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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, 2022

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)

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Calliditas Therapeutics AB
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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, 2022, 59,572,587 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 8, 2023, 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 for Nefecon. 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 and “Nefecon” for all other purposes, including for the global Nefecon product franchise.

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 Nefecon and our current and future product candidates, including full approval of TARPEYO® in the United States and Kinpeygo® in the EU and the UK;
- our TARPEYO sales and commercialization efforts and their results;
- our commercialization partner's Kinpeygo 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 for its patient population on acceptable terms;
- the potential attributes and benefits of Nefecon and our other product candidates and their competitive position with respect to alternative treatments;
- the potential benefit of the FDA's accelerated approval and Section 505(b)(2) application pathway, the European Commission's conditional approval and hybrid marketing authorization application pathway, orphan drug designation and related market exclusivity for our products and product candidates, and equivalent foreign provisions;
- our ability to successfully identify and develop our current and future product candidates;
- the impact of the COVID-19 pandemic, geopolitical tension and other world events on our business and clinical trials as well as 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 TARPEYO, Kinpeygo and Nefecon 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 Nefecon 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, future 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, our business will be materially harmed.
- If we are unable to successfully complete clinical development of, obtain regulatory approval for and commercialize Nefecon 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, the European Commission, or 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 our products and 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 demonstrate adequately 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 revenues from sales of our product candidates, if approved, 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 and development efforts, and if we do not compete effectively, our commercial opportunities will be reduced or eliminated.
- We have only recently begun commercialization of Nefecon (marketed under the brand name TARPEYO in the United States and under the brand name Kinpeygo by our partner STADA in the EU and UK) 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 substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- 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 satisfy their obligations or are unsuccessful, we could be adversely affected.

- We expect 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.

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

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

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. Our net sales for the year ended December 31, 2022 were SEK 802.9 million, of which TARPEYO® net sales amounted to SEK 372.2 million. We do not know whether such revenue levels will increase or be maintained in the future. Other than Nefecon, which has been approved under accelerated approval in the United States, and which was granted conditional marketing authorization in the EU and the UK, 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:

- obtain and 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 the COVID-19 pandemic, 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 commercialize Nefecon 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 US, 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 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. We reported topline results from the full NefIgArd clinical trial, including Part B, 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. The NefIgArd trial is expected to conclude in the third quarter of 2023 when the final 29 patients in China (not required for our regulatory purposes outside of China) have completed nine months of treatment and 15 months of observation. Although we believe that the data from Part B of the Phase 3 NefIgArd clinical trial supports regulatory filing for full approval, 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, and for the treatment of squamous cell carcinoma of the head and neck, or SCCHN. 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/3 clinical trial, in which we randomized the first patient in February 2022. Setanaxib will be administered to approximately 318 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 up to 150 investigational centers. 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. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in the first half of 2024, subject to recruitment rate, and will determine which dose of setanaxib will be used for the Phase 3 part of the study. Setanaxib was granted fast track designation by the FDA in August 2021.We are currently also 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 expect an interim biomarker readout in mid-2023.

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 pivotal and potentially registrational Phase 2/3 TRANSFORM trial evaluating setanaxib in PBC and to establish proof of concept in our Phase 2 trial of setanaxib in SCCHN;
- 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. Although Nefecon has been approved under accelerated approval by the FDA (under the brand name TARPEYO) and has received conditional marketing authorization in the EU and the UK (under the brand name Kinpeygo), it is possible that we and our licensees may not be able to obtain full marketing approval in these jurisdictions, 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 recent years, including 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 to perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. For Nefecon, Part B of our NefIgArd trial was intended to serve as such a post-approval confirmatory trial to measure long-term renal benefit and to verify clinical benefit. We reported topline results from the full NefIgArd Phase 3 clinical trial in March 2023. Although we believe that the data from NefIgArd clinical trial supports regulatory filing for full approval, we cannot guarantee that Nefecon will receive full regulatory approvals on the timelines we expect or at all and we may not ultimately receive full approval from the regulatory agencies. 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. The EC or the MHRA may decide not to renew the conditional marketing authorization, although such measure is rarely applied in practice. 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 FDA, the EC and comparable foreign regulatory authorities may also withdraw any accelerated approval and 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.

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;
- 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. From January 31, 2023 all applications for approval of a clinical trial in the EU must be on the basis of the CTR. Trial authorized on the basis of the Clinical Trials Directive before this date may continue to be conducted in accordance with the Directive 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). However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK.

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. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. 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 demonstrate adequately 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 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 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 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 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 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. In March 2023, we announced positive topline results from our NeflgArd Phase 3 clinical trial, which was designed to describe and verify the clinical benefit of Nefecon treatment. 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 treatment-emergent adverse events (“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.

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 or terminated and the FDA, the EC 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 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 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 EC 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.

We have been granted orphan drug designation for IgAN, PBC and AIH and 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.

