Board of Directors, in an aggregate amount for all such Investments made in reliance of this clause (f) not to exceed [***] at any one time outstanding; provided, that, no Investment otherwise permitted by this clause (f) shall be permitted to be made if any Event of Default has occurred and is continuing or would result therefrom;

(g) (i) Investments consisting of obligations of any Loan Party or any Subsidiary under Swap Contracts permitted under Section 8.03(d) that are incurred for non-speculative purposes in the ordinary course of business and (ii) to the extent constituting an Investment, Permitted Equity Derivatives;

(h) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(i) other Investments not exceeding [***] in the aggregate at any one time outstanding; provided, that, no Investment otherwise permitted by this clause (i) shall be permitted to be made if any Event of Default has occurred and is continuing or would result therefrom; and

(j) to the extent constituting an Investment, fundamental changes permitted by Section 8.04 (other than by reference to this Section 8.02 (or any sub-clause hereof)).

Notwithstanding anything to the contrary in this Agreement or any other Loan Document, (x) in no event shall any Loan Party (A) Dispose of (I) any Material Intellectual Property to any Subsidiary that is not a Loan Party or (II) Nefecon or any Intellectual Property or other rights associated with Nefecon to any Subsidiary that is not a Loan Party or (B) contribute or otherwise invest (I) any Material Intellectual Property in any Subsidiary that is not a Loan Party or (II) Nefecon or any Intellectual Property or other rights associated with Nefecon to any Subsidiary that is not a Loan Party and (y) [***].

8.03 Indebtedness.

Create, incur, assume or suffer to exist any Indebtedness, except:

(a) Indebtedness under the Loan Documents;

(b) Indebtedness of the Borrower and its Subsidiaries existing on the Closing Date and described on Schedule 8.03 (and Permitted Refinancings thereof);

(c) intercompany Indebtedness permitted under Section 8.02 (other than by reference to this Section 8.03 (or any sub-clause hereof));

(d) obligations (contingent or otherwise) of the Borrower or any Subsidiary (other than any Excluded Subsidiary) existing or arising under any Swap Contract, provided, that, (i) such obligations are (or were) entered into by such Person in the ordinary course of business for the purpose of directly mitigating risks associated with liabilities, commitments, investments, assets, or property held or reasonably anticipated by such Person, or changes in the value of securities issued by such Person, and not for purposes of speculation or taking a "market view;" and (ii) such Swap Contract does not contain any express provision exonerating the non-defaulting party from its obligation to make payments on outstanding transactions to the defaulting party;

(e) purchase money Indebtedness (including obligations in respect of Capital Leases or Synthetic Leases) hereafter incurred by the Borrower or any Subsidiary to finance the purchase of fixed assets, and Permitted Refinancings thereof; provided, that, (i) the total of all such Indebtedness for all such Persons taken together shall not exceed at any time outstanding an aggregate principal amount of [***], (ii) such Indebtedness when incurred shall not exceed the purchase price of the asset(s) financed and (iii) no such Indebtedness shall be refinanced, renewed or extended for a principal amount in excess of the principal balance outstanding thereon at the time of such refinancing, renewal or extension;

(f) Permitted Convertible Bond Indebtedness;

(g) Indebtedness incurred in the ordinary course of business in respect of credit cards, credit processing services, debit cards, stored value cards and purchase cards (including so-called "procurement cards" or "P-cards") in an aggregate amount not to exceed [***] at any one time outstanding;

(h) Indebtedness of the Borrower or any Subsidiary in respect of (i) surety and appeal bonds, performance bonds, bid bonds, appeal bonds, completion guarantees and similar obligations; provided, that, the total of all such Indebtedness incurred in reliance on this clause (h)(i) for all such Persons taken together shall not exceed [***] at any one time outstanding and (ii) customary indemnification obligations to purchasers in connection with Dispositions permitted by

Section 8.05 or Investments permitted by Section 8.02, in each case, other than by reference to this Section 8.03 (or any sub-clause hereof);

(i) letters of credit, banker's acceptances or similar instruments, in each case, of the Borrower or any Subsidiary in an aggregate principal amount for all such Persons taken together not to exceed [***] at any one time outstanding;

(j) Guarantees permitted by Section 8.02 (other than by reference to this Section 8.03 (or any sub-clause hereof));

(k) Indebtedness constituting Earn Out Obligations or obligations in respect of working capital adjustments under the agreements used to consummate a Permitted Acquisition or other Investment permitted under Section 8.02 (other than by reference to this Section 8.03 (or any sub-clause hereof)), in each case, of the Borrower or any Subsidiary;

(l) Indebtedness of a Subsidiary acquired after the Closing Date in a Permitted Acquisition (or Indebtedness assumed by the Borrower or any Subsidiary in connection with a Permitted Acquisition as a result of (x) a merger or consolidation permitted by Section 8.04 (other than by reference to this Section 8.02 (or any sub-clause hereof)) or (y) the acquisition of assets securing such Indebtedness); provided, that, (i) such Indebtedness (A) was not incurred in connection with or in anticipation or contemplation of, such Permitted Acquisition and (B) existed immediately prior to such Permitted Acquisition, (ii) in the case of an acquisition of assets subject to such Indebtedness, any Liens do not at any time encumber any property other than the property encumbered prior to such Permitted Acquisition and (iii) the aggregate amount of all such Indebtedness shall not exceed [***] at any one time outstanding;

(m) Attributable Indebtedness of [***]; and

(n) unsecured Indebtedness of the Borrower or any Subsidiary (other than any Excluded Subsidiary) not otherwise permitted by the foregoing clauses of this Section 8.03, in an aggregate amount for all such Persons taken together not to exceed [***] at any one time outstanding.

8.04 Fundamental Changes.

Merge, dissolve, liquidate, consolidate with or into another Person, or Dispose of (whether in one transaction or in a series of transactions) all or substantially all of its assets (whether now owned or hereafter acquired) to or in favor of any Person; provided, that, notwithstanding the foregoing provisions of this Section 8.04 but subject to the terms of Sections 7.12 and 7.14, (a) the Borrower may merge or consolidate with any of its Subsidiaries, provided that the Borrower shall be the continuing or surviving corporation, (b) any Loan Party (other than the Borrower) may merge or consolidate with any other Loan Party (other than the Borrower), (c) any Subsidiary that is not a Loan Party may be merged or consolidated with or into any Loan Party, provided that such Loan Party shall be the continuing or surviving corporation, (d) any Subsidiary that is not a Loan Party may be merged or consolidated with or into any other Subsidiary that is not a Loan Party, (e) any Subsidiary that is not a Loan Party may dissolve, liquidate or wind up its affairs at any time provided that such dissolution, liquidation or winding up could not reasonably be expected to have a Material Adverse Effect and all of its assets and business are transferred to a Loan Party or, solely in the case of a Subsidiary that is not a Loan Party, another Subsidiary that is not a Loan Party, in each case, prior to or concurrently with such dissolution, liquidation or winding up, (f) any Subsidiary that is not a Loan Party may Dispose of any of its Subsidiaries to a Loan Party or another Subsidiary that is not a Loan Party, (g) a Loan Party may merge or consolidate with any other Person in a Permitted Acquisition;

provided, that, such Loan Party shall be the continuing or surviving corporation and (h) the Borrower and its Subsidiaries may consummate Permitted Transfers to the extent permitted under this Agreement without reference to this Section 8.04 (or any sub-clause hereof). Notwithstanding the foregoing, or anything to the contrary set forth in this Agreement, in no event shall any Loan Party or any Subsidiary merge, dissolve, liquidate or consolidate with or into [***].

8.05 Dispositions.

Make any Disposition (other than, for the avoidance of doubt, Permitted Transfers) unless (a) the consideration paid in connection therewith shall be cash or Cash Equivalents paid contemporaneous with consummation of the transaction and shall be in an amount not less than the fair market value of the property disposed of, (b) no Event of Default shall have occurred and be continuing both immediately prior to and after giving effect to such Disposition, (c) such transaction does not involve the sale or other disposition of a minority equity interest in any Subsidiary, (d) such transaction does not involve a Nefecon License or a sale, transfer, license, lease or other disposition of Nefecon or any Intellectual Property or other rights associated with Nefecon, (e) such transaction does not involve the sale or other disposition of assets, [***] and (f) the aggregate fair market value of all of the assets sold or otherwise disposed of in such Disposition together with the aggregate fair market value of all assets sold or otherwise disposed of by the Borrower and its Subsidiaries in all such transactions occurring during the term of this Agreement does not exceed [***].

8.06 Restricted Payments.

Declare or make, directly or indirectly, any Restricted Payment, or incur any obligation (contingent or otherwise) to do so, except that:

(a) (i) each Subsidiary may make Restricted Payments to any Loan Party and (ii) each Subsidiary that is not a Loan Party may make Restricted Payments to each other Subsidiary that is not a Loan Party;

(b) the Borrower may make (i) any payment of cash in lieu of a fractional share in accordance with the terms of any indenture (or equivalent agreement) governing Permitted Convertible Bond Indebtedness and (ii) subject to any subordination provisions applicable thereto, regularly scheduled interest payments (including any additional and/or special interest) and normal course fee payments as and when due in accordance with the terms of any indenture (or equivalent agreement) governing Permitted Convertible Bond Indebtedness;

(c) the Borrower may declare and make dividend payments or other distributions payable solely in its Qualified Capital Stock;

(d) (i) the Borrower may purchase any Permitted Equity Derivatives contemporaneously and otherwise in connection with the issuance of Permitted Convertible Bond Indebtedness and (ii) in connection with the maturity of, or any conversion, redemption or repurchase or Permitted Convertible Bond Indebtedness, the Borrower may settle, terminate or unwind any related Permitted Equity Derivatives;

(e) the Borrower may purchase, redeem or otherwise acquire its Qualified Capital Stock with Qualified Equity Issuance Proceeds received from the substantially concurrent issuance of its Qualified Capital Stock;

(f) the Borrower and any Subsidiary may (i) make repurchases or redemptions of its Equity Interests (x) in connection with the exercise of stock options or restricted stock awards if such Equity Interests represent all or a portion of the exercise price thereof or (y) deemed to occur upon the withholding of a portion of such Equity Interests issued to directors, officers or employees of the Borrower or any Subsidiary under any stock option plan or other benefit plan or agreement for directors, officers and employees of the Borrower and its Subsidiaries to cover withholding tax obligations of such Persons in respect of such issuance and (ii) make other Restricted Payments, not exceeding [***] in the aggregate for any fiscal year, pursuant to and in accordance with stock option plans or other benefit plans or agreements for directors, officers and employees of the Borrower and its Subsidiaries; and

(g) the Borrower may repurchase its stock from former employees, directors, or consultants under the terms of applicable stock option plans, employment agreements, repurchase agreements or otherwise, in an aggregate amount not to exceed [***] in any fiscal year.

Notwithstanding anything to the contrary in this Agreement or any other Loan Document, (x) for the avoidance of doubt, in no event shall any Loan Party make any Restricted Payment constituting or comprised of, in whole or in part, (A) any Material Intellectual Property or (B) Nefecon or any Intellectual Property or other rights associated with Nefecon and (y) in no event shall any Loan Party or any Subsidiary make any Restricted Payment to [***].

8.07 Change in Nature of Business.

Engage in any material line of business substantially different from those lines of business conducted by the Borrower and its Subsidiaries on the Closing Date or any business reasonably related or incidental thereto or a reasonable extension or expansion thereof.

8.08 Transactions with Affiliates and Insiders.

Enter into or permit to exist any transaction or series of transactions with any officer, director or Affiliate of such Person other than (a) advances of working capital to any Loan Party, (b) transfers of cash and assets to any Loan Party, (c) intercompany transactions expressly permitted by Section 8.02, Section 8.03, Section 8.04, Section 8.05 or Section 8.06 (in each case, other than by reference to this Section 8.08 (or any sub-clause hereof)), (d) customary or reasonable compensation, indemnification and reimbursement of expenses of officers and directors in the ordinary course of business and (e) except as otherwise specifically limited in this Agreement, other transactions which are entered into in the ordinary course of such Person's business on terms and conditions substantially as favorable to such Person as would be obtainable by it in a comparable arms-length transaction with a Person other than an officer, director or Affiliate.

8.09 Burdensome Agreements.

Enter into, or permit to exist, any Contractual Obligation that (a) encumbers or restricts the ability of any such Person to (i) make Restricted Payments to any Loan Party, (ii) pay any Indebtedness or other obligations owed to any Loan Party, (iii) make loans or advances to any Loan Party, (iv) transfer any of its property to any Loan Party, (v) pledge its property pursuant to the Loan Documents or any renewals, refinancings, exchanges, refundings or extension thereof or (vi) act as a Loan Party pursuant to the Loan Documents or any renewals, refinancings, exchanges, refundings or extension thereof, except (in respect of any of the matters referred to in clauses (i) through (v) above) for (1) this Agreement and the other Loan Documents, (2) any document or instrument governing Indebtedness permitted by Section 8.03(e), provided, that, any such restriction contained therein relates only to the asset or assets constructed or

acquired in connection therewith, (3) customary provisions in joint venture agreements with respect to joint ventures permitted under Section 8.02 and applicable solely to such joint venture entered into in the ordinary course of business, (4) customary restrictions and conditions contained in any agreement relating to the sale of any property permitted under Section 8.05 pending the consummation of such sale, (5) customary provisions regarding confidentiality or restricting assignment, pledges or transfers of any agreement entered into by the Borrower or any Subsidiary in the ordinary course of business, (6) any Permitted Lien or any document or instrument governing any Permitted Lien; provided, that, any such restriction contained therein relates only to the asset or assets subject to such Permitted Lien, and (7) any customary restrictions in any Permitted Licenses to the extent such licenses otherwise constitute a Permitted License or (b) requires the grant of any security for any obligation if such property is given as security for the Obligations.

8.10 Use of Proceeds.

Use the proceeds of any Loan, whether directly or indirectly, and whether immediately, incidentally or ultimately, to purchase or carry margin stock (within the meaning of Regulation U of the FRB) or to extend credit to others for the purpose of purchasing or carrying margin stock or to refund indebtedness originally incurred for such purpose.

8.11 Prepayment of Other Indebtedness.

Make (or give any notice with respect thereto) (a) any voluntary or optional payment or prepayment or redemption or acquisition for value of (including without limitation, by way of depositing money or securities with the trustee with respect thereto before due for the purpose of paying when due), refund, refinance or exchange of any Indebtedness of any Loan Party or any Subsidiary or (b) any payment or delivery of cash to satisfy any conversion obligation under Convertible Bond Indebtedness, in each case, other than (i) Indebtedness arising under the Loan Documents, (ii) Indebtedness permitted by Section 8.03(e) (solely to the extent made with the proceeds of additional issuances of Indebtedness permitted by Section 8.03(e)), (iii) any Permitted Refinancings of Indebtedness permitted by Section 8.03, and (iv) conversions or exchanges into Qualified Capital Stock of the Borrower (and cash in lieu of fractional shares) of the Permitted Convertible Bond Indebtedness.

8.12 Organization Documents; Fiscal Year; Legal Name, State of Formation and Form of Entity; Certain Amendments.

(a) Amend, modify or change its Organization Documents in a manner materially adverse to the Administrative Agent or any Lender.

(b) Change its fiscal year.

(c) Without providing ten (10) days prior written notice to the Administrative Agent, change its name, state of organization or form of organization.

(d) Amend, change, supplement, waive or otherwise modify (or permit the amendment, change, supplement, waiver or modification of), or enter into any forbearance from exercising any rights with respect to, any of the terms or provisions of any document or agreement entered into in connection with the Permitted Convertible Bond Indebtedness (including, without limitation, in each case, any such amendment, modification or change if the effect thereof would be to add any guarantor thereto or any security therefor), in each case, in a manner materially adverse to the Administrative Agent or any Lender.

(e) Amend, change, supplement, waive or otherwise modify (or permit the amendment, change, supplement, waiver or modification of), or enter into any forbearance from exercising any rights with respect to, any Material Contract or any document or other agreement evidencing Indebtedness in excess of the Threshold Amount, in each case, in any manner materially adverse to the Administrative Agent or any Lender.

8.13 Ownership of Subsidiaries.

Notwithstanding any other provisions of this Agreement to the contrary, (a) permit any Person (other than any Loan Party or any Wholly Owned Subsidiary) to own any Equity Interests of any Subsidiary, except to qualify directors where required by applicable law or to satisfy other requirements of applicable law with respect to the ownership of Equity Interests of Foreign Subsidiaries, (b) permit any Loan Party or any Subsidiary to issue or have outstanding any shares of Disqualified Capital Stock or (c) create, incur, assume or suffer to exist any Lien on any Equity Interests of any Subsidiary, except for Permitted Liens.

8.14 Sale Leasebacks.

Enter into any Sale and Leaseback Transaction.

8.15 Sanctions; Anti-Corruption Laws.

(a) Directly or indirectly, use the proceeds of any Loan, or lend, contribute or otherwise make available such proceeds of any Loan to any Person, to fund any activities of or business with any Person, that, at the time of such funding, is the subject of Sanctions (and would result in a violation of Sanctions), or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as Lender, Administrative Agent or otherwise) of Sanctions.

(b) Directly or indirectly, use the proceeds of any Loan for any purpose which would breach the United States Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 and other anti-corruption legislation in other jurisdictions.

8.16 Liquidity.

Permit the amount of Unrestricted Cash of the Loan Parties at any time to be less than [***].

8.17 Minimum Consolidated Nefecon Net Product and Royalty Revenues.

Permit Consolidated Nefecon Net Product and Royalty Revenues to be less than [***].

ARTICLE IX

EVENTS OF DEFAULT AND REMEDIES

9.01 Events of Default.

Any of the following shall constitute an Event of Default:

(a) Non-Payment. The Borrower or any other Loan Party fails to pay (i) within one (1) Business Day after the same becomes due, any amount of principal of any Loan or (ii) within five (5) Business Days after the same becomes due, any interest on any Loan, or any repayment

premium or fee due hereunder, or any other amount payable hereunder or under any other Loan Document; or

(b) Specific Covenants. Any Loan Party fails to perform or observe any term, covenant or agreement contained in any of Section 7.01, 7.03(a), 7.05(a) (solely as to any Loan Party), 7.11, 7.16 or 7.21 or Article VIII; or

(c) Other Defaults. Any Loan Party fails to perform or observe any other covenant or agreement (not specified in clause (a) or (b) above) contained in any Loan Document on its part to be performed or observed and such failure continues for thirty (30) days after the earlier of the date on which (i) a Responsible Officer of any Loan Party has knowledge of such failure and (ii) written notice thereof shall have been given to the Borrower by the Administrative Agent or any Lender; or

(d) Representations and Warranties. Any representation, warranty, certification or statement of fact made or deemed made by or on behalf of the Borrower or any other Loan Party herein, in any other Loan Document, or in any document delivered in connection herewith or therewith shall be materially incorrect or materially misleading when made or deemed made; or

(e) Cross-Default. (i) Any Loan Party or any Subsidiary (A) fails to make any payment when due (whether by scheduled maturity, required prepayment, acceleration, demand, or otherwise), but only after the expiration of any grace period applicable thereto, in respect of any Indebtedness (including, for the avoidance of doubt, any Permitted Convertible Bond Indebtedness) or Guarantee (other than Indebtedness hereunder and Indebtedness under Swap Contracts) having an aggregate outstanding principal amount (including amounts owing to all creditors under any combined or syndicated credit arrangement) in excess of the Threshold Amount ("Material Indebtedness"), or (B) fails to observe or perform any other agreement or condition relating to any Material Indebtedness or Guarantee or contained in any instrument or agreement evidencing, securing or relating thereto, or any other event occurs, the effect of which default or other event is to cause, or to permit the holder or holders of such Indebtedness or the beneficiary or beneficiaries of any such Guarantee (or a trustee or agent on behalf of such holder or holders or beneficiary or beneficiaries) to cause, with the giving of notice if required, such Material Indebtedness to be demanded or to become due or to be repurchased, prepaid, defeased or redeemed (automatically or otherwise), or an offer to repurchase, prepay, defease or redeem such Material Indebtedness to be made, prior to its stated maturity, or such Guarantee to become payable or cash collateral in respect thereof to be demanded; provided, that, this clause (e)(i) shall not apply to (x) any secured Material Indebtedness that becomes due as a result of the voluntary sale or transfer of the property or assets securing such Material Indebtedness if such sale or transfer is permitted hereunder and under the documents providing for such Material Indebtedness and such Material Indebtedness is repaid when required under the documents providing for such Indebtedness or (y) (A) the occurrence or existence of any event or condition that allows holders of Permitted Convertible Bond Indebtedness to convert such Permitted Convertible Bond Indebtedness, and (B) any conversion of Permitted Convertible Bond Indebtedness; provided, that, in the case of either of the foregoing clause (A) or clause (B), such event or condition does not constitute, and such conversion does not result from, any default or event of default by any Loan Party or any Subsidiary thereunder, a "change of control" or a "fundamental change" or (ii) there occurs under any Swap Contract an Early Termination Date (as defined in such Swap Contract) resulting from (A) any event of default under such Swap Contract as to which the Borrower or any Subsidiary is the Defaulting Party (as defined in such Swap Contract) or (B) any Termination Event (as so defined) under such Swap Contract as to which the Borrower or any Subsidiary is an Affected Party (as so defined) and, in either event,

the Swap Termination Value owed by the Borrower or such Subsidiary as a result thereof is greater than the Threshold Amount; or

(f) Insolvency Proceedings, Etc. Any Loan Party or any Material Subsidiary institutes or consents to the institution of any proceeding under any Debtor Relief Law, or makes an assignment for the benefit of creditors; or applies for or consents to the appointment of any receiver, trustee, custodian, conservator, liquidator, rehabilitator or similar officer for it or for all or any material part of its property; or any receiver, trustee, custodian, conservator, liquidator, rehabilitator or similar officer is appointed without the application or consent of such Person and the appointment continues undischarged or unstayed for sixty (60) calendar days; or any proceeding under any Debtor Relief Law relating to any such Person or to all or any material part of its property is instituted without the consent of such Person and continues undismissed or unstayed for sixty (60) calendar days, or an order for relief is entered in any such proceeding; or

(g) Inability to Pay Debts; Attachment. (i) Any Loan Party or any Material Subsidiary becomes unable or admits in writing its inability or fails generally to pay its debts as they become due, or (ii) any writ or warrant of attachment or execution or similar process is issued or levied against all or any material part of the property of any such Person and is not released, vacated or fully bonded within sixty (60) days after its issue or levy; or

(h) Judgments. There is entered against any Loan Party or any Subsidiary one or more final judgments or orders for the payment of money in an aggregate amount exceeding the Threshold Amount (to the extent not covered by independent third-party insurance as to which the insurer has been notified of the order and does not deny coverage) or any one or more non-monetary final judgments that have, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect and, in either case, (i) enforcement proceedings are commenced by any creditor upon such judgment or order or (ii) there is a period of thirty (30) consecutive days during which a stay of enforcement of such judgment, by reason of a pending appeal or otherwise, is not in effect; or

(i) ERISA. (i) An ERISA Event occurs with respect to a Pension Plan or Multiemployer Plan which has resulted or could reasonably be expected to result in liability of any Loan Party under Title IV of ERISA to the Pension Plan, Multiemployer Plan or the PBGC in an aggregate amount in excess of the Threshold Amount, or (ii) the Borrower or any ERISA Affiliate fails to pay when due, after the expiration of any applicable grace period, any installment payment with respect to its withdrawal liability under Section 4201 of ERISA under a Multiemployer Plan in an aggregate amount in excess of the Threshold Amount; or

(j) Invalidity of Loan Documents. Any Loan Document, at any time after its execution and delivery and for any reason other than as expressly permitted hereunder or thereunder, ceases to be in full force and effect; or any Loan Party contests in writing the validity or enforceability of any Loan Document; or any Loan Party denies that it has any or further liability or obligation under any Loan Document, or purports to revoke, terminate or rescind any Loan Document; or

(k) Material Adverse Effect. There occurs any circumstance or circumstances that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect; or

(l) Change of Control. There occurs any Change of Control; or

(m) Invalidity of Subordination Provisions. Any subordination provision in any document or instrument governing Indebtedness that is purported to be subordinated to the Obligations or any subordination provision in any subordination agreement that relates to any Indebtedness that is to be subordinated to the Obligations, or any subordination provision in any guaranty by any Loan Party of any such Indebtedness, shall cease to be in full force and effect; or

(n) Injunction. Any court order enjoins, restrains, or prevents any Loan Party from conducting any material part of its business; or

(o) Products. (i) The FDA or EMA shall revoke, withdraw, suspend for more than thirty (30) days, cancel, terminate or materially adversely modify any approved Key Permit related to any Product; or (ii) any Safety Notice is issued or initiated in connection with any Product after approval by the FDA, EMA or any other Governmental Authority and Consolidated Revenues shall decrease by [***]; or

(p) Delisting. The ordinary shares (or American depository shares representing ordinary shares) of the Borrower are no longer listed on an internationally recognized stock exchange in the United States, Sweden, Switzerland or the United Kingdom; or

(q) Regulatory Matters. If any of the following occurs: (i) the FDA, CMS, EMA, DEA, or any other Governmental Authority issues a letter or other communication asserting that any Product lacks a required Regulatory Authorization or does not comply with applicable Law; (ii) any involuntary or voluntary recall of Nefecon occurs; or (iii) any Loan Party or any Subsidiary or any Product Distributor (as relating to Products) enters into a settlement agreement with the FDA, CMS, EMA, DEA, or any other Governmental Authority; in each case of clauses (i) through (iii) that could reasonably be expected to have a material adverse effect on the commercialization of Nefecon; or

(r) Targit License. The Targit License is terminated, revoked, suspended, or becomes invalid at a time when: (x) TARPEYO is not (i) protected in the United States by a regulatory exclusivity granted to a Loan Party or (ii) covered by a valid claim of an issued United States Patent listed on Schedule 6.17(a) and exclusively owned by any Loan Party or (y) the termination, revocation, suspension, or invalidation of the Targit License Agreement could reasonably be expected to have a material adverse effect on the commercialization of Nefecon.