In May 2010, the FDA granted orphan drug designation to Nefecon to slow the progression of IgAN and delay kidney failure in patients affected by the disease. In November 2016, the EC granted Nefecon orphan designation for the treatment of primary IgAN. In February 2023 the MHRA granted orphan drug designation together with market authorization and related market exclusivity to Nefecon in the treatment of primary IgAN. We have also received orphan drug designation for PBC and autoimmune hepatitis, or AIH. In addition, setanaxib received orphan drug designation from the FDA and the EC for the treatment of PBC. We may seek orphan drug designations for other 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. 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 revenues from sales of our product candidates, if approved, 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 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 and development 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.D.—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 and EU provide opportunities for data and market exclusivity related to marketing authorizations. In the EU, 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 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 until 10 years have elapsed from the initial marketing authorization of the reference product in the EU. 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’s 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 and head and neck cancer. 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. For example, we have exclusively in-licensed Budenofalk 3 mg oral capsules, which is a formulation of budesonide originally developed to treat Crohn's disease, and we are evaluating its potential to treat AIH. Our license covers all indications for the United States market, excluding orphan indications outside of liver targets.

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 starting 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.

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, approved under accelerated approval in the US (under the brand name TARPEYO) and 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 60 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, 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. 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. 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 any of our product candidates 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 products, if approved.

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, 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. Since the issuance of the final rule, several industry groups have filed federal lawsuits challenging multiple aspects of the final rule, and authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. 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. The regulatory and market implications of the final rulemaking and guidance are unknown at this time.

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 Nefecon (marketed in the US under the brand name TARPEYO) 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 begin commercialization of TARPEYO, we did not previously have a sales and marketing infrastructure and have no experience in the sale or marketing of biopharmaceutical products. We intend 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 launch or market our products effectively 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 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 agree to offer 50% (increased to 70% as of January 1, 2019 pursuant to the Bipartisan Budget Act of 2018) 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. Thus, the ACA will remain in effect in its current form. Further, prior to the US Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. 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 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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 will 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. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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 importation from other countries and bulk purchasing.

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.

In the EU, the policy debate is focused on the impact of intellectual property protection and regulatory incentives on innovation and patient access. Specifically, the EC has gathered information on the experience with the orphan drug regulation and pediatric regulation. It is anticipated that the EC will propose changes to incentives such as market exclusivity for orphan drugs, small scale pharmacy compounding and compulsory licensing of patented drugs in March 2023.

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.

In December 2021 the EU Parliament adopted the HTA regulation which, when it enters into application in 2025, 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; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU Member States. 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 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. 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 is currently only approved by the FDA to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio, or UPCR, ≥1.5gram/gram. Kinpeygo is currently approved by the EC and the MHRA only for the treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 gram/gram. We have trained and will continue to train our marketing and sales force against promoting TARPEYO, Kinpeygo 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 substantial 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 373.2 million and SEK 527.7 million for the years ended December 31, 2022 and December 31, 2021, respectively. As of December 31, 2022, we had an accumulated loss of SEK 1,836.3 million. Our losses resulted principally from costs incurred in clinical development of Nefecon and setanaxib 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 substantially if and as we:

- develop and advance Nefecon, setanaxib and any other present or future product candidates;
- pursue full approval for TARPEYO in the United States and seek regulatory approvals for Nefecon in other 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;
- 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 the COVID-19 pandemic, geopolitical tensions or other world events.

To date, we have funded our operations through public and private placements of equity securities, proceeds from our term loan facility, upfront and milestone payments and interest income from the investment of our cash and financial assets. We have also recently begun to fund our operations with the proceeds from sales of TARPEYO in the United States.

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, such as setanaxib in PBC and head and neck cancer, obtaining regulatory approval for any product candidates that successfully complete clinical trials, including full regulatory approval for TARPEYO in the US and Kinpeygo in the EU and UK and 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 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, 2022, we had SEK 1,249.1 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. 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 and our present 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, filling 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 the COVID-19 pandemic, the Russia-Ukraine military conflict, 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 with Kreos Capital VI (UK) Limited and Kreos Capital 2020 Opportunity (UK) Limited, together referred to as Kreos, 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 loan agreement with Kreos, or the Loan Agreement, Kreos made available to us certain term loans in an aggregate principal amount of up to $75.0 million. The loan facility is divided into three tranches of $25 million each, which we drew down in September 2021, June 2022 and December 2022. The Loan Agreement does not contain any financial covenants. See Item 5.B., Liquidity and Capital Resources, for more details on the Loan 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 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 rely on third parties to manufacture Nefecon and setanaxib, and we expect to continue to rely on third parties for the clinical and commercial supply of Nefecon, setanaxib and other present or future product candidates. The development of Nefecon, setanaxib or such other product candidates, and the commercialization of any approved products, could be stopped, reduced or made less profitable if any such third party fails to provide us with sufficient clinical or commercial quantities of such product candidates or products, fails to do so at acceptable quality levels or prices or fails to achieve or maintain satisfactory regulatory compliance.

We do not currently have, and we do not plan to build, the infrastructure or capability internally to manufacture Nefecon, setanaxib or any other present or future product candidate for use in the conduct of our clinical trials or, if approved, for commercial supply. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the CMOs we contract with and are dependent on those third parties for the production of our product candidates in accordance with relevant regulations such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our clinical or commercial demand for any of our product candidates, we could experience delays in our planned clinical studies or commercialization. We could be unable to find alternative suppliers of acceptable quality that can produce appropriate volumes at an acceptable cost. Moreover, our suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, would significantly delay our clinical studies and the commercialization of our products, if approved, which would materially adversely affect our business, financial condition and results of operation. Additionally, if any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product or product candidate according to the specifications previously submitted to the FDA or another comparable foreign regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical or commercial supplies which could require additional manufacturing development or the conduct of additional clinical trials, or disrupt commercialization.

In complying with the manufacturing regulations of the FDA, the EC, and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA, the EC, or comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our products and product candidates could suffer significant interruptions.

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.

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 authorization received from the EC to STADA and are in the process of transferring the conditional marketing authorization received from the MHRA to STADA. In 2019, we granted a license to Everest Medicines II Limited, or 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. 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 United States Patent and Trademark Office, or 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.

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.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure, and non-competition 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 confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. 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 successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

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. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. 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 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 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.

Following the result of a referendum in 2016, the UK left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules continued to apply. The UK and the EU have signed an EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU's relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice, or GMP, inspections and for the exchange and acceptance of official GMP documents.

The regime does not, however, extended to procedures such as batch release certification. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a "third country", which means a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland continues to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods. As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use. As it relates to marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the EC. For example, the scope of a marketing authorization for a medicinal product granted by the EC or by the competent authorities of EU Member States will no longer encompass Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place medicinal products on the market 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, following the Transition Period, 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 Swedish Krona and Swiss francs. The operating currency of our French and Swiss subsidiaries is the Swiss franc.

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 data, or those of third parties upon which we rely, 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, and other adverse consequences.

In the ordinary course of our business, we may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information). We may 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, third-party providers of cloud-based infrastructure, 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. We may share or receive sensitive information with or from third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats 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 and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including 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, including the Russia-Ukraine military conflict. 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 phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), 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.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of 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. 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 or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. Our partially remote workforce poses increased risks to our information technology systems and data. 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.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption 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 cause 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.

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. 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. These consequences may include: 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; 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, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

In the ordinary course of business, we process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. We and any potential collaborators may be subject to 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, numerous federal and state data privacy and security laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state 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 patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable 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.

As another example, the California Consumer Privacy Act, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA exempts some data processed in the context of clinical trials as well as protected health information that is subject to HIPAA, for any personal information we process that is not subject to those exemptions, the CCPA may increase compliance costs and potential liability. In addition, the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, expands the CCPA, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states have also enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, Colorado passed the Colorado Privacy Act, and Utah passed the Consumer Privacy Act, all of which become effective in 2023. 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 and the third parties upon whom we rely. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU's General Data Protection Regulation, or EU GDPR, and the UK's GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators in the EU Member States and Norway, Iceland and Liechtenstein may impose temporary or definitive bans on data processing, as well as fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, companies may face private litigation related to processing of personal data because the GDPR grants data subjects, or consumer protection organizations authorized at law to represent their interests, the right to claim material and non-material damages resulting from infringement of the GDPR. 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. In the UK, non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. 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 to data privacy and security laws, we may be contractually subject to data privacy and security obligations, including industry standards adopted by industry groups and may become subject to new data privacy and security obligations in the future. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the EC does not consider to provide an adequate level of data privacy and security, such as the United States. The EC released a set of "Standard Contractual Clauses," or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but this mechanism is subject to legal challenge. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection, and certain countries outside Europe (e.g., Russia) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business.

If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the US could significantly and negatively impact our business operations, including by 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; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

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 information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. 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 are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. 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. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so.

Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others.

If we or our third-party processors fail to comply or are perceived to have failed to comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

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 setting Environmental, Social and Corporate Governance (ESG) goals and requiring the provision of new and more robust disclosure of steps taken to implement such goals. The related legislative landscape in the EU has been evolving accordingly. For example, in December 2022, Directive No 2464/2022 on Corporate Sustainability Reporting (CSRD) was adopted and entered into force on January 5, 2023. This new Directive strengthens the rules governing the social and environmental information that companies are required to report. The new rules expand the number of companies that are required to report ESG information and broaden the amount of ESG information that companies must report. The CSRD also requires a "double materiality" analysis. This means that companies will have to report on how sustainability issues might create financial risks for the company and on the company's own impacts on people and the environment. The CSRD will apply to large EU companies, EU parents of a large group, and to listed EU small or medium-sized companies. It will also apply to non-EU companies that have a certain threshold of EU-generated turnover and an EU branch or subsidiary. The specific information that will be subject to reporting will be detailed in the European Sustainability Reporting Standards, or ESRS to be adopted by the EC. The first set ESRS are expected be adopted by June 30, 2023. Companies subject to the CSRD will be required to fulfil their reporting obligations in accordance with a staggered timeline depending on the category of company. The first report is expected in 2025 for the 2024 financial year.