9.02 Remedies Upon Event of Default.

If any Event of Default occurs and is continuing, the Administrative Agent shall, at the request of, or may, with the consent of, the Required Lenders (without (for the purposes of French law) *mise en demeure* or any other judicial or extra-judicial step), take any or all of the following actions:

(a) upon written notice to the Borrower (provided that any failure to give such notice shall in no way limit or otherwise prohibit any such actions taken or to be taken by the Administrative Agent), declare the commitment of each Lender to make Loans to be terminated, whereupon such commitments and obligation shall be terminated;

(b) upon written notice to the Borrower (provided that any failure to give such notice shall in no way limit or otherwise prohibit any such actions taken or to be taken by the Administrative Agent), declare the unpaid principal amount of all outstanding Loans, all interest accrued and unpaid thereon, and all other amounts (including any repayment premium and the exit fee) owing or payable hereunder or under any other Loan Document to be immediately due and

payable, without presentment, demand, protest or other notice of any kind, all of which are hereby expressly waived by the Borrower; and

(c) exercise on behalf of itself and the Lenders all rights and remedies available to it and the Lenders under the Loan Documents;

provided, however, that upon the occurrence of an actual or deemed entry of an order for relief with respect to the Borrower under the Bankruptcy Code of the United States, the obligation of each Lender to make Loans shall automatically terminate, the unpaid principal amount of all outstanding Loans and all interest and other amounts (including any repayment premium and the exit fee) as aforesaid shall automatically become due and payable, in each case without further act of the Administrative Agent or any Lender.

If the Obligations are accelerated for any reason, the repayment premium required by Section 2.03(d) and the exit fee required by Section 2.07(b) will also be due and payable as though such Obligations were voluntarily prepaid and any discount on the Loans shall be deemed earned in full and, in each case, shall constitute part of the Obligations, in view of the impracticability and extreme difficulty of ascertaining actual damages and by mutual agreement of the parties as to a reasonable calculation of each Lender's lost profits as a result thereof. Any repayment premium required by Section 2.03(d) and the exit fee required by Section 2.07(b) payable pursuant to the preceding sentence shall be presumed to be the liquidated damages sustained by each Lender as the result of the early termination and the Borrower agrees that it is reasonable under the circumstances currently existing. The repayment premium required by Section 2.03(d) and the exit fee required by Section 2.07(b) shall also be payable and any discount on the Loans shall be deemed earned in full, in each case, in the event that the Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other means. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE BORROWER AND THE OTHER LOAN PARTIES EXPRESSLY WAIVE THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE OR LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF THE FOREGOING REPAYMENT PREMIUM, EXIT FEE AND ANY DISCOUNT ON THE LOANS IN CONNECTION WITH ANY SUCH ACCELERATION. The Borrower and the other Loan Parties expressly agree that (i) the repayment premium required by Section 2.03(d), the exit fee required by Section 2.07(b) and any discount on the Loans provided for in the Loan Documents is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel, (ii) the repayment premium required by Section 2.03(d), the exit fee required by Section 2.07(b) and any discount on the Loans shall be payable notwithstanding the then prevailing market rates at the time payment is made, (iii) there has been a course of conduct between the Lenders and the Borrower and the other Loan Parties giving specific consideration in this transaction for such agreement to pay the repayment premium required by Section 2.03(d), the exit fee required by Section 2.07(b) and any discount on the Loans, (iv) the Borrower and the other Loan Parties shall be estopped hereafter from claiming differently than as agreed to in this paragraph and (v) the repayment premium required by Section 2.03(d), the exit fee required by Section 2.07(b) and any discount on the Loans represent a good faith, reasonable estimate and calculation of the lost profits or damages of the Lenders and that it would be impractical and extremely difficult to ascertain the actual amount of damages to the Lenders or profits lost by the Lenders as a result of any early termination. The Borrower and the other Loan Parties expressly acknowledge that their agreement to pay the repayment premium required by Section 2.03(d), the exit fee required by Section 2.07(b) and any discount on the Loans to the Lenders as herein described is a material inducement to the Lenders to make the Loans and establish the Commitments hereunder.

9.03 Application of Funds.

After the exercise of remedies provided for in Section 9.02 (or after the Loans have automatically become immediately due and payable as set forth in the proviso to Section 9.02), any amounts received by

any Lender or the Administrative Agent on account of the Obligations shall be applied by the Administrative Agent in the following order:

First, to payment of that portion of the Obligations constituting fees, indemnities, expenses and other amounts (including fees, charges and disbursements of counsel to the Administrative Agent and amounts payable under Article III) payable to the Administrative Agent in its capacity as such;

Second, to payment of that portion of the Obligations constituting fees, indemnities and other amounts (other than principal, interest, repayment premium and exit fees) payable to the Lenders (including fees, charges and disbursements of counsel to the respective Lenders) arising under the Loan Documents and amounts payable under Article III, ratably among them in proportion to the respective amounts described in this clause Second payable to them;

Third, to payment of that portion of the Obligations constituting accrued and unpaid interest on, and repayment premium and exit fees with respect to, the Loans, ratably among the Lenders in proportion to the respective amounts described in this clause Third held by them;

Fourth, to payment of that portion of the Obligations constituting accrued and unpaid principal of the Loans, ratably among the Secured Parties in proportion to the respective amounts described in this clause Fourth held by them; and

Last, the balance, if any, after all of the Obligations have been indefeasibly paid in full, to the Borrower or as otherwise required by Law.

ARTICLE X

ADMINISTRATIVE AGENT

10.01 Appointment and Authority.

(a) Each of the Lenders hereby irrevocably appoints Athyrium Opportunities IV Co-Invest 1 LP, a Delaware limited partnership, to act on its behalf as the Administrative Agent hereunder and under the other Loan Documents and authorizes the Administrative Agent to take such actions on its behalf and to exercise such powers as are delegated to the Administrative Agent by the terms hereof or thereof, together with such actions and powers as are incidental thereto. The provisions of this Article are solely for the benefit of the Administrative Agent and the Lenders, and neither the Borrower nor any other Loan Party shall have rights as a third party beneficiary of any of such provisions. It is understood and agreed that the use of the term "agent" herein or in any other Loan Documents (or any other similar term) with reference to the Administrative Agent is not intended to connote any fiduciary or other implied (or express) obligations arising under agency doctrine of any applicable Law. Instead such term is used as a matter of market custom, and is intended to create or reflect only an administrative relationship between contracting parties.

(b) The Administrative Agent shall also act as the "collateral agent" under the Loan Documents, and each of the Lenders hereby irrevocably appoints and authorizes the Administrative Agent to act as the agent of such Lender for purposes of acquiring, holding and enforcing any and all Liens on Collateral granted by any of the Loan Parties to secure any of the Obligations, together with such powers and discretion as are incidental thereto. In this connection, the Administrative Agent, as "collateral agent" and any co-agents, sub-agents and attorneys-in-fact appointed by the Administrative Agent pursuant to Section 10.05 for purposes of holding or enforcing any Lien on

the Collateral (or any portion thereof) granted under the Collateral Documents, or for exercising any rights and remedies thereunder at the direction of the Administrative Agent, shall be entitled to the benefits of all provisions of this Article X and Article XI (including Section 11.04(c), as though such co-agents, sub-agents and attorneys-in-fact were the "collateral agent" under the Loan Documents) as if set forth in full herein with respect thereto.

(c) In relation to the French Securities Account Pledge Agreement:

(i) each other Secured Party:

(A) appoints the Administrative Agent to act as security agent (*agent des sûretés*) pursuant to articles 2488-6 *et seq*. of the French *Code civil* in respect of the French Securities Account Pledge Agreement; and

(B) irrevocably authorizes the Administrative Agent acting as security agent (*agent des sûretés*) within the meaning of article 2488-6 of the French *Code civil* without limitation and notwithstanding any other rights conferred upon the Administrative Agent under this Agreement:

(I) to negotiate, accept and execute in its name and for the benefit of each other Secured Party the French Securities Account Pledge Agreement (and any ancillary document in connection therewith);

(II) to take, register, administer and enforce any Lien created or expressed to be created pursuant to the French Securities Account Pledge Agreement;

(III) to perform the duties and to exercise the rights, powers and discretions that are specifically delegated to it under or in connection with the French Securities Account Pledge Agreement, and more generally to take any action and exercise any right, power, prerogative and discretion upon the terms and conditions set out in this Agreement or under or in connection with the French Securities Account Pledge Agreement and to protect the rights of the Secured Parties under or in connection with any Collateral created thereunder, in each case together with any other right, power, prerogative and discretion which is incidental thereto;

(IV) in accordance with Section 10.09(a) below, to release Collateral granted under the French Securities Account Pledge Agreement; and

(V) to take any action and exercise any right, power, authority and discretion in accordance with the Loan Documents.

(ii) the Administrative Agent accepts its appointment as "*agent des sûretés*" pursuant to this Section 10.01 for so long as this Agreement is in force or the French Securities Account Pledge Agreement or claim in respect thereof exists, and declares that it holds in its own name the Collateral created or expressed to be created pursuant to the French Securities Account Pledge Agreement in its capacity as security agent (*agent des sûretés*) pursuant to articles 2488-6 et seq. of the French Code civil for the benefit of the Secured Parties on the terms contained in this Agreement, and accordingly any action taken

by the Administrative Agent in connection with or for the purposes of the Collateral governed by French law and the French Securities Account Pledge Agreement in accordance with this Agreement and the French Securities Account Pledge Agreement shall be deemed to be taken by the Administrative Agent acting as security agent (*agent des sûretés*) in its own name and for the benefit of the Secured Parties.

(iii) each other Secured Party acknowledges that the Administrative Agent (acting as security agent (*agent des sûretés*)) shall not be liable on its own estate (*patrimoine propre*) for the payment of any *Soulte* that would be payable to the pledgor under the French Securities Account Pledge Agreement as a result of the enforcement of Collateral created pursuant to the French Securities Account Pledge Agreement.

(iv) each other Secured Party agrees that, to the fullest extent permitted by law, the Administrative Agent (acting as security agent (*agent des sûretés*) appointed pursuant to this Section 10.01) shall be entitled to exercise all rights and benefit from all protections conferred upon the Administrative Agent under this Agreement and any other Loan Documents.

(v) each Secured Party agrees that any change of the Administrative Agent acting as security agent (*agent des sûretés*) (*remplacement conventionnel or remplacement judiciaire*) appointed pursuant to this Section 10.01 shall be made in accordance with Section 10.06 and article 2488-11 of the French Code civil.

(vi) each Secured Party agrees that, notwithstanding any other provision of this Agreement to the contrary, this Section 10.01(c), insofar as it relates to the French Securities Account Pledge Agreement and the role of the Administrative Agent acting as security agent (*agent des sûretés*) in respect thereof, shall be governed by French law.

(vii) payment of the *Soulte*:

(A) if, following any enforcement of the relevant French Collateral, a *Soulte* is owed by the Secured Parties to any Loan Party, that Loan Party agrees that such *Soulte* shall only become due and payable by the relevant Secured Parties on the earlier of:

(I) the date falling 12 months after the date of the enforcement of the relevant French Collateral; and

(II) the date referred to in Section 10.09(a)(i) below; and

(B) for the avoidance of doubt, the obligations of each Secured Party to pay its proportionate share of any *Soulte* are several (*conjointes et non solidaires*).

10.02 Rights as a Lender.

The Person serving as the Administrative Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Administrative Agent and the term "Lender" or "Lenders" shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Administrative Agent hereunder in

its individual capacity. Such Person and its Affiliates may accept deposits from, lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with any Loan Party or any Subsidiary or other Affiliate thereof as if such Person were not the Administrative Agent hereunder and without any duty to account therefor to the Lenders.

10.03 Exculpatory Provisions.

The Administrative Agent shall not have any duties or obligations except those expressly set forth herein and in the other Loan Documents, and its duties hereunder shall be administrative in nature. Without limiting the generality of the foregoing, the Administrative Agent:

(a) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default has occurred and is continuing;

(b) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that the Administrative Agent is required to exercise as directed in writing by the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in the other Loan Documents); provided, that, the Administrative Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Administrative Agent to liability or that is contrary to any Loan Document or applicable law, including for the avoidance of doubt any action that may be in violation of the automatic stay under any Debtor Relief Law or that may affect a forfeiture, modification or termination of property of a Defaulting Lender in violation of any Debtor Relief Law; and

(c) shall not, except as expressly set forth herein and in the other Loan Documents, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to any Loan Party or any of its Affiliates that is communicated to or obtained by the Person serving as the Administrative Agent or any of its Affiliates in any capacity.

The Administrative Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Lenders (or such other number or percentage of the Lenders as shall be necessary, or as the Administrative Agent shall believe in good faith shall be necessary, under the circumstances as provided in Section 11.01 and Section 9.02) or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and non-appealable judgment. The Administrative Agent shall be deemed not to have knowledge of any Default unless and until notice describing such Default is given in writing to the Administrative Agent by the Borrower or a Lender.

The Administrative Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Article V or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Administrative Agent.

10.04 Reliance by Administrative Agent.

The Administrative Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, Internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Administrative Agent also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. In determining compliance with any condition hereunder to the making of a Loan that by its terms must be fulfilled to the satisfaction of a Lender, the Administrative Agent may presume that such condition is satisfactory to such Lender unless the Administrative Agent shall have received notice to the contrary from such Lender prior to the making of such Loan. The Administrative Agent may consult with legal counsel (who may be counsel for the Loan Parties), independent accountants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants or experts.

10.05 Delegation of Duties.

The Administrative Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Loan Document by or through any one or more sub-agents appointed by the Administrative Agent. The Administrative Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The exculpatory provisions of this Article shall apply to any such sub-agent and to the Related Parties of the Administrative Agent and any such sub-agent, and shall apply to their respective activities in connection with the syndication of the credit facilities provided for herein as well as activities as Administrative Agent. The Administrative Agent shall not be responsible for the negligence or misconduct of any sub-agents except to the extent that a court of competent jurisdiction determines in a final and non-appealable judgment that the Administrative Agent acted with gross negligence or willful misconduct in the selection of such sub-agents.

10.06 Resignation of Administrative Agent.

The Administrative Agent may resign as Administrative Agent at any time by giving [***] days advance notice thereof to the Lenders and the Borrower and, thereafter, the retiring Administrative Agent shall be discharged from its duties and obligations hereunder. Upon any such resignation, the Required Lenders shall have the right, subject to the approval of the Borrower (so long as no Event of Default has occurred and is continuing; such approval not to be unreasonably withheld), to appoint a successor Administrative Agent. If no successor Administrative Agent shall have been so appointed by the Required Lenders, been approved (so long as no Event of Default has occurred and is continuing) by the Borrower or have accepted such appointment within [***] days after the Administrative Agent's giving of notice of resignation, then the Administrative Agent may, on behalf of the Lenders, appoint a successor Administrative Agent reasonably acceptable to the Borrower (so long as no Default or Event of Default has occurred and is continuing). Upon the acceptance of any appointment as Administrative Agent hereunder by a successor Administrative Agent, such successor Administrative Agent shall thereupon succeed to and become vested with all rights, powers, privileges and duties of the retiring Administrative Agent. After any retiring Administrative Agent's resignation hereunder as Administrative Agent, the provisions of this Section 10.06 shall continue in effect for its benefit in respect of any actions taken or omitted to be taken by it while it was acting as Administrative Agent. If no successor has accepted appointment as Administrative Agent by the date which is [***] days following a retiring Administrative Agent's notice of resignation, the retiring Administrative Agent's resignation shall nevertheless thereupon become effective and the Required Lenders shall perform all of the duties of the Administrative Agent hereunder until such time, if any, as the Required Lenders appoint a successor agent as provided for above.

10.07 Non-Reliance on Administrative Agent and Other Lenders.

Each Lender acknowledges that it has, independently and without reliance upon the Administrative Agent or any other Lender or any of their Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement. Each Lender also acknowledges that it will, independently and without reliance upon the Administrative Agent or any other Lender or any of their Related Parties and based on such documents and information as it shall from time to time deem appropriate, continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Loan Document or any related agreement or any document furnished hereunder or thereunder.

10.08 Administrative Agent May File Proofs of Claim.

In case of the pendency of any receivership, insolvency, liquidation, bankruptcy, reorganization, arrangement, adjustment, composition or other judicial proceeding relative to any Loan Party, the Administrative Agent (irrespective of whether the principal of any Loan shall then be due and payable as herein expressed or by declaration or otherwise and irrespective of whether the Administrative Agent shall have made any demand on the Borrower) shall be entitled and empowered, by intervention in such proceeding or otherwise:

(a) to file and prove a claim for the whole amount of the principal and interest owing and unpaid in respect of the Loans and all other Obligations that are owing and unpaid and to file such other documents as may be necessary or advisable in order to have the claims of the Lenders and the Administrative Agent (including any claim for the reasonable compensation, expenses, disbursements and advances of the Lenders and the Administrative Agent and their respective agents and counsel and all other amounts due the Lenders and the Administrative Agent under Section 11.04) allowed in such judicial proceeding; and

(b) to collect and receive any monies or other property payable or deliverable on any such claims and to distribute the same;

and any custodian, receiver, assignee, trustee, liquidator, sequestrator or other similar official in any such judicial proceeding is hereby authorized by each Lender to make such payments to the Administrative Agent and, in the event that the Administrative Agent shall consent to the making of such payments directly to the Lenders, to pay to the Administrative Agent any amount due for the reasonable compensation, expenses, disbursements and advances of the Administrative Agent and its agents and counsel, and any other amounts due the Administrative Agent under Section 11.04.

Nothing contained herein shall be deemed to authorize the Administrative Agent to authorize or consent to or accept or adopt on behalf of any Lender any plan of reorganization, arrangement, adjustment or composition affecting the Obligations or the rights of any Lender or to authorize the Administrative Agent to vote in respect of the claim of any Lender in any such proceeding.

10.09 Collateral and Guaranty Matters.

The Lenders irrevocably authorize the Administrative Agent, at its option and in its discretion,

(a) to release any Lien on any Collateral granted to or held by the Administrative Agent under any Loan Document (i) upon termination of all unused Commitments and payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been asserted) under the Loan Documents, (ii) that is sold or otherwise disposed of or to be sold or otherwise disposed of as part of or in connection with any sale or other Disposition permitted hereunder or any Involuntary Disposition, or (iii) as approved in accordance with Section 11.01;

(b) to subordinate any Lien on any property granted to or held by the Administrative Agent under any Loan Document to the holder of any Lien on such property that is permitted by Section 8.01(i); and

(c) to release any Guarantor from its obligations under the Guaranty if such Person ceases to be a Subsidiary as a result of a transaction permitted under the Loan Documents.

Upon request by the Administrative Agent at any time, the Required Lenders will confirm in writing the Administrative Agent's authority to release or subordinate its interest in particular types or items of property, or to release any Guarantor from its obligations under the Guaranty, pursuant to this Section 10.09.

The Administrative Agent shall not be responsible for or have a duty to ascertain or inquire into any representation or warranty regarding the existence, value or collectability of the Collateral, the existence, priority or perfection of the Administrative Agent's Lien thereon, or any certificate prepared by any Loan Party in connection therewith, nor shall the Administrative Agent be responsible or liable to the Lenders for any failure to monitor or maintain any portion of the Collateral.

ARTICLE XI

MISCELLANEOUS

11.01 Amendments, Etc.

No amendment or waiver of any provision of this Agreement or any other Loan Document, and no consent to any departure by the Borrower or any other Loan Party therefrom, shall be effective unless in writing signed by the Required Lenders and the Borrower or the applicable Loan Party, as the case may be, and acknowledged by the Administrative Agent, and each such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given; provided, further, that:

(a) no such amendment, waiver or consent shall:

(i) extend or increase the Commitment of a Lender (or reinstate any Commitment terminated pursuant to Section 9.02) without the written consent of such Lender whose Commitment is being extended or increased (it being understood and agreed that a waiver of any condition precedent set forth in Section 5.02 or of any Default or a mandatory reduction in Commitments is not considered an extension or increase in Commitments of any Lender);

(ii) postpone any date fixed by this Agreement or any other Loan Document for any payment of principal (excluding mandatory prepayments), interest, repayment premiums, fees or other amounts due to the Lenders (or any of them) or any scheduled or mandatory reduction of the Commitments hereunder or under any other Loan Document without the written consent of each Lender entitled to receive such payment or whose Commitments are to be reduced;

(iii) reduce the principal of, the rate of interest specified herein on or the repayment premium specified herein on any Loan, or any fees or other amounts payable hereunder or under any other Loan Document without the written consent of each Lender entitled to receive such payment of principal, interest, fees or other amounts; provided,

however, that, only the consent of the Required Lenders shall be necessary to amend the definition of "Default Rate" or to waive any obligation of the Borrower to pay interest at the Default Rate;

(iv) change any provision of this Section 11.01(a) or the definition of "Required Lenders" without the written consent of each Lender directly affected thereby;

(v) except in connection with a Disposition permitted under Section 8.05, release all or substantially all of the Collateral without the written consent of each Lender directly affected thereby;

(vi) release the Borrower or, except in connection with a merger or consolidation permitted under Section 8.04 or a Disposition permitted under Section 8.05, all or substantially all of the Guarantors without the written consent of each Lender directly affected thereby, except to the extent the release of any Guarantor is permitted pursuant to Section 10.09 (in which case such release may be made by the Administrative Agent acting alone); and

(b) unless also signed by the Administrative Agent, no amendment, waiver or consent shall affect the rights or duties of the Administrative Agent under this Agreement or any other Loan Document;

provided, however, that, notwithstanding anything to the contrary herein, (i) no Defaulting Lender shall have any right to approve or disapprove any amendment, waiver or consent hereunder (and any amendment, waiver or consent which by its terms requires the consent of all Lenders or each affected Lender may be effected with the consent of the applicable Lenders other than Defaulting Lenders), except that (x) the Commitment of any Defaulting Lender may not be increased or extended without the consent of such Lender and (y) any waiver, amendment or modification requiring the consent of all Lenders or each affected Lender that by its terms affects any Defaulting Lender more adversely than other affected Lenders shall require the consent of such Defaulting Lender, (ii) each Lender is entitled to vote as such Lender sees fit on any bankruptcy reorganization plan that affects the Loans, and each Lender acknowledges that the provisions of Section 1126(c) of the Bankruptcy Code of the United States supersedes the unanimous consent provisions set forth herein and (iii) the Required Lenders shall determine whether or not to allow a Loan Party to use cash collateral in the context of a bankruptcy or insolvency proceeding and such determination shall be binding on all of the Lenders.

11.02 Notices and Other Communications; Facsimile Copies.

(a) Notices Generally. Except in the case of notices and other communications expressly permitted to be given by telephone (and except as provided in clause (b) below), all notices and other communications provided for herein shall be in writing and shall be delivered by hand or overnight courier service, mailed by certified or registered mail or sent by facsimile as follows, and all notices and other communications expressly permitted hereunder to be given by telephone shall be made to the applicable telephone number, as follows:

(i) if to the Borrower or any other Loan Party or the Administrative Agent, to the address, facsimile number, electronic mail address or telephone number specified for such Person on Schedule 11.02; and

(ii) if to any other Lender, to the address, facsimile number, electronic mail address or telephone number of its Lending Office (whether specified on Schedule 11.02 or separately specified to the Borrower and the Administrative Agent).

Notices and other communications sent by hand or overnight courier service, or mailed by certified or registered mail, shall be deemed to have been given when received; notices and other communications sent by facsimile shall be deemed to have been given when sent (except that, if not given during normal business hours for the recipient, shall be deemed to have been given at the opening of business on the next Business Day for the recipient). Notices and other communications delivered through electronic communications to the extent provided in clause (b) below, shall be effective as provided in such clause (b).

(b) Electronic Communications. Notices and other communications to the Lenders hereunder may be delivered or furnished by electronic communication (including e-mail and Internet or intranet websites) pursuant to procedures approved by the Administrative Agent, provided, that, the foregoing shall not apply to notices to any Lender pursuant to Article II if such Lender has notified the Administrative Agent that it is incapable of receiving notices under such Article by electronic communication. The Administrative Agent or the Borrower may each, in its discretion, agree to accept notices and other communications to it hereunder by electronic communications pursuant to procedures approved by it, provided, that, approval of such procedures may be limited to particular notices or communications.

Unless the Administrative Agent otherwise prescribes, (i) notices and other communications sent to an e-mail address shall be deemed received upon the sender's receipt of an acknowledgement from the intended recipient (such as by the "return receipt requested", as available, return e-mail or other written acknowledgement), and (ii) notices or communications posted to an Internet or intranet website shall be deemed received upon the deemed receipt by the intended recipient at its e-mail address as described in the foregoing clause (i) of notification that such notice or communication is available and identifying the website address therefor; provided, that, for both clauses (i) and (ii), if such notice, email or other communication is not sent during the normal business hours of the recipient, such notice, email or communication shall be deemed to have been sent at the opening of business on the next business day for the recipient.

(c) Change of Address, Etc. Each of the Borrower, the Lenders and the Administrative Agent may change its address, facsimile or telephone number for notices and other communications hereunder by notice to the other parties hereto. In addition, each Lender agrees to notify the Administrative Agent from time to time to ensure that the Administrative Agent has on record (i) an effective address, contact name, telephone number, facsimile number and electronic mail address to which notices and other communications may be sent and (ii) accurate wire instructions for such Lender.

(d) Reliance by Administrative Agent and Lenders. The Administrative Agent and the Lenders shall be entitled to rely and act upon any notices (including telephonic or electronic Loan Notices) purportedly given by or on behalf of any Loan Party even if (i) such notices were not made in a manner specified herein, were incomplete or were not preceded or followed by any other form of notice specified herein, or (ii) the terms thereof, as understood by the recipient, varied from any confirmation thereof. The Loan Parties shall indemnify the Administrative Agent, each Lender and the Related Parties of each of them from all losses, costs, expenses and liabilities resulting from the reliance by such Person on each notice purportedly given by or on behalf of a Loan Party. All telephonic notices to and other telephonic communications with the Administrative

Agent may be recorded by the Administrative Agent, and each of the parties hereto hereby consents to such recording.

11.03 No Waiver; Cumulative Remedies; Enforcement.

No failure by any Lender or the Administrative Agent to exercise, and no delay by any such Person in exercising, any right, remedy, power or privilege hereunder or under any other Loan Document shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege. The rights, remedies, powers and privileges herein provided, and provided under each other Loan Document, are cumulative and not exclusive of any rights, remedies, powers and privileges provided by law.

Notwithstanding anything to the contrary contained herein or in any other Loan Document, the authority to enforce rights and remedies hereunder and under the other Loan Documents against the Loan Parties or any of them shall be vested exclusively in, and all actions and proceedings at law in connection with such enforcement shall be instituted and maintained exclusively by, the Administrative Agent in accordance with Section 10.01 for the benefit of all the Secured Parties; provided, however, that, the foregoing shall not prohibit (a) the Administrative Agent from exercising on its own behalf the rights and remedies that inure to its benefit (solely in its capacity as Administrative Agent) hereunder and under the other Loan Documents, (b) any Lender from exercising setoff rights in accordance with Section 11.08 (subject to the terms of Section 2.11), or (c) any Lender from filing proofs of claim or appearing and filing pleadings on its own behalf during the pendency of a proceeding relative to any Loan Party under any Debtor Relief Law; and provided, further, that, if at any time there is no Person acting as Administrative Agent hereunder and under the other Loan Documents, then (i) the Required Lenders shall have the rights otherwise ascribed to the Administrative Agent pursuant to Section 10.01 and (ii) in addition to the matters set forth in clauses (b) and (c) of the preceding proviso and subject to Section 2.11, any Lender may, with the consent of the Required Lenders, enforce any rights and remedies available to it and as authorized by the Required Lenders.

11.04 Expenses; Indemnity; and Damage Waiver.

(a) Costs and Expenses. The Loan Parties shall pay (i) all reasonable and documented out-of-pocket expenses incurred by the Administrative Agent and its Affiliates (but limited, in the case of legal counsel, to the reasonable and documented out-of-pocket fees, charges and disbursements of one primary counsel for the Administrative Agent, a single local counsel to the Administrative Agent and its Affiliates in each relevant material jurisdiction, and to the extent required in the good faith judgment of the Administrative Agent, one specialty counsel to the Administrative Agent and its Affiliates in each relevant specialty in each relevant jurisdiction), in connection with (A) the preparation, negotiation, execution and delivery of this Agreement and the other Loan Documents and (B) any amendments, modifications or waivers of the provisions hereof or thereof (whether or not the transactions contemplated hereby or thereby shall be consummated) or the administration of this Agreement and the other Loan Documents and (ii) all reasonable and documented out-of-pocket expenses incurred by the Administrative Agent or any Lender (but limited, in the case of legal counsel, to the reasonable and documented out-of-pocket fees, charges and disbursements of one primary counsel for the Administrative Agent and the Lenders (taken as a whole), a single local counsel to the Administrative Agent and the Lenders (taken as a whole) in each relevant material jurisdiction, and to the extent required in the good faith judgment of the Administrative Agent, one specialty counsel to the Administrative Agent and the Lenders (taken as a whole) in each relevant specialty in each relevant jurisdiction (and, in the case of an actual or perceived conflict of interest where the party affected by such conflict informs the Borrower of

such conflict and thereafter retains its own counsel, of one additional primary firm of counsel for all such affected parties (taken as a whole) and one additional firm of counsel for all such affected parties (taken as a whole) in each relevant material jurisdiction)), and shall pay all reasonable and documented out-of-pocket fees and time charges for attorneys who may be employees of the Administrative Agent or any Lender, in connection with the enforcement or protection of its rights (A) in connection with this Agreement and the other Loan Documents, including its rights under this Section 11.04, or (B) in connection with the Loans made hereunder, including all such out-of-pocket expenses incurred during any workout, restructuring or negotiations in respect of such Loans.

(b) Indemnification by the Loan Parties. The Loan Parties shall indemnify the Administrative Agent (and any sub-agent thereof) and each Lender, and each Related Party of any of the foregoing Persons (each such Person being called an "Indemnitee") against, and hold each Indemnitee harmless from, any and all losses, claims, damages, liabilities and related reasonable and documented expenses (including the reasonable and documented fees, charges and disbursements of any counsel for any Indemnitee) and shall indemnify and hold harmless each Indemnitee from all fees and time charges and disbursements for attorneys who may be employees of any Indemnitee, incurred by any Indemnitee or asserted against any Indemnitee by any Person (including the Borrower or any other Loan Party) arising out of, in connection with, or as a result of (i) the execution or delivery of this Agreement, any other Loan Document or any agreement or instrument contemplated hereby or thereby, the performance by the parties hereto of their respective obligations hereunder or thereunder or the consummation of the transactions contemplated hereby or thereby, or, in the case of the Administrative Agent (and any sub-agent thereof) and its Related Parties only, the administration of this Agreement and the other Loan Documents, (ii) any Loan or the use or proposed use of the proceeds therefrom, (iii) any actual or alleged presence or release of Hazardous Materials on or from any property owned or operated by a Loan Party or any of its Subsidiaries, or any Environmental Liability related in any way to a Loan Party or any of its Subsidiaries, or (iv) any actual or prospective claim, litigation, investigation or proceeding relating to any of the foregoing, whether based on contract, tort or any other theory, whether brought by a third party or by the Borrower or any other Loan Party, and regardless of whether any Indemnitee is a party thereto, in all cases, whether or not caused by or arising, in whole or in part, out of the comparative, contributory or sole negligence of the Indemnitee; provided, that, such indemnity shall not, as to any Indemnitee, be available to the extent that such losses, claims, damages, liabilities or related expenses (i) are determined by a court of competent jurisdiction by final and nonappealable judgment to have resulted from (A) the gross negligence, bad faith or willful misconduct of such Indemnitee, if the Borrower or such Loan Party has obtained a final and nonappealable judgment in its favor on such claim as determined by a court of competent jurisdiction or (B) a claim brought by any Loan Party against an Indemnitee for material breach of such Indemnitee's obligations hereunder or under any other Loan Document, or (ii) arise solely from a dispute among the Indemnitees (except when and to the extent that one of the Indemnitees party to such dispute was acting in its capacity or in fulfilling its role as Administrative Agent, or any similar role under this Agreement or any other Loan Document) that does not involve any act or omission of the Borrower or any of its Subsidiaries.

(c) Reimbursement by Lenders. To the extent that the Loan Parties for any reason fail to indefeasibly pay any amount required under clause (a) or (b) of this Section 11.04 to be paid by them to the Administrative Agent (or any sub-agent thereof) or any Related Party thereof, each Lender severally agrees to pay to the Administrative Agent (or any such sub-agent) or such Related Party, as the case may be, such Lender's pro rata share (determined as of the time that the applicable unreimbursed expense or indemnity payment is sought based on each Lender's share of the Total Credit Exposure at such time) of such unpaid amount (including any such unpaid amount in respect

of a claim asserted by such Lender), such payment to be made severally among them based on such Lenders' Applicable Percentages (determined as of the time that the applicable unreimbursed expense or indemnity payment is sought); provided, further, that, the unreimbursed expense or indemnified loss, claim, damage, liability or related expense, as the case may be, was incurred by or asserted against the Administrative Agent (or any such sub-agent), or against any Related Party thereof acting for the Administrative Agent (or any such sub-agent) in connection with such capacity. The obligations of the Lenders under this clause (c) are subject to the provisions of Section 2.10(b).

(d) Waiver of Consequential Damages, Etc. To the fullest extent permitted by applicable law, no Loan Party shall assert, and each Loan Party hereby waives, and acknowledges that no other Person shall have, any claim against any Indemnitee, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) arising out of, in connection with, or as a result of, this Agreement, any other Loan Document or any agreement or instrument contemplated hereby, the transactions contemplated hereby or thereby, any Loan or the use of the proceeds thereof. No Indemnitee referred to in clause (b) above shall be liable for any damages arising from the use by unintended recipients of any information or other materials distributed by it through telecommunications, electronic or other information transmission systems in connection with this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby.

(e) Payments. All amounts due under this Section 11.04 shall be payable not later than ten (10) Business Days after demand therefor.

(f) Survival. The agreements in this Section and the indemnity provisions of Section 11.02(d) shall survive the resignation of the Administrative Agent, the replacement of any Lender, the termination of the Commitments, the termination of the Loan Documents and the repayment, satisfaction or discharge of all the other Obligations.

11.05 Payments Set Aside.

To the extent that any payment by or on behalf of any Loan Party is made to the Administrative Agent or any Lender, or the Administrative Agent or any Lender exercises its right of setoff, and such payment or the proceeds of such setoff or any part thereof is subsequently invalidated, declared to be fraudulent or preferential, set aside or required (including pursuant to any settlement entered into by the Administrative Agent or such Lender in its discretion) to be repaid to a trustee, receiver or any other party, in connection with any proceeding under any Debtor Relief Law or otherwise, then (a) to the extent of such recovery, the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such setoff had not occurred, and (b) each Lender severally agrees to pay to the Administrative Agent upon demand its applicable share (without duplication) of any amount so recovered from or repaid by the Administrative Agent, plus interest thereon from the date of such demand to the date such payment is made at a rate per annum equal to the Federal Funds Rate from time to time in effect. The obligations of the Lenders under clause (b) of the preceding sentence shall survive the payment in full of the Obligations and the termination of this Agreement and the other Loan Documents.

11.06 Successors and Assigns.

(a) Successors and Assigns Generally. The provisions of this Agreement and the other Loan Documents shall be binding upon and inure to the benefit of the parties hereto and thereto and their respective successors and assigns permitted hereby, except that the Borrower may not

assign or otherwise transfer any of its rights or obligations hereunder or thereunder without the prior written consent of the Administrative Agent and each Lender and no Lender may assign or otherwise transfer any of its rights or obligations hereunder except (i) to an assignee in accordance with the provisions of clause (b) of this Section 11.06, (ii) by way of participation in accordance with the provisions of clause (e) of this Section 11.06 or (iii) by way of pledge or assignment of a security interest subject to the restrictions of clause (f) of this Section 11.06 (and any other attempted assignment or transfer by any party hereto shall be null and void). Nothing in this Agreement, expressed or implied, shall be construed to confer upon any Person (other than the parties hereto, their respective successors and assigns permitted hereby, Participants to the extent provided in clause (e) of this Section 11.06 and, to the extent expressly contemplated hereby, the Related Parties of each of the Administrative Agent and the Lenders) any legal or equitable right, remedy or claim under or by reason of this Agreement.

(b) Assignments by Lenders. Any Lender may at any time assign to one or more assignees all or a portion of its rights and obligations under this Agreement and the other Loan Documents (including all or a portion of its Commitments under the Term Facility and the Loans at the time owing to it); provided, that, any such assignment shall be subject to the following conditions:

(i) Minimum Amounts.

(A) in the case of an assignment of the entire remaining amount of the assigning Lender's Commitment and/or the Loans at the time owing to it or contemporaneous assignments to related Approved Funds that equal at least the amount specified in paragraph (b)(i)(B) of this Section 11.06 in the aggregate or in the case of an assignment to a Lender, an Affiliate of a Lender or an Approved Fund, no minimum amount need be assigned; and

(B) in any case not described in clause (b)(i)(A) of this Section 11.06, the aggregate amount of the applicable Commitment (which for this purpose includes Loans outstanding thereunder) or, if the applicable Commitment is not then in effect, the principal outstanding balance of the Loans of the assigning Lender subject to each such assignment, determined as of the date the Assignment and Assumption with respect to such assignment is delivered to the Administrative Agent or, if "Trade Date" is specified in the Assignment and Assumption, as of the Trade Date, shall not be less than $1,000,000 unless each of the Administrative Agent and, so long as no Event of Default has occurred and is continuing, the Borrower otherwise consents (each such consent not to be unreasonably withheld or delayed);

(ii) Proportionate Amounts. Each partial assignment shall be made as an assignment of a proportionate part of all of the assigning Lender's rights and obligations under this Agreement with respect to the Loans or the Commitment assigned;

(iii) Required Consents. No consent shall be required for any assignment except to the extent required by clause (b)(i)(B) of this Section 11.06 and, in addition:

(A) the consent of the Borrower (such consent not to be unreasonably withheld or delayed) shall be required unless (1) an Event of Default has occurred and is continuing at the time of such assignment or (2) such assignment is to a Lender, an Affiliate of a Lender or an Approved Fund; provided, that, the

Borrower shall be deemed to have consented to any such assignment unless it shall object thereto by written notice to the Administrative Agent within five (5) Business Days after having received notice thereof;

(B) the consent of the Administrative Agent (such consent not to be unreasonably withheld or delayed) shall be required for assignments in respect of (i) any unfunded Commitment if such assignment is to a Person that is not a Lender, an Affiliate of such Lender or an Approved Fund with respect to such Lender or (ii) any Loan to a Person that is not a Lender, an Affiliate of a Lender or an Approved Fund;

(iv) Assignment and Assumption. The parties to each assignment shall execute and deliver to the Administrative Agent an Assignment and Assumption. The assignee, if it is not a Lender, shall deliver to the Administrative Agent such information, including notice information, as the Administrative Agent shall reasonably require.

(v) No Assignment to Certain Persons. No such assignment shall be made (A) to the Borrower or any of the Borrower's Affiliates or Subsidiaries, (B) to any Defaulting Lender or any of its Subsidiaries or any Person who, upon becoming a Lender hereunder, would constitute any of the foregoing Persons described in this clause (B), (C) so long as no Specified Event of Default shall have occurred and be continuing, to any Competitor or (D) to a natural Person.

(vi) Certain Additional Payments. In connection with any assignment of rights and obligations of any Defaulting Lender hereunder, no such assignment shall be effective unless and until, in addition to the other conditions thereto set forth herein, the parties to the assignment shall make such additional payments to the Administrative Agent in an aggregate amount sufficient, upon distribution thereof as appropriate (which may be outright payment, purchases by the assignee of participations or subparticipations, or other compensating actions, including funding, with the consent of the Borrower and the Administrative Agent, the applicable pro rata share of Loans previously requested but not funded by the Defaulting Lender, to each of which the applicable assignee and assignor hereby irrevocably consent), to (x) pay and satisfy in full all payment liabilities then owed by such Defaulting Lender to the Administrative Agent or any Lender hereunder (and interest accrued thereon) and (y) acquire (and fund as appropriate) its full pro rata share of all Loans in accordance with its Applicable Percentage. Notwithstanding the foregoing, in the event that any assignment of rights and obligations of any Defaulting Lender hereunder shall become effective under applicable Law without compliance with the provisions of this paragraph, then the assignee of such interest shall be deemed to be a Defaulting Lender for all purposes of this Agreement until such compliance occurs.

Subject to acceptance and recording thereof by the Administrative Agent pursuant to clause (c) of this Section 11.06, from and after the effective date specified in each Assignment and Assumption, the assignee thereunder shall be a party to this Agreement and, to the extent of the interest assigned by such Assignment and Assumption, have the rights and obligations of a Lender under this Agreement, and the assigning Lender thereunder shall, to the extent of the interest assigned by such Assignment and Assumption, be released from its obligations under this Agreement (and, in the case of an Assignment and Assumption covering all of the assigning Lender's rights and obligations under this Agreement, such Lender shall cease to be a party hereto) but shall continue to be entitled to the benefits of Sections 3.01, 3.02 and 11.04 with respect to facts and circumstances occurring

prior to the effective date of such assignment. Upon request, the Borrower (at its expense) shall execute and deliver a Note to the assignee Lender.

(c) Novation. A transfer of rights and obligations under the Loan Documents by a Lender to an assignee effected in accordance with this Section 11.06 shall constitute a novation within the meaning of articles 1329 *et seq.* of the French Code civil, and each party hereto agrees that upon a transfer completed in accordance with this Section 11.06, the Collateral created under the French Securities Account Pledge Agreement shall be preserved and maintained for the benefit of the Secured Parties pursuant to articles 1334 *et seq.* of the French Code civil.

(d) Register. The Administrative Agent, acting solely for this purpose as a non-fiduciary agent of the Borrower (and such agency being solely for tax purposes), shall maintain at the Administrative Agent's Office a copy of each Assignment and Assumption delivered to it (or the equivalent thereof in electronic form) and a register for the recordation of the names and addresses of the Lenders, and the Commitments of, and principal amounts (and stated interest) of the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "Register"). The entries in the Register shall be conclusive absent manifest error, and the Borrower, the Administrative Agent and the Lenders shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. In addition, the Administrative Agent shall maintain on the Register information regarding the designation, and revocation of designation, of any Lender as a Defaulting Lender. The Register shall be available for inspection by the Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior notice.

(e) Participations. Any Lender may at any time, without the consent of, or notice to, the Borrower or the Administrative Agent, sell participations to any Person (other than a natural Person, a Defaulting Lender or the Borrower or any of the Borrower's Affiliates or Subsidiaries) (each, a "Participant") in all or a portion of such Lender's rights and/or obligations under this Agreement (including all or a portion of its Commitment and/or the Loans owing to it); provided, that, (i) such Lender's obligations under this Agreement shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of such obligations and (iii) the Borrower, the Administrative Agent and the other Lenders shall continue to deal solely and directly with such Lender in connection with such Lender's rights and obligations under this Agreement. For the avoidance of doubt, each Lender shall be responsible for the indemnity under Section 11.04(c) without regard to the existence of any participation.