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. 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 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. 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 proposed 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. On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 1, 2023. We continue to evaluate what effect, if any, the rule will have on our business;

- 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, 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, 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

- European 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 future 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 price of the securities of publicly traded pharmaceutical companies like ours has been highly volatile and is likely to remain highly volatile in the future. Since the ADSs were sold at our initial US public offering in June 2020 at a price of $19.50 per ADS, the price per ADS has ranged as low as $10.82 and as high as $38.00 through December 31, 2022. The market price of the ADSs and our common shares may 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 the COVID-19 pandemic, bank failures, the Russia-Ukraine military conflict, 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, starting with this annual report, 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 year ended December 31, 2022, we have 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, 2021 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 2022, we were able to complete remediation of the prior material weakness related to controls over impairment of goodwill and other intangible assets, 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. As such, we have hired a dedicated US-based Internal Controls leader with risk management and Sarbanes Oxley experience, provided a first wave of SOX and internal controls training, and have implemented a new and enhanced solution for documenting our risks, controls and related assertions to facilitate tracking and analyzing internal control deficiency trends to support timely remediation. We are committed to implement a strong 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, 2022. 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, primarily related to the lack of sufficient skilled personnel with SEC reporting knowledge and experiences for purposes of timely and reliable financial reporting. Specifically, the material weaknesses identified relate to a lack of resources sufficient to prepare and review our consolidated financial statements and related disclosures in accordance with the requirements set forth by the SEC.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we are now 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, 2022, 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 weakness 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 and further impacted by the COVID-19 pandemic 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 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 27.5% of our outstanding common shares (including common shares in the form of ADSs) as of February 28, 2023. 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. Currently, we hold foreign exchange call options on the Euro.

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. These methods generally permit the Sweden court discretion to prescribe the manner of enforcement. 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 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, 2022, we do not believe that we were a PFIC for our taxable year ending December 31, 2022. 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 becoming a PFIC for our current taxable year or any future taxable years. 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 quarterly weighted average value of our assets 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. If our corporate group 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.

The tax treatment of the company 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.

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.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. 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.

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, 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.

In July 2022, we entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or 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. Any such sales, made through our sales agent can be made by any method that is deemed an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act, or in other transactions pursuant to an effective shelf registration statement on Form F-3. We agreed to pay Jefferies a commission of up to 3.0% of the gross proceeds of any sales of ADSs sold pursuant to the Sales Agreement. As of March 31, 2023, we have not sold any shares pursuant to the Sales Agreement.

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. 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. 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 urine protein-to-creatinine ratio ≥1.5 gram/gram on July 15, 2022 and our licensee STADA Arzneimittel AG, or STADA, announced commercial availability in Germany in September 2022. 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.

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.

Nefecon has been granted seven years orphan drug exclusivity in the United States, expiry December 15, 2028, and ten years orphan market exclusivity by the EC, expiry July 15, 2032, and by the MHRA, expiring February 1, 2033.

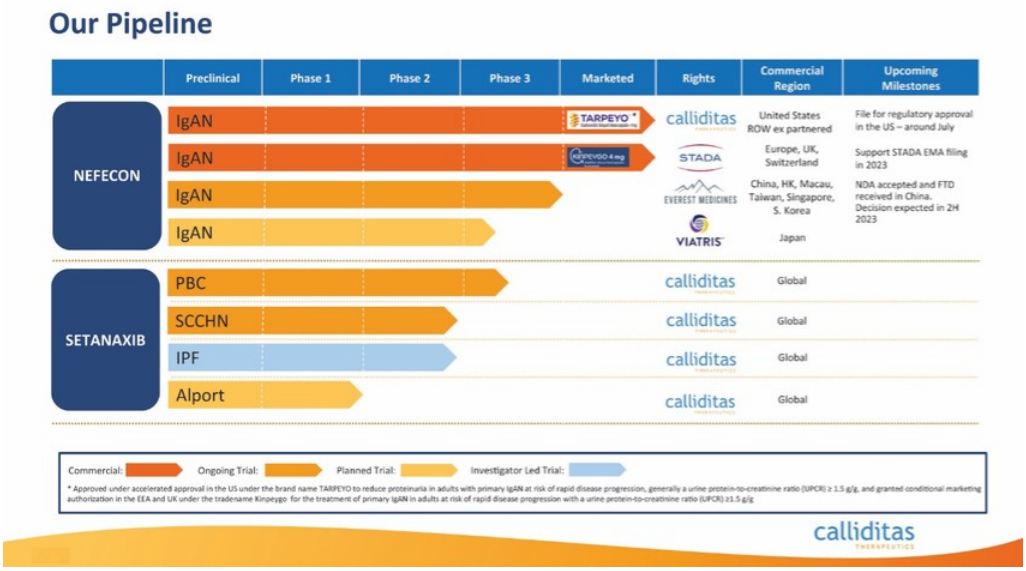
We retain worldwide rights to Nefecon other than in territories where we have established strategic collaborations. In 2019, we entered into an agreement pursuant to which we granted Everest Medicines II Limited, or Everest, an exclusive license to develop and commercialize Nefecon for the treatment 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/3 clinical trial, in which we randomized the first patient in February 2022. Setanaxib will be administered to approximately 318 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 up to 150 investigational centers. 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. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in the first half of 2024, subject to recruitment rate, and will determine which dose of setanaxib will be used for the Phase 3 part of the 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, in order to explore setanaxib's use as a treatment approach in cancers with high levels of tumors associated fibroblasts, or CAFs.