Any agreement or instrument pursuant to which a Lender sells such a participation shall provide that such Lender shall retain the sole right to enforce this Agreement and to approve any amendment, modification or waiver of any provision of this Agreement; provided, that, such agreement or instrument may provide that such Lender will not, without the consent of the Participant, agree to any amendment, waiver or other modification described in clauses (i) through (vi) of Section 11.01(a) that affects such Participant. The Borrower agrees that each Participant shall be entitled to the benefits of Section 3.01 (subject to the requirements and limitations therein (it being understood that the documentation required under Section 3.01(d) shall be delivered to the participating Lender)) and Section 3.02 to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to paragraph (b) of this Section; provided, that, such Participant (A) agrees to be subject to the provisions of Sections 3.03 and 11.13 as if it were an assignee under paragraph (b) of this Section 11.06 and (B) shall not be entitled to receive any greater payment under Sections 3.01 or 3.02, with respect to any participation, than the Lender from whom it acquired the applicable participation would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a Change in Law that occurs

after the Participant acquired the applicable participation. Each Lender that sells a participation agrees, at the Borrower's request and expense, to use reasonable efforts to cooperate with the Borrower to effectuate the provisions of Section 3.03 with respect to any Participant. To the fullest extent permitted by law, each Participant also shall be entitled to the benefits of Section 11.08 as though it were a Lender; provided, that, such Participant agrees to be subject to Section 2.11 as though it were a Lender. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of the Borrower, maintain a register on which it enters the name and address of each Participant and the principal amounts (and stated interest) of each Participant's interest in the Loans or other obligations under the Loan Documents (the "Participant Register"); provided, that, no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any Participant or any information relating to a Participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan or other obligation is in registered form under Section 5f.103-1(c) of the Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, the Administrative Agent (in its capacity as Administrative Agent) shall have no responsibility for maintaining a Participant Register.

(f) Certain Pledges. Any Lender may at any time pledge or assign a security interest in all or any portion of its rights under this Agreement (including under its Note, if any) to secure obligations of such Lender, including any pledge or assignment to secure obligations to a Federal Reserve Bank; provided, that, no such pledge or assignment shall release such Lender from any of its obligations hereunder or substitute any such pledgee or assignee for such Lender as a party hereto.

11.07 Treatment of Certain Information; Confidentiality.

(a) Treatment of Certain Information. Each of the Administrative Agent and the Lenders agrees to maintain the confidentiality of the Information (as defined below), except that Information may be disclosed (a) to its Affiliates, its auditors and to its Related Parties (it being understood that the Persons to whom such disclosure is made will be informed of the confidential nature of such Information and instructed to keep such Information confidential), (b) to the extent required or requested by any regulatory authority purporting to have jurisdiction over such Person or its Related Parties (including any self-regulatory authority, such as the National Association of Insurance Commissioners), (c) to the extent required by applicable laws or regulations or by any subpoena or similar legal process, (d) to any other party hereto, (e) as may be reasonably necessary in connection with the exercise of any remedies hereunder or under any other Loan Document or any action or proceeding relating to this Agreement or any other Loan Document or the enforcement of rights hereunder or thereunder, (f) subject to an agreement containing provisions substantially the same as those of this Section 11.07, to (i) any assignee of or Participant in, or any prospective assignee of or Participant in, any of its rights and obligations under this Agreement or (ii) any actual or prospective party (or its Related Parties) to any swap, derivative or other transaction under which payments are to be made by reference to a Loan Party and its obligations, this Agreement or payments hereunder, (g) on a confidential basis to (i) any rating agency in connection with rating the Borrower or its Subsidiaries or the Loans to be made hereunder or (ii) the CUSIP Service Bureau or any similar agency in connection with the application, issuance, publishing and monitoring of CUSIP numbers or other market identifiers with respect to the credit facilities provided hereunder, (h) with the consent of the Borrower, (i) to the members of its

investment committee (it being understood that the Persons to whom such disclosure is made will be informed of the confidential nature of such Information and instructed to keep such Information confidential) or (j) to the extent such Information (x) becomes publicly available other than as a result of a breach of this Section 11.07, (y) becomes available to the Administrative Agent, any Lender or any of their respective Affiliates on a nonconfidential basis from a source other than the Borrower or (z) is independently discovered or developed by a party hereto without utilizing any Information received from a Loan Party or violating the terms of this Section 11.07.

For purposes of this Section 11.07, "Information" means all information received from a Loan Party or any Subsidiary relating to the Loan Parties or any Subsidiary or any of their respective businesses, other than any such information that is available to the Administrative Agent or any Lender on a nonconfidential basis prior to disclosure by such Loan Party or any Subsidiary. Any Person required to maintain the confidentiality of Information as provided in this Section 11.07 shall be considered to have complied with its obligation to do so if such Person has exercised the same degree of care to maintain the confidentiality of such Information as such Person would accord to its own confidential information. In addition, the Administrative Agent or any Lender may disclose the existence of this Agreement and information about this Agreement to market data collectors, similar service providers to the lending industry and service providers to the Administrative Agent or such Lender in connection with the administration of this Agreement, the other Loan Documents and the Commitments.

Each of the Lenders and the Administrative Agent acknowledges that some or all of the Information is or may be price-sensitive information and that the use of such Information may be regulated or prohibited by applicable legislation including securities law relating to insider dealing and market abuse and each of the Lenders and the Administrative Agent undertakes not to use any Information for any unlawful purpose.

(b) Press Releases. The Loan Parties and their Affiliates agree that they will not in the future issue any press releases or other public disclosure using the name of the Administrative Agent or any Lender or its Affiliates or referring to this Agreement or any of the Loan Documents without the prior written consent of the Administrative Agent, unless (and only to the extent that) the Loan Parties or such Affiliate is required to do so under law and then, in any event the Loan Parties or such Affiliate will consult with such Person before issuing such press release or other public disclosure.

11.08 Set-off.

If an Event of Default shall have occurred and be continuing, each Lender and each of their respective Affiliates is hereby authorized at any time and from time to time, after obtaining the prior written consent of the Administrative Agent, to the fullest extent permitted by applicable law, to set off and apply any and all deposits (general or special, time or demand, provisional or final, in whatever currency) at any time held and other obligations (in whatever currency) at any time owing by such Lender or any such Affiliate to or for the credit or the account of the Borrower or any other Loan Party against any and all of the obligations of the Borrower or such Loan Party now or hereafter existing under this Agreement or any other Loan Document to such Lender or its Affiliates, irrespective of whether or not such Lender or Affiliate shall have made any demand under this Agreement or any other Loan Document and although such obligations of the Borrower or such Loan Party may be contingent or unmatured or are owed to a branch office or Affiliate of such Lender different from the branch office or Affiliate holding such deposit or obligated on such indebtedness; provided, that, in the event that any Defaulting Lender shall exercise any such right of setoff, (x) all amounts so set off shall be paid over immediately to the Administrative Agent for further application in accordance with the provisions of Section 2.12 and, pending such payment, shall

be segregated by such Defaulting Lender from its other funds and deemed held in trust for the benefit of the Administrative Agent and the Lenders and (y) the Defaulting Lender shall provide promptly to the Administrative Agent a statement describing in reasonable detail the Obligations owing to such Defaulting Lender as to which it exercised such right of setoff. The rights of each Lender and their respective Affiliates under this Section 11.08 are in addition to other rights and remedies (including other rights of setoff) that such Lender or their respective Affiliates may have. Each Lender agrees to notify the Borrower and the Administrative Agent promptly after any such setoff and application; provided, that, the failure to give such notice shall not affect the validity of such setoff and application.

11.09 Interest Rate Limitation.

Notwithstanding anything to the contrary contained in any Loan Document, the interest paid or agreed to be paid under the Loan Documents shall not exceed the maximum rate of non-usurious interest permitted by applicable Law (the "Maximum Rate"). If the Administrative Agent or any Lender shall receive interest in an amount that exceeds the Maximum Rate, the excess interest shall be applied to the principal of the Loans or, if it exceeds such unpaid principal, refunded to the Borrower. In determining whether the interest contracted for, charged, or received by the Administrative Agent or a Lender exceeds the Maximum Rate, such Person may, to the extent permitted by applicable Law, (a) characterize any payment that is not principal as an expense, fee, or premium rather than interest, (b) exclude voluntary prepayments and the effects thereof, and (c) amortize, prorate, allocate, and spread in equal or unequal parts the total amount of interest throughout the contemplated term of the Obligations hereunder.

11.10 Counterparts; Integration; Effectiveness.

This Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. This Agreement, the other Loan Documents, and any separate letter agreements with respect to fees payable to the Administrative Agent, constitute the entire contract among the parties relating to the subject matter hereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof. Except as provided in Section 5.01, this Agreement shall become effective when it shall have been executed by the Administrative Agent and when the Administrative Agent shall have received counterparts hereof that, when taken together, bear the signatures of each of the other parties hereto. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Agreement.

11.11 Survival of Representations and Warranties.

All representations and warranties made hereunder and in any other Loan Document or other document delivered pursuant hereto or thereto or in connection herewith or therewith shall survive the execution and delivery hereof and thereof and shall continue in full force and effect as long as any Loan or other Obligation (other than contingent indemnification obligations for which no claim has been asserted) hereunder shall remain unpaid or unsatisfied. Such representations and warranties have been or will be relied upon by the Administrative Agent and each Lender, regardless of any investigation made by the Administrative Agent or any Lender or on their behalf and notwithstanding that the Administrative Agent or any Lender may have had notice or knowledge of any Default at the time of any Borrowing, and shall continue in full force and effect as long as any Loan or any other Obligation (other than contingent indemnification obligations for which no claim has been asserted) hereunder shall remain unpaid or unsatisfied.

11.12 Severability.

If any provision of this Agreement or the other Loan Documents is held to be illegal, invalid or unenforceable, (a) the legality, validity and enforceability of the remaining provisions of this Agreement and the other Loan Documents shall not be affected or impaired thereby and (b) the parties shall endeavor in good faith negotiations to replace the illegal, invalid or unenforceable provisions with valid provisions the economic effect of which comes as close as possible to that of the illegal, invalid or unenforceable provisions. The invalidity of a provision in a particular jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. Without limiting the foregoing provisions of this Section 11.12, if and to the extent that the enforceability of any provisions in this Agreement relating to Defaulting Lenders shall be limited by Debtor Relief Laws, as determined in good faith by the Administrative Agent, then such provisions shall be deemed to be in effect only to the extent not so limited.

11.13 Replacement of Lenders.

If the Borrower is entitled to replace a Lender pursuant to the provisions of Section 3.03 or if any Lender is a Defaulting Lender or a Non-Consenting Lender, then the Borrower may, at its sole expense and effort, upon written notice to such Lender and the Administrative Agent, require such Lender to assign and delegate, without recourse (in accordance with and subject to the restrictions contained in, and consents required by, Section 11.06), all of its interests, rights (other than its existing rights to payments pursuant to Sections 3.01 and 3.02) and obligations under this Agreement and the related Loan Documents to an assignee that shall assume such obligations (which assignee may be another Lender, if a Lender accepts such assignment), provided, that:

(a) such Lender shall have received payment of an amount equal to one hundred percent (100%) of (x) the outstanding principal of its Loans, accrued interest thereon and all other amounts payable to it hereunder and under the other Loan Documents (other than repayment premium and exit fees) from the assignee (to the extent of such outstanding principal and accrued interest) or the Borrower (in the case of all other amounts) and (y) the repayment premium required by Section 2.03(d) and the exit fee required by Section 2.07(b), in each case, from the Borrower, as if such assignment was a prepayment of one hundred percent (100%) of the outstanding principal amount of such assignor's Loans on the effective date of such assignment;

(b) such assignment does not conflict with applicable Laws;

(c) in the case of any such assignment resulting from a claim for compensation under Section 3.02 or payments required to be made pursuant to Section 3.01, such assignment will result in a reduction in such compensation or payments thereafter; and

(d) in the case of any such assignment resulting from a Non-Consenting Lender's failure to consent to a proposed change, waiver, discharge or termination with respect to any Loan Document, the applicable replacement bank, financial institution or Fund consents to the proposed change, waiver, discharge or termination; provided, that, the failure by such Non-Consenting Lender to execute and deliver an Assignment and Assumption shall not impair the validity of the removal of such Non-Consenting Lender and the mandatory assignment of such Non-Consenting Lender's outstanding Loans pursuant to this Section 11.13 shall nevertheless be effective without the execution by such Non-Consenting Lender of an Assignment and Assumption.

A Lender shall not be required to make any such assignment or delegation if, prior thereto, as a result of a waiver by such Lender or otherwise, the circumstances entitling the Borrower to require such assignment and delegation cease to apply.

11.14 Governing Law; Jurisdiction; Etc.

(a) GOVERNING LAW. THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS (EXCEPT, AS TO ANY OTHER LOAN DOCUMENT, AS EXPRESSLY SET FORTH THEREIN) AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT (EXCEPT, AS TO ANY OTHER LOAN DOCUMENT, AS EXPRESSLY SET FORTH THEREIN) AND THE TRANSACTIONS CONTEMPLATED HEREBY AND THEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

(b) SUBMISSION TO JURISDICTION. THE BORROWER AND EACH OTHER LOAN PARTY IRREVOCABLY AND UNCONDITIONALLY AGREES THAT IT WILL NOT COMMENCE ANY ACTION, LITIGATION OR PROCEEDING OF ANY KIND OR DESCRIPTION, WHETHER IN LAW OR EQUITY, WHETHER IN CONTRACT OR IN TORT OR OTHERWISE, AGAINST THE ADMINISTRATIVE AGENT, ANY LENDER OR ANY RELATED PARTY OF THE FOREGOING IN ANY WAY RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT OR THE TRANSACTIONS RELATING HERETO OR THERETO, IN ANY OTHER FORUM OTHER THAN THE COURTS OF THE STATE OF NEW YORK AND ANY UNITED STATES DISTRICT COURT IN THE STATE OF NEW YORK, AND ANY APPELLATE COURT FROM ANY THEREOF LOCATED IN NEW YORK COUNTY, NEW YORK, AND EACH OF THE PARTIES HERETO IRREVOCABLY AND UNCONDITIONALLY SUBMITS TO THE JURISDICTION OF SUCH COURTS AND AGREES THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION, LITIGATION OR PROCEEDING MAY BE HEARD AND DETERMINED IN SUCH NEW YORK STATE COURT OR, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, IN SUCH FEDERAL COURT. EACH OF THE PARTIES HERETO AGREES THAT A FINAL JUDGMENT IN ANY SUCH ACTION OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY LAW. NOTHING IN THIS AGREEMENT OR IN ANY OTHER LOAN DOCUMENT SHALL AFFECT ANY RIGHT THAT THE ADMINISTRATIVE AGENT OR ANY LENDER MAY OTHERWISE HAVE TO BRING ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT AGAINST THE BORROWER OR ANY OTHER LOAN PARTY OR ITS PROPERTIES IN THE COURTS OF ANY JURISDICTION.

(c) WAIVER OF VENUE. THE BORROWER AND EACH OTHER LOAN PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT IN ANY COURT REFERRED TO IN PARAGRAPH (B) OF THIS SECTION 11.14. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT.

(d) SERVICE OF PROCESS. EACH PARTY HERETO IRREVOCABLY CONSENTS TO SERVICE OF PROCESS IN THE MANNER PROVIDED FOR NOTICES IN SECTION 11.02. NOTHING IN THIS AGREEMENT WILL AFFECT THE RIGHT OF ANY PARTY HERETO TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY APPLICABLE LAW.

11.15 Waiver of Right to Trial by Jury.

EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PERSON HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

11.16 Electronic Execution; Electronic Records; Counterparts.

This Agreement, any Loan Document and any other Communication, including Communications required to be in writing, may be in the form of an Electronic Record and may be executed using Electronic Signatures. Each of the Loan Parties and each of the Administrative Agent and each Lender agrees that any Electronic Signature on or associated with any Communication shall be valid and binding on such Person to the same extent as a manual, original signature, and that any Communication entered into by Electronic Signature, will constitute the legal, valid and binding obligation of such Person enforceable against such Person in accordance with the terms thereof to the same extent as if a manually executed original signature was delivered. Any Communication may be executed in as many counterparts as necessary or convenient, including both paper and electronic counterparts, but all such counterparts are one and the same Communication. For the avoidance of doubt, the authorization under this paragraph may include, without limitation, use or acceptance of a manually signed paper Communication which has been converted into electronic form (such as scanned into .pdf format), or an electronically signed Communication converted into another format, for transmission, delivery and/or retention. The Administrative Agent and each of the Lenders may, at its option, create one or more copies of any Communication in the form of an imaged Electronic Record ("Electronic Copy"), which shall be deemed created in the ordinary course of such Person's business, and destroy the original paper document. All Communications in the form of an Electronic Record, including an Electronic Copy, shall be considered an original for all purposes, and shall have the same legal effect, validity and enforceability as a paper record. Notwithstanding anything contained herein to the contrary, the Administrative Agent is not under any obligation to accept an Electronic Signature in any form or in any format unless expressly agreed to by such Person pursuant to procedures approved by it; provided, that, without limiting the foregoing, (a) to the extent the Administrative Agent has agreed to accept such Electronic Signature, the Administrative Agent and each of the Lenders shall be entitled to rely on any such Electronic Signature purportedly given by or on behalf of any Loan Party and/or any Lender without further verification and (b) upon the request of the Administrative Agent or any Lender, any Electronic Signature shall be promptly followed by such manually executed counterpart.

The Administrative Agent shall not be responsible for or have any duty to ascertain or inquire into the sufficiency, validity, enforceability, effectiveness or genuineness of any Loan Document or any other agreement, instrument or document (including, for the avoidance of doubt, in connection with the Administrative Agent's reliance on any Electronic Signature transmitted by telecopy, emailed .pdf or any other electronic means). The Administrative Agent shall be entitled to rely on, and shall incur no liability under or in respect of this Agreement or any other Loan Document by acting upon, any Communication (which writing may be a fax, any electronic message, Internet or intranet website posting or other

distribution or signed using an Electronic Signature) or any statement made to it orally or by telephone and believed by it to be genuine and signed or sent or otherwise authenticated (whether or not such Person in fact meets the requirements set forth in the Loan Documents for being the maker thereof).

Each of the Loan Parties and each Lender hereby waives (i) any argument, defense or right to contest the legal effect, validity or enforceability of this Agreement, any other Loan Document based solely on the lack of paper original copies of this Agreement, such other Loan Document, and (ii) any claim against the Administrative Agent, each Lender and each Related Party for any liabilities arising solely from the Administrative Agent's and/or any Lender's reliance on or use of Electronic Signatures, including any liabilities arising as a result of the failure of the Loan Parties to use any available security measures in connection with the execution, delivery or transmission of any Electronic Signature.

11.17 USA PATRIOT Act.

Each Lender that is subject to the Act (as hereinafter defined) and the Administrative Agent (for itself and not on behalf of any Lender) hereby notifies the Borrower and the other Loan Parties that pursuant to the requirements of the USA PATRIOT Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "Act"), it is required to obtain, verify and record information that identifies each Loan Party, which information includes the name and address of each Loan Party and other information that will allow such Lender or the Administrative Agent, as applicable, to identify each Loan Party in accordance with the Act. The Borrower and the Loan Parties agree to, promptly following a request by the Administrative Agent or any Lender, provide all such other documentation and information that the Administrative Agent or such Lender requests in order to comply with its ongoing obligations under applicable "know your customer" and anti-money laundering rules and regulations, including the Act.

11.18 No Advisory or Fiduciary Relationship.

In connection with all aspects of each transaction contemplated hereby (including in connection with any amendment, waiver or other modification hereof or of any other Loan Document), the Borrower acknowledges and agrees, and acknowledges its Affiliates' understanding, that: (a)(i) the arranging and other services regarding this Agreement provided by the Administrative Agent, Athyrium, and the Lenders are arm's-length commercial transactions between the Borrower and its Affiliates, on the one hand, and the Administrative Agent, Athyrium and the Lenders on the other hand, (ii) the Borrower has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate, and (iii) the Borrower is capable of evaluating, and understands and accepts, the terms, risks and conditions of the transactions contemplated hereby and by the other Loan Documents; (b)(i) the Administrative Agent, Athyrium and each Lender is and has been acting solely as a principal and, except as expressly agreed in writing by the relevant parties, has not been, is not and will not be acting as an advisor, agent or fiduciary, for the Borrower or any of Affiliates or any other Person and (ii) neither the Administrative Agent nor any Lender has any obligation to the Borrower or any of its Affiliates with respect to the transactions contemplated hereby except those obligations expressly set forth herein and in the other Loan Documents; and (c) the Administrative Agent, Athyrium and the Lenders and their respective Affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Borrower and its Affiliates, and neither the Administrative Agent, Athyrium nor any Lender has any obligation to disclose any of such interests to the Borrower or its Affiliates. To the fullest extent permitted by law, the Borrower hereby waives and releases, any claims that it may have against the Administrative Agent, Athyrium or any Lender with respect to any breach or alleged breach of agency or fiduciary duty in connection with any aspect of any transaction contemplated hereby.

11.19 Acknowledgement and Consent to Bail-In of Affected Financial Institutions.

Notwithstanding anything to the contrary in any Loan Document or in any other agreement, arrangement or understanding among any such parties, each party hereto acknowledges that any liability of any Lender that is an Affected Financial Institution arising under any Loan Document, to the extent such liability is unsecured, may be subject to the write-down and conversion powers of the applicable Resolution Authority and agrees and consents to, and acknowledges and agrees to be bound by (a) the application of any Write-Down and Conversion Powers by the applicable Resolution Authority to any such liabilities arising hereunder which may be payable to it by any Lender that is an Affected Financial Institution; and (b) the effects of any Bail-In Action on any such liability, including, if applicable: (i) a reduction in full or in part or cancellation of any such liability; (ii) a conversion of all, or a portion of, such liability into shares or other instruments of ownership in such Affected Financial Institution, its parent undertaking, or a bridge institution that may be issued to it or otherwise conferred on it, and that such shares or other instruments of ownership will be accepted by it in lieu of any rights with respect to any such liability under this Agreement or any other Loan Document; or (iii) the variation of the terms of such liability in connection with the exercise of the write-down and conversion powers of the applicable Resolution Authority.

11.20 Judgment Currency.

If, for the purposes of obtaining judgment in any court, it is necessary to convert a sum due hereunder or any other Loan Document in one currency into another currency, the rate of exchange used shall be that at which in accordance with normal banking procedures the Administrative Agent could purchase the first currency with such other currency on the Business Day preceding that on which final judgment is given. The obligation of each Loan Party in respect of any such sum due from it to the Administrative Agent or any Lender hereunder or under the other Loan Documents shall, notwithstanding any judgment in a currency (the "Judgment Currency") other than that in which such sum is denominated in accordance with the applicable provisions of this Agreement (the "Agreement Currency"), be discharged only to the extent that on the Business Day following receipt by the Administrative Agent or such Lender, as the case may be, of any sum adjudged to be so due in the Judgment Currency, the Administrative Agent or such Lender, as the case may be, may in accordance with normal banking procedures purchase the Agreement Currency with the Judgment Currency. If the amount of the Agreement Currency so purchased is less than the sum originally due to the Administrative Agent or any Lender from any Loan Party in the Agreement Currency, such Loan Party agrees, as a separate obligation and notwithstanding any such judgment, to indemnify the Administrative Agent or such Lender, as the case may be, against such loss. If the amount of the Agreement Currency so purchased is greater than the sum originally due to the Administrative Agent or any Lender in such currency, the Administrative Agent or such Lender, as the case may be, agrees to return the amount of any excess to such Loan Party (or to any other Person who may be entitled thereto under applicable Law).

11.21 Collateral and Guaranty Release.

Upon the request of the Borrower, the Administrative Agent agrees to promptly execute and deliver to the applicable Loan Party such documents as the Borrower may reasonably request, in each case in accordance with the terms of the Loan Documents and this Section 11.21:

(a) to release any Lien on any property granted to or held by the Administrative Agent under any Loan Document (i) upon termination of all unused Commitments and payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been asserted) under the Loan Documents, (ii) that is sold or otherwise disposed of or to be sold or otherwise disposed of as part of or in connection with any sale or other Disposition permitted hereunder or under any other Loan Document or any Involuntary Disposition, or (iii) as approved in accordance with Section 11.01;

(b) to release or subordinate any Lien on any property granted to or held by the Administrative Agent under any Loan Document to the holder of any Lien on such property that is permitted by Section 8.01(i);

(c) to release any Guarantor from its obligations under the Guaranty (i) if such Person ceases to be a Subsidiary as a result of a transaction permitted under the Loan Documents or (ii) upon termination of all unused Commitments and payment in full of all Obligations (other than contingent indemnification obligations for which no claim has been asserted) under the Loan Documents.