In addition, we have in-licensed Budenofalk 3 mg oral capsules and intend to develop Budenofalk in the United States for the treatment of autoimmune hepatitis, or AIH, subject to regulatory feedback. We discussed development plans with the FDA for AIH during 2020 and have refined our clinical approach during 2021 and 2022 with a target to arrive at a definitive clinical development plan in 2023, subject to further interactions with KOLs and the FDA.

Our Pipeline

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



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:

- **Apply for full marketing approval for TARPEYO and Kinpeygo**. We reported topline results from the full NefIgArd Phase 3 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 NefIgArd trial is expected to conclude in the third quarter of 2023 when the final 29 patients in China (not required for global submission purposes) have completed nine months of treatment and 15 months of observation. We believe that the topline results from the NefIgArd trial support filing for a full approval for adult patients with primary IgAN based on the Phase 3 study population, and we plan to file for such approval with the FDA during 2023.

- **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 small and dedicated number of marketing and medical sales specialists to efficiently cover the approximately 4,000 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 squamous cell carcinoma of the head and neck cancer 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 plan to initiate a Phase 2a study with setanaxib in about 20 patients with Alport syndrome in the second quarter of 2023.

- **Leverage our proprietary formulations and significant experience with drug release technology to explore treatments in select orphan hepatic diseases**. We believe that there is a potential to treat orphan hepatic diseases in which therapeutic benefits can be achieved by a local release of a potent immunosuppressant targeted at the liver while limiting systemic side effects. We are exploring additional indications such as AIH. There are currently no approved therapies in the United States for AIH. We discussed our development plans with the FDA for AIH during 2020 and have received helpful feedback as to the potential regulatory pathway forward. During 2021 and 2022, we continued to develop our clinical plans and expect to arrive at a definitive clinical plan approach in 2023, subject to interactions with KOLs and the FDA.

- **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 and Astra Zeneca. 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.

COVID-19 Pandemic & Global Developments

As of the date of this annual report, the impact of the COVID-19 pandemic to our business has been limited. To date, we do not anticipate that the COVID-19 pandemic has impacted or will significantly impact the ongoing clinical activities related to NefIgArd, our Phase 3 pivotal trial in IgAN. Nefecon is orally administered by patients at home and the trial is conducted globally and designed to require only limited interaction among patients and the healthcare system, with the result that the impact of the COVID-19 pandemic on the trial was limited. With sites in 19 countries participating in the trial, there are several geographies facing challenging situations in their healthcare systems, but we were able to put in place effective measures designed to address patient safety and preserve trial data integrity, in close cooperation with national coordinators, primary investigators, study nurses and our contract research organization. In January 2021, we completed the enrollment of 366 patients in the global NefIgArd trial, including a number of patients in China. In March 2023, we announced positive topline results from the Phase 3 NefIgArd trial. The NefIgArd trial is expected to conclude in the third quarter of 2023 when the final 29 patients in China (not required for global submission purposes) have completed nine months of treatment and 15 months of observation. Although we believe we have implemented strategies to minimize the impact of the COVID-19 pandemic to our business, we expect that we may experience delays with respect to the initiation and conduct of our clinical trials involving setanaxib. The extent to which COVID-19 continues to impact the timing of these additional trials will depend on ongoing developments to contain and treat the disease and the ability of hospitals and trial sites to conduct trials in different geographic locations, which remains somewhat uncertain. We will continue to evaluate the impact of the COVID-19 pandemic to our business.

The Russian-Ukraine military conflict, the resulting armed conflict and retaliatory measures by the global community have created global security concerns, including the possibility of expanded regional or global conflict, which have had, and 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, including patient enrollment. Although we do not have any direct operations in Ukraine or Russia, our collaborators and other third parties upon which we relay may have operations that could be directly and significantly impacted by this armed conflict. Delays in research activities, supply chain or clinical trials could increase associated costs and, depending upon the duration of any delays, require us to find alternative suppliers or providers at additional expense. In addition, this armed conflict has had significant ramifications on global financial markets, which may adversely impact our ability to raise capital on favorable terms or at all.

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 is expected to conclude in the third quarter of 2023 when the final 29 patients in China (not required for global submission purposes) have 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. Continued approval for the approved indication may be contingent upon verification and description of clinical benefit in the confirmatory part of the trial.

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 urine protein-to-creatinine ratio (UPCR) ≥1.5 gram/gram. On February 1, 2023, the MHRA granted Conditional Marketing Authorization for Kinpeygo for the same indication as the EC.