The Administrative Agent will promptly, in connection with the foregoing, at the Borrower's expense, and the Lenders hereby authorize the Administrative Agent to, deliver to the applicable Loan Party any Collateral in the Administrative Agent's possession following the release of such Collateral pursuant to the terms hereof.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the date first above written.

BORROWER:

CALLIDITAS THERAPEUTICS AB (publ),
a Swedish public limited liability company with Swedish registration number 556659-9766

By: /s/ Renee Aguiar Lucander
Name: Renee Aguiar Lucander
Title: Chief Executive Officer

GUARANTORS:

CALLIDITAS THERAPEUTICS US INC.,
a Delaware corporation

By: /s/ Andrew Udell
Name: Andrew Udell
Title: President

CALLIDITAS NA ENTERPRISES INC.,
a Delaware corporation

By: /s/ Andrew Udell
Name: Andrew Udell
Title: President

ADMINISTRATIVE AGENT:

ATHYRIUM OPPORTUNITIES IV CO-INVEST 1 LP,
a Delaware limited partnership

By: ATHYRIUM OPPORTUNITIES ASSOCIATES IV CO-INVEST LLC, its General Partner

By: /s/ Rashida Adams
Name: Rashida Adams
Title: Authorized Signatory

LENDER:

ATHYRIUM OPPORTUNITIES IV CO-INVEST 1 LP,
a Delaware limited partnership

By: ATHYRIUM OPPORTUNITIES ASSOCIATES IV CO-INVEST LLC, its General Partner

By: /s/ Rashida Adams
Name: Rashida Adams
Title: Authorized Signatory

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT WAS OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[***]".

Master Manufacturing Services Agreement

Effective Date: December 30, 2020

PARTIES

PATHEON PHARMACEUTICALS INC.,

a corporation existing under the laws of the State of Delaware, with its principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237 ("***Patheon***"),

- and -

CALLIDITAS THERAPEUTICS AB,

a company existing under the laws of Sweden, with its registered office and mailing address at PO Box 70351, SE-107 24 Stockholm, Sweden and its principal office and address for courier delivery at Kungsbron 1, C8, SE-111 22 Stockholm ("***Client***").

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With effect from the date stated at the start of this Agreement (the "***Effective Date***"), the parties have agreed to the following terms:

1. STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon in the business of performing manufacturing services may perform Manufacturing Services for Client or any Affiliate of Client. This master form of agreement is intended to allow the parties, or any of their Affiliates, to contract for the manufacture of Product through Patheon's global network of manufacturing sites by entering into specific Product Agreements without having to re-negotiate the general terms and conditions that apply.

1.2 Product Agreements.

This Agreement is structured so that Product Agreements may be entered into by the parties (or their Affiliates) for the manufacture of Product at any Patheon manufacturing site. Each Product Agreement will be governed by and will incorporate the terms and conditions of this Agreement, except to the extent that the parties to the Product Agreement modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the parties, each Product Agreement will be substantially in the general form, and contain the information referred to, in Appendix 1. In case of any inconsistency between the Product Agreement and this Agreement, the Product Agreement will prevail.

1.3 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"***Affiliate***" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party; or

(b) a business entity which is controlled by a party, either directly or indirectly; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party;

For this definition, "control" means the lawful right to determine (by ownership of shares or otherwise) the election of the majority of directors (or equivalent managers) of a business entity;

"***Annual Volume***" means, for the purpose of the Price, Patheon's assumed minimum volume of Product to be manufactured and delivered in any Year as set out in the "*Annual Volume Forecast*" section of Schedule A of the applicable Product Agreement;

"***API***" means the active materials listed in the applicable Product Agreement (references to "Active Materials" or "Active Pharmaceutical Ingredient" in documents forming part of this Agreement or of a Product Agreement will mean "***API***");

"***API Credit Value***" means the value of the API for certain purposes of this Agreement, as set out in the applicable Product Agreement;

"***Applicable Laws***" the Laws of all jurisdictions where Product is manufactured, distributed, and marketed as these are agreed by the parties in the Product Agreement;

"***Authority***" means any governmental, quasi-governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether intra- national, supra-national, federal, state, provincial, county or municipal, with competent jurisdiction over a party, the Manufacturing Services, or the relevant Product (or its use);

"***Business Day***" means a day other than a Saturday, Sunday or a day that is a statutory holiday in Client's resident jurisdiction, or the jurisdiction where the Manufacturing Site is located;

"***Capital Equipment Agreement***" means the separate agreement that the parties may enter into that addresses the rights and responsibilities of the parties regarding capital equipment and facility modifications that may be required to perform the Manufacturing Services under a particular Product Agreement;

"***cGMPs***" means, as applicable, current good manufacturing practices as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) Commission Directive (EU) 2017/1572 (art. 2) (and such equivalent UK regulation as may be applicable post Brexit); and

(c) Division 2 of Part C of the Food and Drug Regulations (Canada);

together with current final industry-accepted Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

"***Client Intellectual Property***" means Intellectual Property, Inventions and Know-How (i) generated or derived by Client or its Affiliates before entering into the applicable Product Agreement or independent of this Agreement or the Product Agreement; or (ii) by Patheon while performing any Manufacturing Services which Intellectual Property; Inventions or Know-How is specific to, or dependent upon, the Product or other Client Intellectual Property, Client Inventions, Client Know-How or Client Confidential Information; including, without limitation, Inventions and Intellectual Property which may apply to the manufacturing processes, the delivery system or the formulation or development of the Product.

"***Client-Supplied Components***" means those Components supplied or to be supplied by or on behalf of Client as identified in Schedule A of a Product Agreement (if any);

"***Components***" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture or package Product in accordance with the Processing Instructions, other than the API;

"***Confidential Information***" has the meaning specified in Section 11.1;

"***Conversion Fee***" means the Price for performing the Manufacturing Services excluding the cost of Components as specified in the Product Agreement;

"***Cost Improvement Plan***" has the meaning specified in Section 4.4;

"***DEA***" means the Drug Enforcement Administration of the United States Department of Justice;

"***Deficient Product***" has the meaning specified in Section 6.1(a);

"***Dispute***" has the meaning specified in Section 13.15.

"***Disclosing Party***" has the meaning specified in Section 11.1;

"***Duties***" have the meaning specified in Section 13.14(b);

"***EMA***" means the European Medicines Agency;

"***FDA***" means the United States Food and Drug Administration;

"***Firm Order***" has the meaning specified in Section 5.1(d);

"***Health Canada***" means the department of the Canadian Government known as Health Canada and includes, among other relevant branches, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

"***Initial Product Term***" has the meaning specified in Section 8.1;

"***Intellectual Property***" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and Know-How;

"***Invention***" means any innovation, improvement, development, discovery, computer program, device, trade secret, method, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"***Inventory***" means, at a point in time, all inventories of Components and work-in-process under Patheon's care or control used for the manufacture or packaging of Product;

"*Know-How*" means (i) all technical information or data relating to the Products, including processes, Specifications, formulas, procedures, techniques, practices and instructions of, and scientific, analytical and technical data and studies for, the synthesis, manufacturing, pharmaceutical processing, formulation, packaging, labelling, storage and transportation of the Products; and (ii) non-clinical and clinical data and studies relating to the Products including documents containing such information. The fact that an item is known to the public will not be taken to exclude the possibility that a compilation including the item, or a development relating to the item, is not known to the public. Know-How includes any rights including trade secrets, copyright, database or design rights protecting the Know-How.

"***Laws***" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"***Local Currency***" has the meaning specified in Appendix 4;

"***Long Term Forecast***" has the meaning specified in Section 5.1(a);

"***Manufacturing Services***" means the manufacturing, quality control, quality assurance, stability testing, packaging, labelling, release and related services for the manufacture of Product for distribution in the Territory, as further detailed in the relevant Product Agreement;

"***Manufacturing Site***" means the facility identified in a Product Agreement where the Manufacturing Services will be performed;

"***MHRA***" means the Medicines and Healthcare Regulatory Agency (U.K. agency responsible for reviewing, approving and inspecting drug products);

"***Minimum Market Requirement***" has the meaning specified in Section 2.1;

"***Minimum Order Quantity***" means, for each manufacturing campaign ordered, the minimum number of units or batches of a Product that Client must purchase, as set out in Schedule A of the applicable Product Agreement;

"***Non-Severable Intellectual Property***" has the meaning specified in Section 12.1(c).

"***Obsolete Stock***" has the meaning specified in Section 5.2(b);

"***Patheon Competitor***" means a business that derives greater than 50% of its revenues from performing contract pharmaceutical or biopharmaceutical process development or commercial manufacturing services;

"***Patheon Intellectual Property***" means Intellectual Property generated or derived by Patheon or its Affiliates before performing any Manufacturing Services, developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business which Intellectual Property is not specific to, or dependent upon, the Product, Client Intellectual Property, Client Inventions, Client Know-How or Client Confidential Information including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes, delivery systems, or the formulation or development of drug products unrelated to the specific requirements of the Product or its manufacture;

"***Price***" means the fees to be charged by Patheon for:

(a) performing the Manufacturing Services;

(b) the cost of Components (other than Client-Supplied Components); and

(c) any separate cost items and other fees,

as set out in Schedule A of the applicable Product Agreement;

"***Processing Instructions***" means the agreed file, for each Product, which is provided by Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A and which contains documents relating to each Product, including, without limitation:

(a) quality control testing methods for API and Components;

(b) manufacturing instructions, directions, and processes;

(c) any storage requirements for the API, Components, or Product;

(d) all environmental, health and safety information for the Product including material safety data sheets;

(e) the finished Product quality control testing methods, packaging instructions, storage and shipping requirements for the Product; and

(f) Specifications.

"***Product***" means a product listed in Schedule A of a Product Agreement;

"***Product Agreement***" means the agreement between Patheon and Client (or their applicable Affiliates) substantially in the form set out in Appendix 1 of this Agreement, under which Patheon will perform Manufacturing Services;

"***Product Claims***" has the meaning specified in Section 6.1(a);

"***Quality Agreement***" means a separate agreement that sets out the quality assurance standards for the Manufacturing Services;

"***Recall***" has the meaning specified in Section 6.2(a);

"***Recipient***" has the meaning specified in Section 11.1;

"***Regulatory Approval***" has the meaning specified in Section 7.5(a);

"***Regulatory Authority***" means the FDA, EMA, MHRA, Health Canada and NMA and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical or biopharmaceutical products, including the Products, in the Territory;

"***Reimbursed Stock***" has the meaning specified in Section 7.5(a);

"***Release Date***" means in relation to each batch of Product the scheduled date by which the Product will be released by Patheon's quality department (by confirmation or certification) as agreed in the Quality Agreement and made available for shipment, and as confirmed by Patheon in a Firm Order;

"***Representatives***" means, a party's directors, officers, employees, advisers, agents, consultants, subcontractors, service partners or professional advisors;

"***Rolling Forecast***" has the meaning specified in Section 5.1(b);

"***Severable Intellectual Property***" has the meaning specified in Section 12.1(d);

"***Specifications***" mean specifications for Active Materials and Components, the finished Product specifications, and the packaging specifications for each Product, all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

"***Technical Dispute***" has the meaning specified in Appendix 2;

"***Territory***" means the geographic area described in a Product Agreement where Product manufactured by Patheon will be distributed;

"***Third Party Rights***" means the Intellectual Property of any third party;

"***Transaction Tax***" has the meaning specified in Section 13.14(a);

"***VAT***" has the meaning specified in Section 13.14(a);

"***Year***" means in the first year of this Agreement or a Product Agreement, the time from the Effective Date up to and including December 31 of the same calendar year, and after that will mean a calendar year; and

"***Yearly Forecast Volume***" has the meaning specified in Section 5.1(f).

1.4 Interpretation.

The division of this Agreement into Sections, Subsections, Appendices and Schedules, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix or Schedule refers to the specified Section, Appendix or Schedule to this Agreement. In this Agreement, the term "***this Agreement***" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix or Schedule of this Agreement. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

This Agreement and each Product Agreement entered into hereunder is an agreement for the provision of Manufacturing Services and not an agreement for the purchase and sale of goods. References to purchases, orders and prices of Product in this Agreement are to purchases, orders and prices of the Manufacturing Services related to Product provided for hereunder. Without limitation on the provisions of Section 13.1 (Insurance), title to all API and Client-Supplied Components will remain vested in Client while these items are in the possession and control of Patheon, title to all inventories of Product (including work in progress) manufactured by Patheon will vest in Client from their creation, and title to all Components sourced by Patheon and held for manufacture of Product will transfer to Client upon their incorporation into Product or, if earlier, Client's reimbursement of Patheon's procurement cost as provided in Section 5.2(b).

2. PATHEON'S MANUFACTURING SERVICES

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services as set out in the relevant Product Agreement for the Price and in accordance with the Quality Agreement. Subject to the preceding sentence, Patheon will receive, quality control and convert API and Components into Product, and provide supportive Manufacturing Services such as quality assurance (for example quality controls, analytical testing, and stability programs), primary and secondary packaging, and any other related Manufacturing Services as agreed between the parties.

The percentage of Client's requirements for each Year for deliveries of Product that Patheon will manufacture (the "***Minimum Market Requirement***") will be determined in each Product Agreement. Unless otherwise specifically agreed in a Product Agreement for a particular Product all Manufacturing Services covered by this Agreement will be provided on a non-exclusive basis.

2.2 Subcontracting.

Patheon may only subcontract the Manufacturing Services under a Product Agreement or any other of its obligations under this Agreement to any of its Affiliates or any third party ("***Third Party Subcontractor***") with Client's prior written consent. Patheon will remain exclusively liable to Client for any breach of this Agreement or negligence by its Affiliates or any Third Party Sub-Contractor in the course of performing: (i) subcontracted Manufacturing Services under a Product Agreement; or (ii) obligations under

the Quality Agreement. But Patheon's liability for Third Party Subcontractors will remain subject to all limitations on Patheon's liability as set out in this Agreement. Patheon will have no liability arising from the performance of services by Third Party Subcontractors to the extent that the Third Party Subcontractor is following the direct instructions of Client.

3. CLIENT'S OBLIGATIONS

3.1 Payment.

Client will pay Patheon the applicable Price in accordance with Sections 4 and 5. All cost items that are not included in the Price (as specified in the applicable Product Agreement) are subject to additional fees to be paid by Client.

3.2 Processing Instructions.

Before the start of commercial manufacturing of Product under this Agreement, Client will give Patheon a copy of the Processing Instructions, which must be accompanied by the applicable API, Component and finished product Specifications (if applicable, matching the Specifications approved by the applicable Regulatory Authority). If the Processing Instructions or accompanying documents received are amended or no longer reflect those currently approved by the Regulatory Authority, then Client will give Patheon a copy of the revised documents (if applicable, matching the revised Specifications approved by the applicable Regulatory Authority). Upon receipt of the revised Processing Instructions and accompanying documents, Patheon will give Client a signed and dated receipt and make amendments to the Manufacturing Services as necessary by following the procedure set out in the Quality Agreement. At Patheon's request, Client will provide evidence of the executed original documents submitted by or on behalf of Client to the Regulatory Authority to the extent necessary in order for Patheon to provide the Manufacturing Services.

3.3 API and Components.

(a) Client will at its sole cost and expense deliver the API and any Client-Supplied Components to the Manufacturing Site DDP (Incoterms 2010). Patheon will supply all other materials and Components which are not API or Client-Supplied Components required to perform the Manufacturing Services and these materials will be included in the Price. Client's obligation will include obtaining the release of the API and any Client-Supplied Components from the applicable customs agency and Regulatory Authority. Unless otherwise agreed in writing, Client or Client's designated broker will be the "***Importer***" or "***Importer of Record***" (or equivalent, as understood under Applicable Laws) for API, Client-Supplied Components and drug products (if applicable) provided by Client and imported to the Manufacturing Site, and Client is responsible for compliance with Applicable Laws (and the cost of compliance) relating to that role. For API or Client-Supplied Components which may be subject to import or export to or from the United States, Client agrees that it will require its vendors and carriers to comply with applicable requirements of the U.S. Customs and Border Protection Service and the Customs Trade Partnership Against Terrorism.

(b) Unless otherwise agreed in writing between the parties, the API and any Client-Supplied Components must be delivered by the Client to the Manufacturing Site at least [***] before the scheduled manufacture date for Product covered by a Firm Order in sufficient quantity to enable Patheon to manufacture the agreed quantities of Product. Patheon reserves the right to refuse to store any quantity of API in excess of the amount necessary for the Firm Order, at its sole discretion at any

time. If Client fails to deliver the API or Client-Supplied Components within the agreed time period and, making commercially reasonable efforts, Patheon is unable to manufacture Product on the scheduled date because of the delay, the Firm Order will be considered cancelled by Client and Section 5.1(e) will apply.

(c) Patheon will control the unloading of API and Client-Supplied Components arriving at the Manufacturing Site and Client will request its carrier to comply with all reasonable related directions of Patheon. The API and Client-Supplied Components will be held by Patheon on behalf of Client as set out in this Agreement. The API and Client-Supplied Components will at all times remain the property of Client. Any API and Client-Supplied Components received by Patheon will only be used by Patheon to perform the Manufacturing Services or any development services if and as instructed by Client and may not be used for any other purpose.

(d) Client will ensure that: (i) all delivered API meets the Specifications for that API; and (ii) all shipments of API are accompanied by the required documentation as specified in the applicable Quality Agreement.

(e) Patheon will (i) inspect and perform all tests with respect to the API specified in the Product Agreement; and (ii) store and keep all API in accordance with the Processing Instructions.

(f) If Client asks Patheon to qualify an additional supplier for the API or any Component, the parties must agree on the scope of work to be performed by Patheon and the additional fees to be paid by Client. For any API or any Component, this work at a minimum will include: [***].

(g) Patheon will promptly advise Client if it encounters API or Component supply problems, including delays, shortfalls or delivery of non-conforming API or Components from a Client designated additional supplier. The parties will cooperate to reduce or eliminate any supply problems from these designated suppliers. If the supply problems persist from suppliers of Client-Supplied Components or suppliers of API where the Client provides API, Patheon may suspend the Manufacturing Services affected by the problems until it is satisfied that the Client has resolved the problems with its supplier or appointed an alternative supplier. Client will qualify or certify (as appropriate) all Client designated additional suppliers. Client will qualify or certify (as appropriate) all Client designated additional suppliers at its expense and will provide Patheon with a statement concerning this qualification. If Patheon agrees to certify or qualify a Client designated additional supplier on behalf of Client, it will do so for an additional fee payable by Client. Patheon will be responsible to solve any issues with any Component suppliers which are not suppliers of Client-Supplied Components or suppliers of API where the Client provides API, and will keep Client updated on the progress.

(h) Shortage, Damage or Defect. If any shipment of API delivered by Client contains any damage, shortage or defect of the API, Patheon will notify Client (i) within [***] days of receipt of the shipment if the damage, shortage or defect can be ascertained by the exercise of reasonable diligence upon examination by Patheon on receipt of the shipment, or (ii) within [***] days after discovery if the damage, shortage or defect cannot be ascertained by the exercise of reasonable diligence

upon examination by Patheon on receipt of the shipment (including without any limitation non-conformities relating to stability).

(i) Subject to Section 3.3(b), if there is any damage to, defect in or shortfall of any API delivered by Client or in any associated documentation, Client will at Client's option either: (i) replace the non-conforming API with conforming API at Client's costs; or (ii) adjust the Firm Order for Product affected by the damage, defect or shortfall.

3.4 Packaging and Artwork.

Client will be responsible for the cost of artwork development and approval of all artwork. Client will be responsible for changes to labels, product inserts, and other packaging for the Product, including obtaining all required approvals. Unless otherwise agreed, Client will be responsible for the cost of labelling obsolescence as contemplated in Section 5.2. Patheon's name will not appear on the label or anywhere else on the Product unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name. If possible, at least [***] days prior to the Release Date of Product for which new or modified artwork is required, Client will provide at no cost to Patheon and in accordance with the applicable Specifications, final camera ready artwork for all packaging Components to be used in the manufacture of the Product. Client will be responsible for any additional reasonable costs as agreed by the parties associated with complying with any and all regulatory requirements for the labelling and tracking of the manufactured Product, including product serialisation, product data transfer and anti-counterfeiting requirements in the Territory.

The Parties agree and accept that regulatory changes may be required within the [***] days and that it might not be possible to uphold the [***] days during the launch period. In such case, Client will reimburse Patheon for any reasonable direct and verifiable additional costs for implementing the artwork on time.

4. PRICE AND PRICE ADJUSTMENTS

4.1 First Year Pricing.

The Price for each Product will be listed in Schedule A of a Product Agreement and may be adjusted under this Section 4.

4.2 Annual Price Adjustments.

Patheon may adjust the Price effective January 1st of each Year as follows:

(a) **Inflation**. Patheon may adjust the Conversion Fee for inflation in accordance with Appendix 4.

(b) **Currency Fluctuations**. If the parties agree in a Product Agreement to invoice in a currency other than the Local Currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated in accordance with Appendix 4 after all other annual Price adjustments under this Section 4.2 have been made.

(c) **Pricing Basis**. Unless otherwise agreed in a Product Agreement, Client acknowledges that the Conversion Fee in any Year is agreed based upon the applicable Minimum Market Requirement, Annual Volume, and Minimum Order Quantity for that Year. If Patheon reasonably concludes, or is notified by Client, that the Minimum Market Requirement, Annual Volume or Minimum Order Quantity

will not be ordered as required for a Year, Patheon may make a commercially reasonable adjustment in the Conversion Fee for remaining purchase orders with a requested Release Date in that Year, this adjusted price to be applicable to orders placed by Client after the receipt of the notice of adjustment. If this adjustment is made, Patheon will take its effect into account when calculating any potential shortfall Conversion Fee as set out in Section 5.1(f). The prices of Components will be adjusted as set out in Section 4.2(e).

(d) **Tier Pricing**. If the Pricing is divided into Annual Volume tiers, unless otherwise agreed in a Product Agreement, Client will be invoiced during the Year based at the forecasted Annual Volume tier. Within [***] days after the end of each Year or on termination of the Product Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by Client during the Year at the actual applicable Pricing tiers. If the reconciliation shows an overpayment, Patheon will issue a credit to Client for the amount of the overpayment within [***] days after the end of the Year or will reimburse the overpayment within [***] days after termination. The parties will work together in good faith to resolve any disagreement over the reconciliation.

(e) **Component Price**: The price for Components will be adjusted annually corresponding to the direct and verifiable price increase or decrease for the Components purchased for use in the subsequent Year.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about [***] of each Year (unless otherwise agreed in writing) a letter stating the adjusted Pricing under a Product Agreement to be effective for Product with a confirmed Release Date after [***] of the next Year including any Firm Orders accepted by Patheon before that date. Any omitted adjustment in a Year does not waive Patheon's right to make a prospective, cumulative adjustment with the next permitted adjustment. Patheon will provide reasonable documentation to Client to support this prospective, cumulative adjustment. Client will not be obligated to pay any additional costs retrospectively.

4.3 **Price Adjustments at any Time**.

The Prices may be adjusted by Patheon at any time upon written notice to Client as follows:

(a) **Extraordinary Increases in Component Costs**. If the cost of a Component increases cumulatively by at least [***]% since the last annual adjustment under Section 4.2 as a result of market factors outside of Patheon's control, then Patheon will be entitled to adjust the Price for the Component to reflect the verified increase and as otherwise agreed in the Product Agreement. The revised Price will become effective with the first use of the higher cost Component in the manufacture of the Product but in any event not earlier than a month following the notice to Client of the Price increase. For a Price adjustment under this Section 4.3(a), Patheon will deliver to Client a revised Schedule A to the Product Agreement. If this Price increase is due to a temporary market factor, the Price will be adjusted downward after the temporary market factor is resolved and Patheon's cost for the Component decreases.

(b) **Changes**. The scope of the Manufacturing Services is set by the agreed Processing Instructions, the Regulatory Approvals, the Quality Agreement and any assumptions, inclusions, exclusions and other parameters set out in the applicable Product Agreement. Changes to the scope of the Manufacturing Services and related changes to the Price must be agreed in writing by the parties (using a

"***Change of Scope***" agreement, or similar, setting out the agreed activities and costs of implementation) and are subject to the change control provisions of the Quality Agreement. Where Patheon requests a change to the Manufacturing Services, the change will be implemented following written approval of Client. If the change will affect a regulatory filing, the parties will reasonably discuss and resolve the issue, but Client will still have to approve the change before it is implemented. If Patheon requests a change for the sole benefit of Patheon that will have an impact on either the process requiring qualification or the regulatory files, Patheon will carry the cost for the re-qualification and re-registrations in the full extent of the Client's responsibilities, including Client's customer's cost to implement the change, if applicable.

4.4 Cost Improvement Plan.

Patheon and Client will discuss on an ongoing basis any improvement and competitive best practice strategies to improve the Manufacturing Services and achieve cost efficiencies for the Products with the goal of maintaining the commercial viability of the Product long term beyond (and excluding) those resulting from changes in Manufacturing Services agreed to in the Product Agreement and changes to ensure compliance with cGMP ("***Cost Improvement Plan***"). Prior to executing the Cost Improvement Plan, Patheon and Client will agree to a reasonable cost sharing agreement for any projected costs related to the Cost Improvement Plan. The cost efficiencies will be incorporated into the Price for Product when the Cost Improvement Plans have been implemented.

If [***] initiates and drives the Cost Improvement Plan, the efficiencies will be [***].

5. PURCHASING PRODUCT

5.1 Orders and Forecasts.

(a) **Long Term Forecast**. On or before [***] of each Year, Client will, solely for planning purposes, give Patheon a non-binding written forecast of Client's volume requirements for the Product for each of the next [***] Years ("***Long Term Forecast***"), based on requested Release Dates. If Patheon foresees any capacity constraint affecting any portion of the Long Term Forecast, it will notify Client without undue delay and the parties will discuss actions to increase the capacity.

(b) **Rolling Forecast**. Before each Product Agreement is executed, Client will give Patheon a written forecast of the volume of Product that Client expects to order with a requested Release Date in each of the next [***] months (the "***Rolling Forecast***"). Client will provide an updated Rolling Forecast: (i) on or before the tenth day of each month; and (ii) if at any time it determines that the total forecast volumes estimated in the most recent Rolling Forecast have changed by more than [***]. Each updated Rolling Forecast supersedes all previous Rolling Forecasts.

(c) **Orders**. On or before the tenth day of each month, Client will issue a new purchase order for any required Product. Each purchase order must meet the Minimum Order Quantity and specify the purchase order number, quantities by Product type, and requested Release Dates for the Product (which must occur at least [***] after [***]).

(d) **Acceptance of Purchase Orders**. To the extent that a purchase order covers Product that is forecast in the Rolling Forecast, Patheon will accept the purchase

order by sending an acknowledgement to Client, including the confirmed Release Dates. Subject to Section 5.1(f), if Patheon fails to acknowledge receipt of a purchase order within [***] Business Days, the purchase order will be considered accepted by Patheon. An accepted purchase order will be binding on the parties (a "***Firm Order***"), except that either party may request to change any Release Date beyond [***] after [***]. The parties may negotiate in good faith and agree on any requested alternative Release Date. Neither party may unreasonably reject an alternative Release Date requested under this Section 5.1(d) by the other party, but, if the parties cannot agree, the original Release Date set out in the Firm Order will apply.

(e) **Cancellation or Postponement**. Patheon will determine the manufacturing schedule of all Product covered by Firm Orders. If Client cancels or reduces a Firm Order or wishes to postpone the applicable Release Date (subject to Section 5.1(d)), Client will remain liable to pay Patheon the Conversion Fee. Patheon will use commercially reasonable efforts to place the lost manufacturing capacity from a cancelled or postponed Firm Order with another Patheon client. To the extent Patheon is able to do so, it will not charge Client for the cancelled or postponed Firm Order.

(f) **Capacity Reservation**. Starting on [***], in the year immediately following the calendar year in which the Product was launched, Patheon will use the Rolling Forecast provided in [***] each year to reserve its manufacturing capacity in the following Year (the "***Yearly Forecast Volume***").

At the end of each Year, if the aggregate actual volume of Product ordered by Client with a confirmed Release Date within the Year, taking into account any Product paid for but not ordered, ("***Actual Yearly Volume***") is less than [***], then Patheon may invoice and Client will pay to Patheon:

The Conversion Fee for the shortfall of Product below the tolerance during the Year in an amount calculated as follows:

[***]

The Conversion Fee with respect to a Year for which a Price adjustment was made as provided in Section 4.2(c) will be subject to adjustment as provided therein.

Patheon is obliged to supply product up to [***] of the Yearly Forecast Volume. If the quantity of Product requested by Client in a Year (in purchase orders received by Patheon) exceeds the Yearly Forecast Volume for that Year, Patheon will use commercially reasonable efforts to supply the additional Product volumes. Patheon will not be considered to have accepted any purchase order for the additional Product volumes without written confirmation.

(g) **Controlled Substance Quota Requirements (if applicable)**. Client will give Patheon the information set out below for obtaining any required DEA or equivalent agency quotas ("***Quota***") needed to perform the Manufacturing Services. Patheon will be responsible for routine management of Quota information in accordance with Applicable Laws. The parties will cooperate to communicate the information and to assist each other in Regulatory Authority information requirements related to the Product as follows: (i) by April 1 of each Year for the applicable Product, Client will provide to Patheon the next Year's annual Quota requirements for the

Product; (ii) by August 1 of each Year, Client will provide to Patheon any changes to the next Year's Quota requirements; (iii) Client will pro-actively communicate any changes to the Quota requirements for the then-current Year in sufficient time to allow Patheon to file and finalize Regulatory Authority filings supporting the changes; (iv) upon Patheon receiving the necessary forecast information from Client in order to request additional Quota, Patheon will submit to the applicable Regulatory Authority, on a timely basis, all filings necessary to obtain Quotas for API and will use commercially reasonable efforts to secure sufficient Quota from the applicable Regulatory Authority so as to achieve Release Dates for Product as set out in applicable purchase orders and forecasts submitted to Patheon by Client or its designee; and (v) Patheon will not be responsible for any Regulatory Authority's refusal or failure to grant sufficient Quota for reasons beyond the reasonable control of Patheon (including where Client fails to provide the required information in accordance with this Section 5.1).

5.2 Reimbursed and Obsolete Stock.

(a) Client understands and acknowledges that Patheon will rely on purchase orders, Firm Orders, and the Rolling Forecast in ordering the Components (other than Client-Supplied Components) required to meet anticipated Firm Orders. Patheon may purchase the Components in sufficient volumes, and reasonably in advance of the expected use of the Component (taking into account lead times and shelf-life), to meet the production requirements for Products covered by anticipated Firm Orders or to meet the production requirements of any longer period agreed to by the parties. Notwithstanding the above, Patheon will not without Client's written consent (i) exceed any maximum agreed stock level of Components agreed in the Product Agreement; or (i) procure more than what is required for the next [***] of manufacture according to the latest Rolling Forecast. When purchasing Components, Patheon will at least apply its ordinary practices and procedures for procurement as it would have if Patheon itself bore the cost of the Components.

(b) Provided that a change is not initiated by Patheon for its sole benefit and that the change has been mutually agreed before the start of the work, Client will reimburse Patheon for the cost of Components ordered by Patheon specifically for Firm Orders or for any longer period mutually agreed that (a) are not used in the Manufacturing Services within [***] after the forecasted month for which the purchases have been made ("***Reimbursed Stock***"), or (b) have expired or are rendered obsolete due to changes in any forecast or Processing Instructions, GMP, artwork or Applicable Laws during the period (such expired or obsolete Components collectively, "***Obsolete Stock***"). This reimbursement will include (x) Patheon's purchase and in-coming shipping costs, (y) [***] handling fee to cover testing, stocking and handling costs excluded from purchase and in-coming shipping costs, and (z) costs of destruction if, after consultation with Client, any Obsolete Stock is destroyed. If any non-expired Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client. Patheon will use commercially reasonable effort to minimize the amount of any Reimbursed Stock or Obsolete Stock.

5.3 Storage.

If: (i) Client fails to take possession or arrange for the destruction of Obsolete Stock or any Reimbursed Stock is not used in the Manufacturing Services within [***] after the forecasted month for which the purchases have been made, within [***] of receipt of written notice from Patheon identifying the

Obsolete Stock or Reimbursed Stock; (ii) any equipment (other than existing Patheon equipment) is stored at the Manufacturing Site at any time prior to its use in the Manufacturing Services; or (iii) Product is not collected by Client within [***] of the Release Date notified by Patheon, Client will pay Patheon [***] for storing the, the Obsolete Stock, Reimbursed Stock, equipment or Product. Storage fees for Obsolete Stock, Reimbursed Stock or Product which contain controlled substances or require refrigeration will be charged at [***]. Storage fees are subject to a [***] minimum charge [***]. Patheon may ship Product held by it longer than [***] to Client at Client's expense on [***] written notice to Client. If Patheon is unable to store any material due to capacity constraints, Patheon may, with Client's prior written consent, use an Affiliate or qualified third party to store (outside the Manufacturing Site) any material under this Agreement provided that it can be stored in compliance with the terms of this Agreement and the Quality Agreement. After the limited storage periods stated above, Client will assume all risk of loss or damage to materials and Client will be responsible for having appropriate insurance coverage in place for this risk.

5.4 Invoices and Payment.

For shipments of Product, Patheon will issue invoices to Client on or after the Release Date of the Product. Otherwise, Patheon will issue invoices for Manufacturing Services on completion or as agreed in the Product Agreement. Patheon will also submit to Client, with each shipment of Product, a duplicate copy of the invoice covering the shipment. Invoices will be sent by email on the date issued to the email address given by Client to Patheon in writing. Each invoice will, to the extent applicable, identify Client's Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within [***] of the date of invoice. If any portion of an invoice is disputed, Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Interest on undisputed past due accounts will accrue at [***]% per month. Patheon may, on giving [***] written notice to Client, suspend all Manufacturing Services, including release and shipment of Product, until all undisputed past due invoices have been paid in full. If Patheon has not received a confirmation that this notice has been received by Client within [***], Patheon will send one more written notice to Client with registered mail. Patheon will have no liability to Client for losses caused by this suspension, including without limitation, losses due to delayed Product delivery or Product shortages. The right to suspension will not apply in case Client has been unable to pay any invoiced due to Force Majeure. Patheon will lift the suspension under this Section 5.4 and restart the Manufacturing Services as soon as all undisputed past due invoices have been paid in full.

5.5 Delivery and Shipping.

Delivery of Product and any other materials will be made EXW (Incoterms 2020) from Patheon's Manufacturing Site unless otherwise agreed in a Product Agreement. Subject to Section 8.3, risk of loss or of damage to Product will remain with Patheon until Patheon loads the Product onto the carrier's vehicle for shipment at the shipping point at which time risk of loss or damage will transfer to Client. But if Client fails to collect Product within [***] after it has been released for shipment by Patheon, Client will assume all risk of loss or damage to the released Product. Patheon may, in accordance with Client's instructions and as agent for Client, at Client's risk, arrange for shipping (to Client or any third party nominated by Client) to be paid by Client. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Product and may monitor Patheon's shipping and freight activity under this Agreement.

6. PRODUCT CLAIMS AND RECALLS

6.1 Product Claims.

(a) **Rejection**. Client may reject any manufactured Product that it reasonably considers to be deficient based on documentation provided by Patheon or Client's own inspection or testing of delivered Product.

(b) **Product Claims**.

(i) Client may claim a remedy (a "***Product Claim***") for any batch of Product or portion thereof for which Patheon did not perform the Manufacturing Services in accordance with the agreed Processing Instructions, cGMPs, or Applicable Laws, or what is otherwise set out in this Agreement or the Quality Agreement ("***Deficient Product***"). Client will visually inspect Product manufactured by Patheon, or batch documentation provided by Patheon, upon receipt and will give Patheon written notice (an e-mail will suffice) of all Product Claims within [***] after receipt (or, in the case of any deficiency not reasonably susceptible to discovery upon visual inspection, within [***] after discovery by Client, but not after the expiration date of the Product). If Client fails to provide a Product Claim within the applicable [***] period, then the Product will be considered to have been accepted by Client on the [***]. Patheon will have no liability for any deficiency for which it has not received notice within the applicable [***] period.

(ii) This Section 6 sets out the only liability of Patheon for Deficient Products. Patheon will provide a remedy for Product Claims as specified in Section 10.2, but Patheon will have no obligation for any Product Claims to the extent the Deficient Product was caused by: (i) deficiencies in the Processing Instructions, Specifications, the safety, efficacy, or marketability of the Product or its distribution; (ii) a defect in the API or an incorporated Component that was not reasonably discoverable by Patheon using the test methods set out in the Processing Instructions or are required under GMP or Applicable Laws; (iii) actions of Client or third parties occurring after the Product is delivered by Patheon; (iv) packaging design or labelling defects or omissions for which Patheon has no responsibility; or (v) any other breach by Client of its obligations under this Agreement. If after a full investigation as set out in the Quality Agreement and this Section 6.1(b)(ii), it is determined that Patheon manufactured Product in accordance with the agreed Processing Instructions, cGMPs and Applicable Laws and with the due care and skill of a reputable contract manufacturer of pharmaceuticals, but a batch or portion of batch of Product is not released, Client will pay Patheon the Price for the Product with the deduction of any liability Patheon has for API loss as set out in Appendix 3.

(c) **Determination of Deficiency**. Upon receipt of a Product Claim, the parties will investigate the matter in accordance with the Quality Agreement. If, after joint testing or investigation has been performed, the parties still cannot agree on the root cause, the provisions of Appendix 2 will apply and, after the required negotiation, the dispute will be handled as a Technical Dispute.

(d) If there is any shortfall in any shipment of Product delivered, as against the relevant Firm Order, Patheon will at Client's option either:

(i) deliver the shortfall to Client, as soon as reasonably possible, at Patheon's cost; or

(ii) credit or refund to Client, at Client's discretion, the amount equivalent to the value of the shortfall within [***].

(e) **Shortages and Deficiency Disputes**. If a dispute arises between the Parties as to any claimed damage or defect in or shortages of the Product delivered, which cannot be resolved by the parties within [***] of a claim being notified by Client to Patheon, the dispute will be handled under Appendix 2, Dispute Resolution.

6.2 Product Recalls and Returns.

(a) **Records and Notice**. The parties will each maintain records necessary to permit a recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other party of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in accordance with the Quality Agreement. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client in its sole discretion. "Recall" will mean any action: (i) by Client to recover title to or possession of quantities of the Product sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Product from the market); (ii) by any Regulatory Authority to detain or destroy any of the Product; or (iii) by either party to refrain from selling or shipping quantities of the Product to third parties which would be subject to a Recall if sold or shipped.

(b) **Recalls**. If: (i) any Regulatory Authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled; (ii) a court of competent jurisdiction orders a Recall; or (iii) Client determines that any Product should be Recalled or that a "*Dear Doctor*" letter is required relating the restrictions on the use of any Product, then Patheon will co-operate as reasonably required by Client, having regard to all Applicable Laws.

(c) **Recalled Product**. To the extent that a Recall results from, or arises from Deficient Product, Patheon will be responsible for the reasonable documented out-of-pocket expenses of the Recall. Deficient Products will be remedied as set out in Section 10. If a Recall is necessary for reasons in addition to the fault or negligence of Patheon, then Patheon and Client will be responsible for a proportionate share of these costs, to be agreed between the parties. Subject to the above, Client will bear the costs of any recall in all other circumstances. Patheon's only liability for API loss is set out in Appendix 3.

6.3 Disposition of Deficient Product.

Client will not dispose of any damaged, returned, or Deficient Product for which it intends to assert a Product Claim against Patheon without Patheon's prior written authorization to do so. Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of return and disposition of any Deficient Products. In all other circumstances, Client will bear the cost of return and disposition of the Product if it turns out that the Product is not Deficient Product.

7. CO-OPERATION AND REGULATORY AFFAIRS

7.1 Governance.

Each party will without delay upon execution of this Agreement or a Product Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet a minimum of once per Year to review the current status of the business relationship, including review of key performance indicators such as Product and API delivery, on-time delivery, right first time, investigation closure on time, rejected batches, attainment of the Minimum Market Requirement, Patheon's long term capacity plan, communication and approvals under the Quality Agreement, and to manage any issues that have arisen. The parties will meet a minimum of once per quarter to review ongoing business as well as fulfilment of the KPIs.

7.2 Governmental Agencies.

Subject to any restrictions in the Quality Agreement, each party may communicate with any Regulatory Authority responsible for granting Regulatory Approval for the Product (or in Patheon's case the Manufacture of Products) and any other relevant Authority regarding the Product (or in Patheon's case the Manufacture of Products) if, in the opinion of that party's counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of the Authority or Applicable Laws. Otherwise, the parties will consult with each other in relation to regulatory communications relating to the Product in accordance with the Quality Agreement. If Patheon has communicated with any Regulatory Authority in relation to the Manufacture of the Product or that may otherwise be related to the Product, Patheon will without undue delay provide copies of the communication to Client (to the extent it is legally permitted to do so).

7.3 Records.

Patheon will keep records of the manufacture, testing, and shipping of the Product, and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, Applicable Laws, cGMP and the Quality Agreement. Copies of the records and samples will be retained as and for the period specified in the Quality Agreement. Patheon reserves the right to destroy or return to Client, at Client's sole expense, any document or samples for which the retention period has expired, but Patheon must give at least 30 days written notice to Client before destroying any records.

7.4 Audits.

Subject to the limits agreed in the Quality Agreement, Patheon will give Client and any Client representative or partner reasonable access at agreed times to the areas of the Manufacturing Site in which the Product is manufactured or where Product, Components or API are stored, analysed, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws and what is otherwise set out in this Agreement or the Quality Agreement. If Client wishes to audit Patheon beyond the agreed limits set out in the Quality Agreement, except where the audit is required for cause, Client will pay to Patheon a fee of [***]. Under no circumstances will: (a) Client have a right of access to Patheon's financial records or (b) any Patheon Competitor be permitted access to the Manufacturing Site.

7.5 Regulatory Filings.

(a) **Regulatory Authority Documentation.** Client will provide copies of all relevant documents relating to Regulatory Authority approval for the commercial manufacture, distribution and sale of the Product ("***Regulatory Approval***") to Patheon as required under the Quality Agreement. Patheon will review and verify the accuracy of these documents in accordance with the Quality Agreement.

(b) **Deficiencies**. If Patheon reasonably considers that that any regulatory information given by Client is inaccurate or deficient in any manner whatsoever (the

"***Deficiencies***"), Patheon will without undue delay notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to the date of filing of the relevant application and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed.

(c) **Inspection by Regulatory Authorities**. If Client does not give Patheon the necessary documents requested under this Section 7.5 or the Quality Agreement and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized, Patheon may, following good faith discussion with Client, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

(d) **Pharmacovigilance**. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Product in accordance with Applicable Laws and the monitoring and management of post-marketing complaints and queries at its cost (including, without limitation, the reasonable cost of assistance required of Patheon under the Quality Agreement).

(e) **No Patheon Responsibility**. Except as otherwise agreed in the Quality Agreement or otherwise agreed to in writing, Patheon will not assume any responsibility for: (a) the submission, accuracy or cost of any application for Regulatory Approval or related documentation (or the success of those applications) which relates specifically to the Product; (b) any activity that is required by Applicable Laws for Regulatory Approval (including pharmacovigilance and complaints handling, and preparation and submission of any regular quality or other update) which relates to the Product; or (c) any dealings with the relevant Regulatory Authority on behalf of Client for Regulatory Approval. Nothing in this Section 7.5 (e) is intended to limit Patheon's liability for activities or services in relation to regulatory filings which Patheon has agreed to undertake. If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities specifically in relation to the Products which are unexpected and extraordinary, then Patheon will notify Client in writing and the parties will discuss in good faith appropriate mutually acceptable actions, including fee/cost sharing. Patheon will be not be obliged to undertake these activities or to pay for the fees or costs until the parties reach agreement on scope and fees for Patheon's assistance.

7.6 Release.

The parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Product will not by itself indicate compliance by Patheon with its obligations relating to the Manufacturing Services. Nothing in this Agreement will remove or limit the authority of the relevant quality function (as specified by the Quality Agreement) to determine whether the Product will be released for sale or distribution.

7.7 Withdrawal on Completion.

No later than [***] days following completion or permanent cessation of the Manufacturing Services at the applicable Manufacturing Site, Client will: (a) ensure that any regulatory filings relating to the Product are notified to the relevant authorities as withdrawn or amended to remove all references to the Manufacturing Site and, as applicable, Patheon or its Affiliates and their facilities (except in an historic context); and (b) provide to Patheon written confirmation of its compliance with this Section 7.7. If this time

is not sufficient to meet the requirements of certain Regulatory Authorities, despite Client's reasonable commercial efforts, then the period will be extended to meet the requirements of the relevant Regulatory Authority.

8. TERM AND TERMINATION

8.1 Initial Term.

This Agreement will become effective as of the Effective Date and will continue until December 31, 2026 (the "***Initial Term***"), unless terminated earlier by one of the parties for cause. This Agreement will automatically renew after the Initial Term for successive terms of [***] each if there is a Product Agreement in effect, unless (i) either party gives written notice to the other party of its intention to terminate this Agreement in Patheon's case at least [***] and in Client's case at least [***] before the end of the then current term or; (ii) this Agreement is terminated for cause. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect. Each Product Agreement will have an initial term from the Effective Date of the Product Agreement until [***] of the Year agreed to by the parties in the Product Agreement (each, an "***Initial Product Term***"). Product Agreements will automatically renew after the Initial Product Term for successive terms of [***] each unless either party gives written notice to the other party of its intention to terminate the Product Agreement in Patheon's case at least [***] and in Client's case at least [***] before the end of the then current term.

8.2 Termination for Cause.

(a) Either party may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of this Agreement or the Product Agreement within [***] (the "***Remediation Period***") following receipt of a written notice of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "***Breach Notice***"). The aggrieved party's right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for a period of [***] following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be considered to have waived the breach described in the Breach Notice. The right to terminate a Product Agreement under this Section 8.2(a) does not extend to any other Product Agreements where there has been no material breach of those other Product Agreements unless the breach is of such nature that it cannot reasonably be expected for the parties to continue to work together.