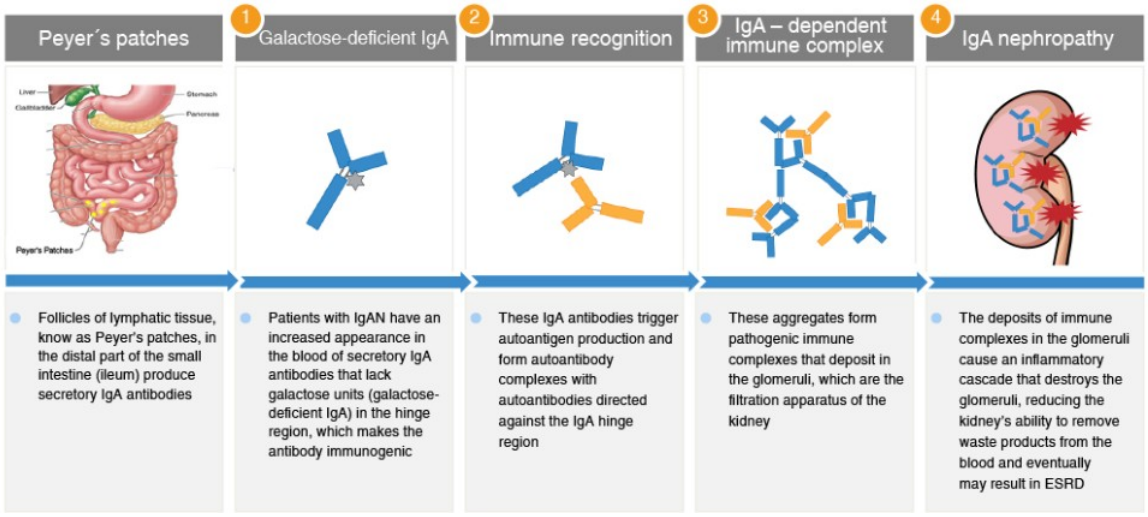
Nefecon has been granted seven years orphan drug exclusivity in the United States and ten years orphan market exclusivity by the EC and by the MHRA. Since the approval of TARPEYO in the United States in December 2021, we have been commercializing TARPEYO independently in the United States through a targeted 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, Switzerland and the UK. 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 (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), a standard clinical assessment classification system used to predict risk for progression of kidney disease, 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.

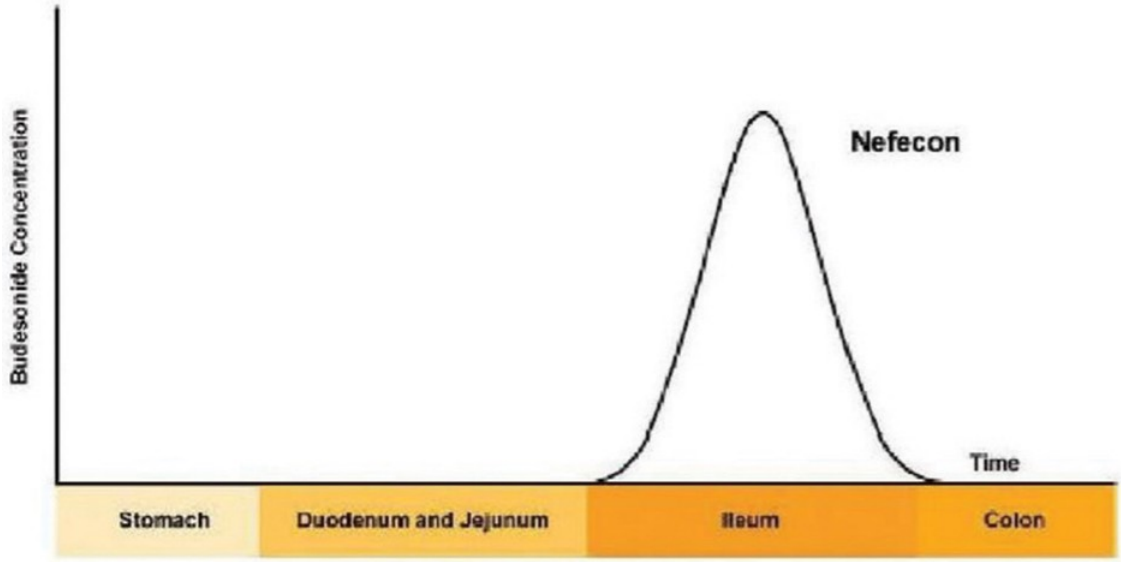
The seriousness of these adverse events in patients with IgAN has been documented in two independent clinical trials investigating the safety and efficacy of systemic corticosteroids monotherapy and in combination with immunosuppressives. In the Therapeutic Evaluation of Steroids in IgA Nephropathy Global, 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.