(b) Either party may immediately terminate this Agreement or a Product Agreement upon written notice to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy or insolvency is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate a Product Agreement upon written notice if any Authority takes any action, or raises any objection, that permanently prevents Client from selling the Product in the Territory.

(d) Client may terminate a Product Agreement with respect to a Product for which manufacturing has not commenced upon [***] prior written notice if it intends to no longer order Manufacturing Services for a Product due to the Product's discontinuance or if Client is obliged to cease selling a Product by order of a

regulatory authority, a court order or for safety reasons. If this notice is not practical under the circumstances, the parties will negotiate in good faith an orderly termination or a commercially reasonable adjustment of the terms of the Product Agreement to reflect the discontinuance or cessation.

(e) Patheon may terminate this Agreement or any Product Agreement upon [***] prior written notice if Client assigns under Section 13.4 any of its rights and obligations under this Agreement or a Product Agreement to an assignee that Patheon reasonably concludes, no later than [***] after the notice is received, is: (i) based upon publically available financial records, is objectively unlikely to be able to meet the obligations of this Agreement or a Product Agreement; or (ii) a Patheon Competitor.

(f) Patheon may terminate any Product Agreement if payment in full of overdue, undisputed invoices is not received within [***] following the date of suspension of Manufacturing Services by Patheon under Section 5.4 if Patheon gives Client at least [***] prior written notice of its intent to terminate the Manufacturing Services.

(g) If Client in any Year, following the Year in which the first Yearly Forecast Volume was provided, forecasts [***] for [***] during the term of a Product Agreement, then Patheon may terminate the Product Agreement by providing [***] prior written notice to Client. Within that period, Client may either: (i) withdraw the [***] forecast and re-submit a [***] forecast, after which Patheon will withdraw the termination notice; or (ii) negotiate other terms and conditions on which the Product Agreement will remain in effect.

8.3 Obligations on Termination.

If a Product Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured or packaged in accordance with this Agreement under a Firm Order, at the Price in effect at the time the Firm Order was released. This Section 8.3(a) will not apply to Deficient Products as defined in Section 6.1;

(b) Unless otherwise agreed, Client will purchase all Inventory that was purchased, maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory), if the Inventory cannot reasonably be used by Patheon for other manufacturing for Client or a third party within [***] of the date of termination;

(c) Client, at its own expense, will remove from the Manufacturing Site (or instruct Patheon to destroy or remove), within [***] following the completion, termination, or expiration of the Product Agreement, all unused API and Client-Supplied Components, all applicable Inventory (whether current or obsolete, which cannot be used by Patheon for other manufacturing for Client or a third party), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at the Manufacturing Site or that is otherwise under Patheon's care and control ("***Client Property***"). If Client fails to remove Client Property or provide instruction for such property to Patheon within the [***] period, Client will pay Patheon [***]. Patheon may ship Client Property to

Client or to an external warehouse at Client's risk and expense. Patheon will invoice Client for these storage charges as set out in Section 5.3 of this Agreement. If Client fails to remove Client Property within [***] following the completion, termination, or expiration of the Product Agreement, Client will assume all risk of loss or damage to the stored Client Property and it will be Client's responsibility to have appropriate insurance coverage in place for this risk. If Client asks Patheon to destroy any Client Property, Client will be responsible for the mutually agreed cost of destruction;

(d) If Patheon gives Client notice of non-renewal under Section 8.1, Patheon will continue to perform the Manufacturing Services in order to provide Client with an additional [***] supply of Product on the same terms and conditions as applied immediately before the Product Agreement is completed, expires or terminates; and

(e) any completion, termination or expiration of this Agreement or a Product Agreement will not affect any prior outstanding obligations or payments due nor will it prejudice any other remedies that the parties may have under this Agreement, the Quality Agreement, a Product Agreement or any related Capital Equipment Agreement. Completion, termination or expiration of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the parties under Sections 1.3, 1.4, 5.1(e), 5.1(f), 5.4, 5.5, 6, 7.3, 8.3, 8.4, 9. 10, 11, 12, and 13 (except 13.6) all of which survive any completion, termination or expiration, as well as any other provisions that are by implication or otherwise intended to survive any completion, termination or expiration. Notwithstanding the foregoing, Section 6 will survive for five Years and Sections 8.4 and 9 will survive for three Years after any completion, termination or expiration of this Agreement or a Product Agreement. Where Patheon has agreed to provide stability services beyond the final supply of Product, the relevant provisions of this Agreement and the Quality Agreement will survive for the agreed duration of those stability services.

8.4 Technology Transfer.

Following termination of a Product Agreement for any reason, or at Client's request within [***] before the end of the term of the Product Agreement or [***], Patheon will provide assistance to transfer part or all of Client's manufacturing process, know-how and analytical testing methodology for the Product to Client or a third party appointed by Client ("***Technology Transfer***") to assist Client to manufacture the Product. Patheon will also disclose to Client any Patheon Intellectual Property that is reasonably required to manufacture the Product. Patheon will, upon request of Client, prepare a written reasonable proposal to perform the Technology Transfer. Client will pay any reasonable agreed fees for the Technology Transfer performed by Patheon.

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement.

9.2 Client Warranties.

(a) **Non-Infringement**. Client covenants, represents, and warrants that:

(i) the Processing Instructions and Specifications for the Product are its or its Affiliate's property and that Client may lawfully disclose the Processing Instructions and Specifications to Patheon for use in accordance with this Agreement;

(ii) any Client Intellectual Property used by Patheon in performing the Manufacturing Services (A) is Client's or its Affiliate's unencumbered property, (B) may be lawfully used as directed by Client and agreed in this Agreement, and (C) to its knowledge does not infringe and will not infringe any Third Party Rights;

(iii) the performance of the Manufacturing Services by Patheon or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement or any Product Agreement does not to Client's knowledge infringe any Third Party Rights; and

(iv) as of the Effective Date of the Agreement there are no actions or other legal proceedings involving Client or its Affiliates that concerns the infringement of Third Party Rights related to any of the Processing Instructions or Specifications, or any of the API or Client-Supplied Components, or the sale, use, or other disposition of Product made in accordance with the Processing Instructions.

(b) **Quality and Compliance**. Client covenants, represents, and warrants that:

(i) the Processing Instructions and Specifications for the Product conforms to all applicable cGMPs and Applicable Laws;

(ii) on receipt by Patheon, the API will conform to the Specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled in accordance with Applicable Laws and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Processing Instructions, cGMPs, the Quality Agreement, and Applicable Laws and with the due skill and care of a professional and reputable contract manufacturer;

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) to its knowledge does not infringe and will not infringe any Third Party Rights;

(c) it will not in the performance of its obligations under this Agreement use the services of any person it knows is debarred or suspended under 21 U.S.C. §335(a) or (b) or under any other relevant regulatory rules; and

(d) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States or any other jurisdiction for conduct relating to the regulation of any drug product under the United States Federal Food, Drug, and Cosmetic Act or other relevant legislations.

9.4 Permits.

(a) Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Product, including, without limitation, all marketing and post- marketing approvals, and any specific approvals referred to in the Quality Agreement.

(b) Patheon will maintain at all relevant times when performing the Manufacturing Services all required governmental permits, licenses, approvals, and authorities.

9.5 No Warranty.

PATHEON MAKES NO WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET OUT IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCT.

10. LIABILITY AND REMEDIES

10.1 Consequential and Other Damages.

Neither party will be liable to the other in contract, tort, negligence, indemnity, or otherwise for: (i) any (direct or indirect), penalty, loss of profits, of anticipated savings, of business, of goodwill, or of use of the Product or costs of any substitute services; or (ii) any reliance damages, including but not limited to costs or expenditures incurred to evaluate the viability of entering into this Agreement or to prepare for performance under this Agreement; or (iii) for any other liability, damage, costs, penalty, or expense of any kind incurred by the other party of an indirect or consequential nature, provided that this limitation will not apply to damages arising from a party's gross negligence or wilful misconduct and will not limit equitable remedies.

10.2 Limitation of Liability.

(a) **Remedies for Deficient Product**. If Client makes a Product Claim under Section 6.1 and the parties agree the Product is Deficient Product, or the Product is determined to be Deficient Product under Section 6, Patheon will promptly, at Client's election, either:

(i) replace the Product at Patheon's cost (after which Patheon may invoice for the replacement, if Patheon has cancelled the first invoice and no money has been paid by Client for the Deficient Product) if Patheon is able to manufacture the replacement Product at the Manufacturing Site and contingent upon the receipt from Client of all API and Client- Supplied Components required for the manufacture of the replacement Product; or

(ii) refund [***] of the Price paid for the Deficient Product (by credit or offset against other amounts due to Patheon under the Product Agreement).

Except for the indemnity set out in Section 10.3 or if the Deficient Product was caused by Patheon's gross negligence or wilful misconduct, any claim for expenses related to a Recall under Section 6.2(c), and compensation for loss of API included in the Deficient Product up to the maximum amount set out in Section 10.2 (b), the remedy under this Section 10.2, if applicable (including in the case of Recall), will be Client's sole remedy in contract, tort, negligence, equity or otherwise, for Deficient Product. Notwithstanding the foregoing, Client will receive the full benefit of any insurance recovery by Patheon for loss of Product, Client-Supplied Components or API.

The remedy under this Section 10.2, if applicable (including in the case of Recall), will apply only to the extent that the affected Deficient Product is unsold to a final customer (e.g. a patient in the market), returned (including but not limited to by a final customer (e.g. a patient), or destroyed or otherwise disposed of by Client in accordance with this Agreement.

(b) **API**. Without limitation on the provisions of Appendix 3, under no circumstances whatsoever will Patheon be liable to Client in contract, tort, negligence, indemnity, or otherwise for any loss or damage to the API. Patheon's maximum aggregate liability for loss of or damage to the API will not exceed on a per Product basis [***]% of revenues (being payments of the Price) received by Patheon for that Product under the applicable Product Agreement during the previous Year (or, until the end of the first calendar Year, the expected revenue for that Product if the agreed Yearly Forecast Volumes were ordered). This limitation of liability will not apply to the extent the loss or damage to the API was caused by Patheon's gross negligence or wilful misconduct. Notwithstanding the foregoing, Client will receive the full benefit of any insurance recovery by Patheon for loss of API.

(c) **Maximum Liability**. In any Year, in addition to the specific remedies under Section 10.2(a) for Deficient Product, Patheon's maximum aggregate liability to Client under or in connection with this Agreement or any Product Agreement (however arising, including contract, tort, negligence, indemnity, losses of API, or otherwise) will not exceed on a per Product basis [***]% of revenues (being payments of the Price) received by Patheon for that Product under the applicable Product Agreement during the previous Year (or, except in the case of the first Year, [***]% of the expected revenues for that Product if the agreed Yearly Forecast Volumes were ordered). This limitation of liability will not apply to any liabilities arising from Patheon's gross negligence or wilful misconduct, or from breach of its Confidentiality obligations under Article 11, its obligations related to Intellectual Property under Article 12, or to its indemnity obligations under Section 10.3.

(d) **Death, Personal Injury and Fraudulent Misrepresentation**. Nothing contained in this Agreement will act to exclude or limit either party's liability for personal injury (including but not limited to medical care and monitoring) or death caused by the negligence, breach of any requirements of this Agreement of either party or fraudulent misrepresentation.

10.3 Patheon Indemnity.

(a) Patheon agrees to defend and indemnify Client, its officers and employees, against all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) incurred by them to the extent resulting from or arising out of or in connection with any third party claims resulting from (a) Patheon's infringement of any Third Party Rights in Patheon's

processes used to perform the Manufacturing Services; (b) Patheon's breach of any obligation under this Agreement or the inaccuracy or breach of any representation or warranty made by Patheon; or (c) any claim for bodily injury or property damage to the extent that the injury or damage is the result of a failure by Patheon to perform the Manufacturing Services in accordance with the Processing Instructions, cGMPs, and Applicable Laws except to the extent that the losses, damages, costs, claims, demands, subpoenas, judgments, and liability are due to the negligence or wrongful acts of Client, its officers, employees, or Affiliates.

(b) If a claim occurs, Client will: (i) promptly notify Patheon of the claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Patheon in the defense of the claim; and (iv) permit Patheon to control the defense and settlement of the claim, all at Patheon's cost and expense.

10.4 Client Indemnity.

(a) Client agrees to defend and indemnify Patheon, its officers and employees, against all losses, damages, costs, claims, demands, subpoenas, judgments and liability to, from and in favour of third parties (other than Affiliates) incurred by them to the extent resulting from or arising out of or in connection with any third party claims resulting from (a) Client's infringement of any Third Party Rights in or to the Products or that relates to the manufacture of the Product by a proprietary process disclosed by Client; (b) Client's breach of any obligation under this Agreement or the inaccuracy or breach of any representation or warranty made by Client; (c) Patheon's use of Client's Intellectual Property to perform the Manufacturing Services; or (d) any claim of bodily injury or property damage to the extent that the injury or damage arises other than from a breach of the relevant Product Agreement or this Agreement by Patheon, including, without limitation, any representation or warranty contained in this Agreement, except to the extent that the losses, damages, costs, claims, demands, subpoenas, judgments, and liability are due to the negligence or wrongful acts of Patheon, its officers, employees, or Affiliates.

(b) If a claim occurs, Patheon will: (i) promptly notify Client of the claim; (ii) use commercially reasonable efforts to mitigate the effects of the claim; (iii) reasonably cooperate with Client in the defense of the claim; and (iv) permit Client to control the defense and settlement of the claim, all at Client's cost and expense.

10.5 Reasonable Allocation of Risk.

This Agreement (including, without limitation, this Section 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Product. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Product because Client has developed and holds the marketing approval for the Product, Client requires Patheon to manufacture and label the Product strictly in accordance with the Processing Instructions, requirements in this Agreement and the Quality Agreement, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Product.

10.6 Validation Batches.

Where Product is manufactured by Patheon (or any of its Affiliates) under a separate pharmaceutical development or technology transfer agreement (the "***Development Agreement***") and then released by Patheon for commercial sale or distribution by Client, the performance of the applicable

pharmaceutical development or technology transfer services including the manufacture of the Product will be governed by the terms of the Development Agreement and will not be subject to the terms and conditions of this Agreement. The terms of this Agreement and the applicable Product Agreement will apply to any Product during the commercial supply phase (including validation batches) after release by Patheon.

11. CONFIDENTIALITY

11.1 Confidential Information.

"***Confidential Information***" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients and its clients' confidential information, finances, marketing, products and processes and all price quotations, distribution, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing Confidential Information will be considered Confidential Information. Samples or materials provided under this Agreement as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. A party's rights and obligations under this Section 11 will apply to any Confidential Information that is disclosed by or received by that party's Representatives. For the purposes of this Section 11, a party receiving Confidential Information under this Agreement (including through its Representatives) is a "***Recipient***", and a party disclosing Confidential Information under this Agreement (including through its Representatives) is the "***Disclosing Party***". The existence, parties to, and terms of this Agreement or of any Product Agreement will be considered Confidential Information.

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (i) have a need to know the Confidential Information for the purpose of this Agreement; (ii) have been advised of the confidential nature of the Confidential Information and (iii) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will not be less than those exercised by Recipient for its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality in this Section 11 will not apply to the extent that the Recipient can demonstrate that Confidential Information:

(a) is or becomes publicly known through no breach of this Agreement or fault of the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, if the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party for the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information is not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information are covered by exceptions in this Section 11.3, unless the combination itself is covered by any of those exceptions.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. But the Recipient will advise the Disclosing Party in advance of the disclosure and limit the required disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out in this Agreement. If any public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Marking.

The Disclosing Party will use reasonable efforts to summarize in writing the content of any oral disclosure or other non-tangible disclosure of Confidential Information within 30 days of the disclosure, but failure to provide this summary will not affect the nature of the Confidential Information disclosed if the Confidential Information was identified as confidential or proprietary when disclosed orally or in any other non-tangible form.

11.7 Return of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies, summaries, compilations, analyses or other notes derived from the Confidential Information except for (i) one copy which may be maintained by the Recipient for its records; and (ii) any data back-ups made in the ordinary course of business. The retained copy will remain subject to all confidentiality provisions contained in this Agreement. Client will not

unreasonably require the return of Confidential Information that is necessary or useful to perform the Manufacturing Services.

11.8 Remedies.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Section 11 and agree that the non-breaching party will be entitled to seek specific performance, injunctive or other equitable relief to prevent breaches of this Section 11 and to specifically enforce Section 11 in addition to any other remedies available at law or in equity. These remedies will not be the exclusive remedies for breach of this Section 11 but will be in addition to any and all other remedies available at law or in equity.

12. INTELLECTUAL PROPERTY

12.1 Inventions.

(a) For the term of this Agreement, Client grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property solely for the purpose of Patheon to perform the Manufacturing Services for Client.

(b) All Client Intellectual Property will be the exclusive property of Client.

(c) All Intellectual Property generated or derived by Patheon while performing the Services, to the extent it is specific to, or dependent upon, the development, manufacture, use or sale of the Product that is subject to the services or other Client Intellectual Property, Client Inventions, Client Know-How or Client Confidential Information ("***Non-Severable Intellectual Property***"), will be the exclusive property of Client and Patheon hereby assigns all rights, title and interest in such Non-Severable Intellectual Property to Client. Patheon will, upon Client's request and at Client's expense, execute all documents and do all things reasonably necessary to vest the entire right, title and interest to the Non-Severable Intellectual Property in Client.

(d) All Intellectual Property generated or derived by Patheon while performing the Services which is not specific to, or dependent upon, Client´s Product, Client Intellectual Property, Client Inventions, Client Know-How or Client Confidential Information and which has application to manufacturing processes, delivery systems, the formulation or development of drug products ("***Severable Intellectual Property***") will be the exclusive property of Patheon.

(e) All Patheon Intellectual Property will be the exclusive property of Patheon. Unless Patheon identifies in advance of the start of manufacturing any specific Patheon Intellectual Property that will be subject to a separate licensing agreement between the parties, Patheon grants to Client a non-exclusive, perpetual, fully paid-up, royalty-free, sub-licensable transferable license of the Patheon Intellectual Property and Severable Intellectual Property used by Patheon in the manufacture of the Product for use in relation to the manufacture of the Product as well as to exploit the Product (including but not limited to distribution and sale).

(f) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(g) Patheon will give the Client written notice, as promptly as practicable, of all Inventions which can reasonably be considered to be improvements or other modifications of the Product, processes or technology owned or otherwise controlled by the Client or other Client Intellectual Property.

12.2 Intellectual Property.

Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in this Agreement or otherwise in writing. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13. MISCELLANEOUS

13.1 Insurance.

During the term of this Agreement and for three Years thereafter, each party will maintain insurance coverage of the types and in the amounts typically carried by companies in each party's respective business. In addition, Patheon will maintain property damage insurance coverage for any loss of Product, Client- Supplied Components or API in its possession (including damage caused by fire, storms, flooding and thefts). If requested each party will give the other a certificate of insurance evidencing its insurance cover and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability.

13.2 Independent Contractors.

The parties are independent contractors and this Agreement and any Product Agreement does not create between the parties any other relationship such as, by way of example only, that of employer and employee, principal and agent, joint-venturers, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.3 No Waiver.

Neither party's failure to require the other party to comply with any provision of this Agreement or any Product Agreement will be considered a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.4 Assignment.

(a) Patheon may not assign this Agreement or any Product Agreement without Client's written consent this consent not to be unreasonably withheld, Client may refuse to consent to an assignment if the assignment would have an effect on any regulatory filing for the Product.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. Client will give Patheon prior written notice of any assignment as soon as it is permitted to do so and the assignment will be effective, as concerns Patheon, only after receipt of the notice. In connection with any such assignment, the assignee will covenant in writing to be bound with respect to Patheon by the terms of this Agreement or the Product Agreement binding on Client.

(c) Despite the preceding provisions of this Section 13.4, either party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business related to this Agreement. Notwithstanding the foregoing, Patheon may not assign this Agreement or any Product Agreement to an Affiliate or a successor without Client's consent if the assignment would have an effect on any regulatory filing for the Product. The assigning party will give the on-assigning party prior written notice of any assignment as soon as it is permitted to do so and the assignment will be effective, as concerns the non- assigning party, only from and after receipt of the notice. In connection with any such assignment, the assignee will covenant in writing to be bound with respect to the non-assigning party by the terms of this Agreement or the Product Agreement binding on the assigning party.

13.5 Force Majeure.

Neither party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that party's reasonable control, including, but not limited to, strikes or other labor disturbances (with the exception of labour disturbances which are within a party's reasonable control), lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, cyber-attacks, fires, floods, storms, lack of or inability to obtain fuel, power or components due to a general shortage in the market, or compliance with any order, regulation, or enforcement decision of any government entity (a "***Force Majeure Event***"). Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for delayed payment) which would otherwise be due and payable under this Agreement or any Product Agreement.

A party affected by a Force Majeure Event will:

(a) promptly in writing notify the other party, explaining the nature, details and expected duration of the event. The party will also notify the other party from time to time as to when the affected party reasonably expects to resume performance in whole or in part of its obligations hereunder, and notify the other party of the cessation of the event; and

(b) use commercially reasonable efforts to resume full performance of its obligations under this Agreement as soon as practical; and

(c) pending this resumption, use its commercially reasonable efforts to mitigate the effects of the Force Majeure and to facilitate any efforts that the other party may make to procure an alternative method by which its obligations under this Agreement may be performed.

If a party anticipates that a Force Majeure Event may occur, that party will notify the other party of the nature, details and expected duration of the event.

If, as a result of Force Majeure, Patheon is unable to provide the Manufacturing Services and supply the full amount of Product ordered by Client or which Client would have ordered but for the circumstances, then:

(a) Client will purchase the amount of Products Patheon is able to supply, but at the Price which would have applied had Patheon been able to Supply and had Client purchased the quantities actually required by Client, and the amount Client would

have ordered but for the Force Majeure will be taken into account when calculating any volume discount as if Client had purchased the full amount from Patheon; and

(b) if the circumstances continue or are forecasted to continue for more than [***], Patheon will use commercially reasonable efforts to offer to Client alternative capacity or Supply for Product (at prices and on terms to be agreed) which can be operable within a further [***], to standards compliant with the Quality Agreement.

If, as a result of Force Majeure Event, Client is unable to take or use the Product which has been ordered, or which would have been ordered but for Client's inability to take or use the Product, Client will only be obliged to purchase Products for which Firm Orders have been placed.

If a Force Majeure prevails for a continuous period in excess of [***], Client may terminate this Agreement, or any Firm Order (including adjusting its forecast and subsequently any applicable Minimum Market Requirement, Annual Volume, and Minimum Order Quantity for that Year affected by the Force Majeure) with immediate effect, by giving written notice to Patheon.

13.6 Additional Product and Services.

Additional Product may be added to, or existing Product deleted from, any Product Agreement by amendment to the Product Agreement including its Schedules as applicable. If Client requests services other than those expressly set out in this Agreement or in any Product Agreement (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), or any cost items that are specifically excluded from the Price, Patheon will provide a written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be agreed in writing by the parties.

13.7 Notices.

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted under this Agreement will be sufficient if made or given to the other party by personal delivery or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses or email addresses set out below:

If to Client:

Calliditas Therapeutics
AB Kungsbron 1, C8
111 22 Stockholm Sweden
Attention: CEO
Email address: [***]

With a copies to: [***]

If to Patheon:

Patheon Pharmaceuticals Inc.
2110 East Galbraith Road
Cincinnati, OH 45237
Attention: Director of Legal Services
Email address: [***]

or to any other addresses or email addresses given to the other party in accordance with the terms of this Section 13.7. Notices or written communications made or given by personal delivery, or email will be considered to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt (supported by reasonable written evidence), whichever is sooner.