On February 17, 2023, the FDA approved Travere Therapeutics, Inc.'s FILSPARI (sparsentan), under accelerated approval to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR ≥1.5gram/gram. This approval was granted based on positive proteinuria results from the Phase III trial with no supportive eGFR being presented. Continued approval of FILSPARI may depend on long term eGFR confirmatory data from this study. Due to risks of liver injury and birth defects, FILSPARI has a boxed warning and will only be available through an FDA mandated Risk Evaluation and Mitigation Strategy (REMS) program, 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. FILSPARI also requires that patients, prior to initiating treatment, discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs) or aliskiren.

Our Solution: Nefecon

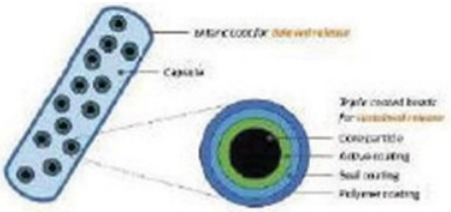
Nefecon is a proprietary, novel oral, formulation of budesonide, designed to deliver budesonide to the ileum of the small intestine, where the Peyer's patches are concentrated. Budesonide is a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial 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. In addition, Nefecon has been granted orphan drug exclusivity in the United States until December 15, 2028 (seven years from our initial FDA approval in December 2021). Nefecon has also been 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 are currently conducting a global pivotal Phase 3 clinical trial in IgAN, which we refer to as NefIgArd. NefIgArd is 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, and we reported positive topline data in March 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 is 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, is informative of 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 in order 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, NefIgArd has enrolled a total of 366 patients in the global study.

NeflgArd Part A Results

We reported Part A topline results in November 2020. The complete Part A 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 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 m2 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 m2 for Nefecon 16 mg versus -7.52 mL/min/1.73 m2 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.

The NefIgArd trial is expected to conclude in the third quarter of 2023 when the final 29 patients in China (not required for global submission purposes) have completed nine months of treatment and 15 months of observation.

Open-Label Extension Trial

We have initiated an open-label extension trial or the OLE trial, for eligible patients who have completed treatment in Part A and Part B of NefIgArd. 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.

Nefecon Phase 2 Clinical Trial (NEFIGAN Trial)

In 2015, we completed a double-blind, placebo-controlled clinical trial, known as NEFIGAN, in 153 adult patients. In this trial, patients were randomized to receive either 8 mg or 16 mg per day of Nefecon or placebo, each on top of optimized RAS blockade to lower blood pressure, the predominant current standard of care. This trial involved 62 sites across ten countries in Europe, and was at the time the largest double-blind trial ever conducted with an investigational candidate in IgAN patients.

The primary endpoint of mean reduction in proteinuria as measured by UPCR was achieved during the planned predefined analysis, and under the predefined protocol, no further analysis of the primary endpoint was to be conducted.

In this trial, Nefecon was also observed to statistically significantly reduce proteinuria and to provide clinical benefit by preserving kidney function, as measured by eGFR, which is considered a key metric for measuring kidney disease progression. NEFIGAN achieved its primary endpoint of reduction in proteinuria at a pre-defined interim analysis for both the combined 16 mg/day + 8 mg/day dose groups compared to placebo (p=0.0066) (the primary objective) and the 16 mg dose cohort compared to placebo (p=0.0092). As measured by UPCR, patients in the placebo cohort exhibited an increase in proteinuria of 2.7%, while patients in the 16 mg dose cohort exhibited statistically significant and clinically meaningful reductions in proteinuria of 27.3%. Results were consistent at the final analysis.

Nefecon was observed to be generally well tolerated. We observed no clinically meaningful changes in blood pressure, body weight or hemoglobin A1C, a measure of blood sugar metabolism, from baseline, and there were no serious infections reported in the trial. Only four possibly drug-related serious adverse events were reported, one in each of the 8 mg and 16 mg cohorts, and two in the placebo cohort (which classification was made by the investigator at the time when the safety results were blinded). Adverse events observed in NEFIGAN were consistent with those known to be associated with budesonide. Most of the patients who discontinued treatment experienced mild to moderate symptoms including, most frequently, acne and other transitory cosmetic side effects.

Nefecon Phase 2a Clinical Trial

In 2010, we completed a single-cohort, open-label Phase 2a clinical trial in which six biopsy-confirmed IgAN patients received 8 mg of Nefecon orally daily for six months, with a three-month follow-up period after discontinuation of treatment. The primary objective was an assessment of the effect of Nefecon on protein albumin in the urine, or albuminuria, which is a sign of kidney disease, and the secondary objective was to evaluate the effect of Nefecon on eGFR. Patients in this trial had a mean reduction in albuminuria of 23% at the end of treatment, with a further reduction to 40% two months after the end of treatment, and an increase in eGFR of 8%.

Nefecon was observed to be well tolerated, with no serious adverse events reported. Of the adverse events reported, 76% were classified as mild and 24% were classified as moderate. Three patients withdrew from the trial due to adverse events.

Regulatory 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 EC granted conditional marketing authorization for Kinpeygo on July 15, 2022 and our licensee STADA announced commercial availability in Germany in September 2022. On February 1, 2023, the MHRA granted Conditional Marketing Authorization for Kinpeygo.