13.8 Severability.

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.9 Entire Agreement.

This Agreement, together with its Appendices, the applicable Product Agreement, Capital Equipment Agreement (if any), and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter of the Agreement and supersedes all previous written or oral negotiations, commitments, representations, agreements, transactions, or understandings concerning the subject matter of this Agreement. The basis of the parties' agreement is set out expressly and they have not been induced by or relied on any statement or representation that is not set out in this Agreement. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be the Product Agreement to the extent it modifies this Agreement, this Agreement, and the Quality Agreement (except that the Quality Agreement will prevail in relation to quality matters).

13.10 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by the parties will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of a party to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by both parties.

13.11 No Third Party Benefit or Right.

Nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement or any Product Agreement. In particular, the Contracts (Rights of Third Parties) Act 1999 will not apply to this Agreement and no person who is not a party to this Agreement (including any employee, officer, agent, representative or subcontractor of any party) will have the right (whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise) to enforce any term of this Agreement that expressly or by implication confers a benefit on that person without the express prior agreement in writing of the parties which agreement must refer to this Section 13.5. The rights of the parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any other person.

13.12 Execution in Counterparts.

This Agreement and any Product Agreement may be executed in two or more counterparts, by original or electronic (including "***pdf***") signature, each of which will be considered an original, but all of which together will constitute one and the same instrument.

13.13 Use of Name.

Neither party may use the other party's name, trademarks or logo or any variations of them, alone or with any other word or words, without the prior written consent of the other party.

13.14 Taxes.

(a) VAT. Any payment due to Patheon under this Agreement or a Product Agreement in consideration for the provision of Services to Client by Patheon is exclusive of value added taxes ("***VAT***"), sales taxes or similar taxes, including any related interest and penalties that are not attributable to Patheon or Patheon's conduct (together, "***Transaction Tax***").

Where applicable, Patheon will use its reasonable commercial efforts to ensure that its invoices to Client are issued in a way to meet the requirements for deduction of input VAT by Client, if Client is permitted by law to do so.

If Patheon is acting as Client's buying agent, Patheon will always charge to Client Transaction Tax in the relevant territory in addition to the amount paid by Patheon to supplier, if and as agreed in a separate agreement between the parties regulating Patheon's role as buying agent.

Reference to the Services in this Section also includes any element (or the entirety) of the Services characterized as a supply of goods by Patheon, it's subcontractor or any tax authority for Transaction Tax purposes.

(b) Duties. Client will bear the cost of all duties, levies, tariffs and similar charges (and any related interest and penalties not attributable to Patheon or Patheon's conduct) (together, "***Duties***") however designated, arising from the sale of Product by Patheon to Client or its Affiliates or designees including (without limitation) those imposed as a result of the shipping of materials (including Drug Substance, materials, components and finished Client Product) to, or from Patheon Facilities if applicable, provided however, that Duties will be excluded from the Price unless it has been agreed in writing that a specific Duty will be included in the Price. If these Duties are incurred by Patheon, then Patheon will be entitled to invoice Client for these Duties at the time that they are incurred.

(c) Withholding Tax. Where any sum due to be paid to Patheon hereunder is subject to any withholding or similar tax, Client will pay the withholding or similar tax to the appropriate government authority and deduct the amount then due to Patheon in a timely manner and without undue delay transmit to Patheon an official certificate or other evidence of the withholding sufficient to enable Patheon to claim payment of these taxes. The parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations for royalties (if applicable), milestone payments, and other payments made by a party to the other party under this Agreement or a Product Agreement.

Patheon will provide Client any tax forms that may be reasonably necessary in order for Client not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.

Each party will provide the other with reasonable assistance to enable the recovery, as permitted by applicable laws, of withholding taxes, or similar obligations resulting from payments made under this Agreement or a Product Agreement, any recovery to be for the benefit of the party bearing the withholding tax.

13.15 Governing Law and Dispute Resolution.

This Agreement and any Product Agreement, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with them or their subject matter or formation are governed by the laws of England and Wales without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. The parties further expressly agree that the UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

The parties will first try to resolve any dispute (which is not a Technical Dispute) arising out of or in connection with this Agreement, including any question relating to its existence, negotiation, validity, formation, interpretation, breach, performance, termination or application ("***Dispute***") according to the negotiation procedure set out in Appendix 2. If a Dispute is not resolved during the negotiation procedure, the Dispute will be referred to and finally resolved by arbitration under the London Court of International Arbitration (LCIA) Rules, which Rules are deemed to be incorporated by reference into this clause. The number of arbitrators will be one. The seat, or legal place, of arbitration will be London, England. The language to be used in the arbitral proceedings will be English.

[Signature page to follow]

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON PHARMACEUTICALS INC.		**CALLIDITAS THERAPEUTICS AB**	
By:	/s/ Miguel Faustino	By:	/s/ Renee Aguiar-Lucander
Name:	Miguel Faustino	Name:	Renee Aguiar-Lucander
Title:	VP & GM - Cincinnati Regional Op	Title:	CEO
Date:	13 December 2020	Date:	30 December 2020

APPENDIX 1 – Form of Product Agreement

[***]

Schedule A – Commercial Supply Pricing

[***]

APPENDIX 2 – Dispute Resolution

Negotiation

If any dispute arises out of this Agreement or any Product Agreement, the parties will first try to resolve it amicably. Any party may send a notice of a dispute to the other, and each party will appoint, within ten Business Days from receipt of the notice, an appropriate single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within one month from their appointment, or if a party fails to appoint a representative as required above: for Technical Disputes, the expert determination procedure may be started by either party; and for all other Disputes, each party will refer the dispute immediately to the Chief Operating Officer or equivalent (or another senior manager as he/she may designate) ("***Senior Officers***") who will meet and discuss as necessary to try to resolve the Dispute amicably. If the Dispute is not resolved by the Senior Officers within 30 calendar days after the Dispute was referred to them, the Dispute may be referred to the London Court of International Arbitration as set out in Section 13.16 of the Agreement.

Technical Disputes

If a dispute arises between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement, including conformance of Product to applicable Specifications (a "***Technical Dispute***"), the parties will use all reasonable efforts to resolve the dispute by amicable negotiations as provided above. If the parties are unable to resolve a Technical Dispute by negotiation, the Technical Dispute will, at the written request of either party, be referred for determination to an expert in the following manner:

(a) **Appointment of Expert**. Within ten Business Days after the written request, the parties will appoint a single agreed expert with experience and expertise in the subject matter of the dispute. If the parties fail to agree the appointment within that period, then either party may request that a neutral from the International Institute of Conflict Prevention and Resolution appoints a suitable expert (and both parties will accept that appointment in the absence of evident conflict or bias). As a condition of the expert's appointment, the parties will ensure that the expert agrees to disclose any actual or potential conflicts of interest promptly as they arise. The parties do not intend that the expert acts as an arbitrator.

(b) **Procedure**. The parties will require the expert to provide an opinion on each referred issue (with reasonably detailed reasoning) within 15 Business Days (or as agreed by the parties with the expert). Each party will give to the expert all the evidence and information within their respective possession or control as the expert may reasonably request, which they will disclose promptly and in any event within five Business Days of a written request from the expert to do so. At all times the parties will co-operate in good faith and seek to narrow and limit the issues to be determined.

(c) **Final and Binding**. The determination of the expert will, except for fraud or manifest error or where an unapproved conflict of interest is discovered, be final and binding upon the parties with respect to the referred Technical Dispute.

(d) **Costs**. Each party will bear its own costs for any matter referred to an expert under this Appendix 2 and, in the absence of express agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

APPENDIX 3 – API Yield Calculation

[***]

APPENDIX 4 – Price Adjustments

[***]

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT WAS OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[***]".

Product Agreement for Nefecon 4mg

This Product Agreement (this "**Product Agreement**") is issued under the Master Manufacturing Services Agreement dated December 30, 2020 between Patheon Pharmaceuticals Inc. and Calliditas Therapeutics AB (the "**Master Agreement**"), and is entered into on December 30, 2020 (the "**Effective Date**") between Patheon Pharmaceuticals Inc., a corporation existing under the laws of the State of Delaware, with its principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237 ("**Patheon**") and Calliditas Therapeutics AB, a company existing under the laws of Sweden, with its principal place of business at Kungsbron 1, C8, SE-111 22 Stockholm ("**Client**"). For the purpose of this Product Agreement, references in the Master Agreement to "Patheon" and "Client" mean the entities defined respectively as Patheon and Client in this Product Agreement.

The terms and conditions of the Master Agreement are incorporated into this Product Agreement except to the extent this Product Agreement expressly modifies specific provisions in the Master Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

Patheon has provided certain development services to Client during the development of the Product, including but not limited to (i) qualification of the manufacturing and packaging process; (ii) documentation of the manufacturing and packaging process; (iii) development and verification of analytical methods for API, Components and Products; and (iv) writing, reviewing and preparing the Regulatory documents under the Master Agreement for Pharmaceutical Development Services dated July 4, 2011 between Patheon and Pharmalink AB (the "**Master PDS Agreement**"). Client is the successor to Pharmalink AB under the Master PDS Agreement. Nothing in this Product Agreement or the MSA intends to limit Patheon's or Client's responsibilities that are covered under previous agreements entered into between the parties including the Master PDS Agreement and Validation Services Agreement C-CRC-242943-R2 (or latest revision) and Technology Transfer and Scale-up Agreement C-CRC-231449-R2 (or latest revision) that were issued under the Master PDS Agreement.

1. **Initial Product Term**: From the Effective Date until December 31, 2026

2. **Manufacturing Site**: The Manufacturing Services will be performed at the following Manufacturing Site: Patheon Pharmaceuticals Inc., 2110 East Galbraith Road, Cincinnati, OH 45237

3. **Minimum Market Requirement**: Patheon will manufacture a minimum of [***]% of Client's annual requirements for Product in a Year in [***].

4. **Annual Volume, Minimum Order Quantity and Price:** (See Schedule A)

5. **Processing Instructions:** (See attached Exhibit 1)

6. **Client-Supplied Components and Client-Designated Suppliers:** (See attached Exhibit 2)

7. **Components Supplied by Patheon that are unique to Nefecon 4 mg and/or have order lead times greater than 90 days**: (See attached Exhibit 3).

8. **Notices**: Per Section of the Master Agreement.

9. **API Name**: Budesonide micronized

10. **API Credit Value:** Client's actual cost for API not to exceed USD $[***] per kilogram. API value to be provided by Client and supported by such reasonable evidence as Patheon requests.

11. **Local Currency**: USD

12. **Billing Currency**: USD

13. **Initial Exchange Rate**: Not applicable

14. **Inflation Index**: [***]

15. **Governing Law:** The laws of England and Wales

16. **Other Modifications to the Master Agreement (if any)**:

a) **Stock of API**

Patheon will hold stock of API as follows:

Maximum Volume equivalent to [***] forecasted demand (according to the latest

Rolling Forecast) or maximum [***] of API whichever is lowest ("**Max Volume**").

Stock of API held at or below Max Volume will be [***]. Volume of API held above Max Volume may be charge at [***] (provided that an additional pallet is required for the additional volume above Max Volume).

All API and Product will be stored under the storage conditions set out in the Processing Instructions in a dedicated area. Patheon will mark this property as the property of Client and take all other measures necessary under local law to guarantee that Client may pick up its property in case of Patheon's insolvency or for any other reason.

b) **Price for Capacity Reservation**

Notwithstanding what is set out in Section 5.1(f) of the Master Agreement, the Price for any capacity reservation for the Product will be based on the [***] pricing or Conversion Fee set out in Schedule A based on the Forecasted Annual Volume.

c) **Modification to Section 5.1(d) of the Master Agreement**

If [***] is required, the Parties will negotiate and agree upon a revised PO due date, at least [***] after the originally agreed upon due date.

d) **Modification to Section 8.3(d) of the Master Agreement**

Section 8.3(d) of the Master Agreement is deleted in its entirety and is replaced with the following:

If Patheon gives Client notice of non-renewal under Section 8.1, Patheon will continue to perform the Manufacturing Services in order to provide Client with an additional [***] supply of Product on the same terms and conditions as applied immediately before the Product Agreement is completed, expires or terminates;

17. **Schedule A – Commercial Supply Pricing**: Description of the Manufacturing Services and related terms of this Product Agreement, which includes: Product

Features and Assumptions, Key Assumptions to be Finalized, Annual Volume Forecasts, Pricing Tables, Costs Included in Price, Costs Not Included in Price, Equipment Requirements (if applicable), Manufacturing Parameters, Packaging Parameters, Testing Conditions are included in Schedule A attached to this Product Agreement.

In case of conflict between Schedule A and this Product Agreement, this Product Agreement will prevail.

This Product Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON PHARMACEUTICALS INC.

By: /s/ Amanda Bosse
Name: Amanda Bosse
Title: President, DPD NA
Date: 14 January 2021

CALLIDITAS THERAPEUTICS AB

By: /s/ Renee Aguiar-Lucander
Name: Renee Aguiar-Lucander
Title: CEO
Date: 30 December 2020

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT WAS OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[***]".

Schedule A – Commercial Supply Pricing

[***]

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Exhibit 1

[***]

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. INFORMATION THAT WAS OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[***]".

Exhibit 2

[***]

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Exhibit 3

[***]

Exhibit 12.1

SECTION 302 CERTIFICATION

I, Renée Aguiar-Lucander, certify that:

1. I have reviewed this annual report on Form 20-F of Calliditas Therapeutics AB;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 24, 2024

/s/ Renée Aguiar-Lucander
Renée Aguiar-Lucander
Chief Executive Officer

Exhibit 12.2

SECTION 302 CERTIFICATION

I, Fredrik Johansson, certify that:

1. I have reviewed this annual report on Form 20-F of Calliditas Therapeutics AB;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 24, 2024

/s/ Fredrik Johansson
Fredrik Johansson
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CEO PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Renée Aguiar-Lucander, Chief Executive Officer of Calliditas Therapeutics AB (the "Company"), hereby certifies that, to the best of her knowledge:

1. The Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2023, to which this Certification is attached as Exhibit 13.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 24, 2024

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 24th day of April 2024.

/s/ Renée Aguiar-Lucander
Renée Aguiar-Lucander
Chief Executive Officer

This certification accompanies the Form 20-F to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Calliditas Therapeutics AB under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 20-F), irrespective of any general incorporation language contained in such filing.

Exhibit 13.2

CERTIFICATION OF CFO PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Fredrik Johansson, Chief Financial Officer of Calliditas Therapeutics AB (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2023, to which this Certification is attached as Exhibit 13.2 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 24, 2024

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 24th day of April, 2024.

/s/ Fredrik Johansson
Fredrik Johansson
Chief Financial Officer

This certification accompanies the Form 20-F to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Calliditas Therapeutics AB under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 20-F), irrespective of any general incorporation language contained in such filing.

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 333-240126) pertaining to the ESOP 2020 United States Sub-Plan (the "U.S. Sub-Plan") and the Long-term Performance Based Incentive Program (the "Board LTIP 2020") of Calliditas Therapeutics AB,

(2) Registration Statement (Form S-8 333-272594) pertaining to the ESOP 2021 United States Sub-Plan, the ESOP 2022 United States Sub-Plan, the ESOP 2023 United States Sub-Plan Plan, the Board LTIP 2021, the Board LTIP 2022 and the Board LTIP 2023 of Calliditas Therapeutics AB, and

(3) Registration Statement Form (F-3 333-265881) of Calliditas Therapeutics AB;

of our reports dated April 24, 2024, with respect to the consolidated financial statements of Calliditas Therapeutics AB and the effectiveness of internal control over financial reporting of Calliditas Therapeutics AB included in this Annual Report (Form 20-F) of Calliditas Therapeutics AB for the year ended December 31, 2023.

Ernst & Young AB

Stockholm, Sweden
April 24, 2024

calliditas THERAPEUTICS

Standard Operating Procedure

Executive Officer Incentive Compensation Clawback			
Document No.	Version	Lifecycle State	Effective Date **1 December 2023**
Document Owner			
Owning Department **Finance**			

Contents

1. Purpose

The Remuneration Committee (the "Remuneration Committee") of the Board of Directors (the "Board") of Calliditas Therapeutics AB, a Swedish public limited company ("Calliditas"), has determined that it is in the best interests of Calliditas and its shareholders to adopt this Incentive Compensation Recoupment Standard Operating Procedure (this "SOP") providing for Calliditas' recoupment of Recoverable Incentive Compensation that is received by Covered Officers of Calliditas under certain circumstances. Certain capitalized terms used in this SOP have the meanings given to such terms in Section 3 below.

2. Scope

This SOP is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the U.S. Exchange Act, Rule 10D-1 promulgated thereunder ("Rule 10D-1") and Nasdaq Listing Rule 5608 (the "Listing Standards").

3. Responsibilities

Function	Responsibility
Remuneration Committee	Responsible for proposing, reviewing, and monitoring compliance with this SOP
Board	Responsible for adopting and amending this SOP
CEO	Determines the list of officers included in the definition of "Executive Officers" for purposes of this SOP
CFO	Proposes changes in the list of officers included in the definition of "Executive Officers" for purposes of this SOP Responsible for maintaining and providing financial information as provided in this SOP Responsible for assisting in obtaining repayment of any Recoverable Incentive Compensation Responsible for alerting the Remuneration Committee of the pendency and implementation of any Accounting Restatement
Head of HR	Responsible for ensuring that all Executive Officers read and acknowledge this SOP and for maintaining records of their agreement to comply with the provisions of this SOP

4. Definitions

Term/Abbreviation	Definition
Accounting Restatement	An accounting restatement that Calliditas is required to prepare due to the material noncompliance of Calliditas with any financial reporting requirement under relevant securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period
Accounting Restatement Date	The earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of Calliditas authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that Calliditas is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs Calliditas to prepare an Accounting Restatement
Administrator	The Remuneration Committee of the Board or, in the absence of such committee, the Board
Code	The U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder
Covered Officer	Each current and former Executive Officer
Exchange	The Nasdaq Stock Market
Exchange Act	The U.S. Securities Exchange Act of 1934, as amended.

Term/Abbreviation	Definition
Executive Officer	Calliditas' CEO, CFO, CMO, President, North America, VP Regulatory Affairs, and any other executive officers identified by decision of the CEO
Financial Reporting Measures	Measures that are determined and presented in accordance with the accounting principles used in preparing Calliditas' financial statements, and any measures derived wholly or in part from such measures, including Calliditas' share price and total shareholder return ("TSR")
Incentive Compensation	Any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure
Lookback Period	The three completed financial years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in Calliditas' financial year) within or immediately following those three completed financial years (except that a transition period of at least nine months shall count as a completed financial year). Notwithstanding the foregoing, the Lookback Period shall not include financial years 2022 and before
Recoverable Incentive Compensation	Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax or social security withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this SOP shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on share price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the share price or TSR upon which the Incentive Compensation was received. Incentive Compensation is deemed "received" in Calliditas' financial year in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.
SEC	The U.S. Securities and Exchange Commission

5. Procedure

5.1. Applicability of SOP

5.1.1. This SOP shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023.

5.1.2. This SOP applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while Calliditas had a class of securities listed in the United States on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

5.1.3. This SOP shall be binding and enforceable against all Covered Officers and, to the extent required by applicable law (including Rule 10D-1 and/or the applicable Listing Standards), their beneficiaries, heirs, executors, administrators or other legal representatives.

5.2. Recoupment

5.2.1. Recoupment Obligation. If there is an Accounting Restatement, Calliditas must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 5.2.2 of this SOP are met and the Remuneration Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and Calliditas' obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

5.2.2. Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this SOP would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, Calliditas shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards;

(ii) recoupment of the applicable Recoverable Incentive Compensation would violate home country law where that law was adopted prior to November 28, 2022; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on violation of home country law, Calliditas shall obtain an opinion of home country counsel, acceptable to the Exchange, that recoupment would result in such a violation,

and shall provide such opinion to the Exchange in accordance with the Listing Standards; or

(iii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of Calliditas, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

5.2.3. Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity- based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A (if applicable) or any equivalent local laws applicable to the Covered Officer; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this SOP from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Calliditas plan or program, e.g., base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation. The CFO or his or her delegee shall be responsible for assisting the Administrator in connection with any recoupment.

5.2.4. No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy, or any other agreement or provision of Calliditas' organizational documents to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this SOP by Calliditas, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to Calliditas under this SOP.

5.2.5. Effect of Recoupment on Employment Agreement. Any action by Calliditas to recoup or any recoupment of Recoverable Incentive Compensation under this SOP from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5.3. Administration

5.3.1. Amendments and Modifications. The Board may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. In

addition, the Administrator may amend this Policy as it deems necessary to comply with applicable law or any Listing Standard and shall report any such change to the Board at its next meeting.

5.3.2. General Administration. Except as specifically set forth herein, this SOP shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this SOP. Any determination by the Administrator with respect to this SOP shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this SOP. In carrying out the administration of this SOP, the Administrator is authorized and directed to consult with the full Board or other committees of the Board as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of Calliditas to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this SOP (other than with respect to any recovery under this SOP involving such officer or employee).

5.3.3. CEO Responsibilities. The CEO shall be responsible for modifying the list of Executive Officers, after consultation with the CFO.

5.3.4. CFO Responsibilities

(i) The CFO may propose to the CEO from time-to-time changes in the list of Calliditas personnel to be considered Executive Officers.

(ii) The CFO shall be responsible for alerting the Administrator of the pendency and implementation of any Accounting Restatement.

(iii) The CFO shall be responsible for maintaining and providing financial information as provided in this SOP. In particular, the CFO shall maintain documentation of the determination of a reasonable estimate of the effect of the Accounting Restatement on the share price or TSR upon which the Incentive Compensation was received and provide such documentation to the Exchange in accordance with the Listing Standards.

(iv) The CFO shall be responsible for assisting in obtaining repayment of any Recoverable Incentive Compensation.

(v) The CFO shall be responsible for ensuring that Calliditas makes any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

5.3.5. Head of HR Responsibilities. The Head of HR shall be responsible for ensuring that all Executive Officers read and acknowledge this SOP and for maintaining records of their agreement to comply with the provisions of this SOP, annually as part of the establishment of bonus criteria and personal goals, beginning with the bonus program for 2024.

5.3.6. Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this SOP, shall not be personally liable for any action, determination or interpretation made with respect to this SOP and shall be indemnified by Calliditas to the fullest extent under applicable law and Calliditas' organizational documents and policies with respect to any such action, determination or interpretation.

5.3.7. No Impairment of Other Remedies. Nothing contained in this SOP, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies Calliditas or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This SOP does not preclude Calliditas or any subsidiary thereof from taking any other action to enforce a Covered Officer's obligations to Calliditas, including, without limitation, termination of employment and/or institution of civil proceedings. This SOP is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("SOX 304") that are applicable to Calliditas' CEO and CFO and to any other compensation recoupment SOP or policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which Calliditas or any subsidiary thereof is a party or which Calliditas or any subsidiary thereof has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

6. Supporting Documents

Document No.	Document Name
1.	
2.	

7. Literature References

Document No.	Document Name
1.	
2.	

8. Attachments

Attachment No.	Attachment Name
1.	
2.	

9. Revision History

Version	Short description of the change	Effective Date
1.0	New Document	See page 1