TARPEYO has been granted orphan drug exclusivity in the United States and Kinpeygo has been granted market exclusivity in the EEA and Great Britain.

The FDA accelerated approval of TARPEYO is based on evaluation of the surrogate endpoint of proteinuria reduction. Continued approval for the approved indication may be contingent upon verification and description of clinical benefit in the confirmatory part of the trial. The EC and the MHRA apply a similar approach via the conditional approval pathway in the EU and Great Britain.

We believe that the topline results from the NefIgArd trial support filing for a full approval for adult patients with primary IgAN based on the Phase 3 study population, and we plan to file for such approval with the FDA, during 2023.

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 60 experienced rare disease account managers, focused on the approximate 4,000 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.

In July 2021, we entered into a license agreement with STADA to commercialize Nefecon for the treatment of IgAN in the EEA, Switzerland and the UK. STADA is commercializing the product under the brand name Kinpeygo. STADA announced commercial availability of Kinpeygo in Germany in September 2022.

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 (H2O2).

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. Our lead product candidate setanaxib inhibits NOX1 and NOX4, enzymes which are implicated in inflammation and fibrosis pathways.

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 have initiated a Phase 2b/3 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.

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 have initiated a Phase 2b/3 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.

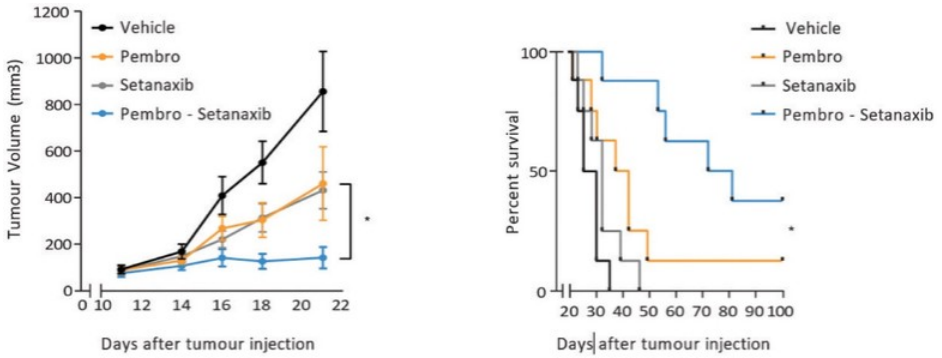
Based on the positive data from the Phase 1 trial of setanaxib doses up to 1600 mg/day, we have initiated a 52-week, randomized, placebo-controlled, double-blind trial in PBC with an adaptive Phase 2b/3 design, incorporating higher doses than previously used in the Phase 2 trial and using a composite biochemical response that includes the change in ALP as a primary endpoint. The first patient was randomized in this trial in February 2022. Setanaxib will be administered to approximately 318 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to UDCA in a global trial conducted in up to 150 investigational centers. 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 1200mg/daily and 1600mg/daily. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in the first half of 2024, subject to recruitment rate, and will determine which dose of setanaxib will be used for the Phase 3 part of the study.

Setanaxib – SCCHN

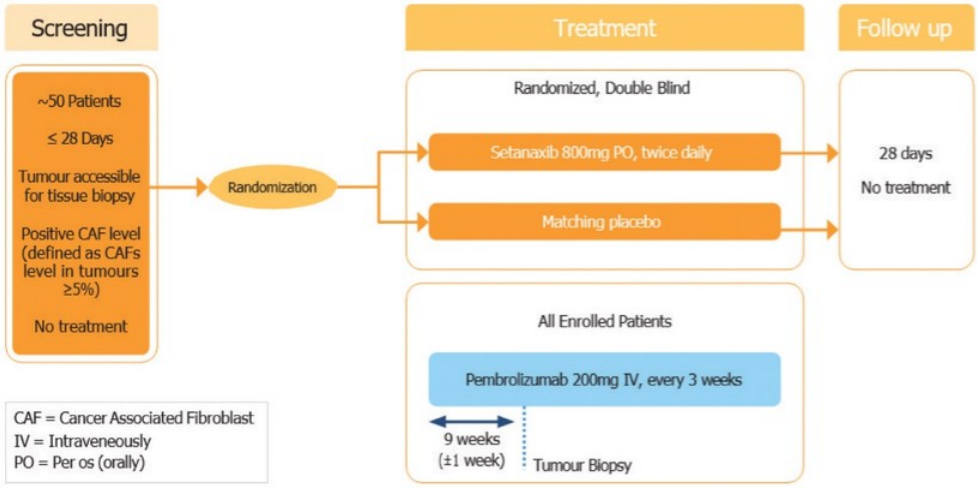
We also intend to evaluate setanaxib in head and neck cancer, building on promising *in vivo* preclinical data that suggests that setanaxib could function as an adjunct therapy to immune-oncology therapies. The response to immuno-oncology therapies can be affected by the tumor microenvironment, in particular 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 likely involve approximately 50 patients. The first patient was randomized in the second quarter of 2022, with an interim biomarker readout expected in mid-2023.

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 (lenticonus). There are no approved treatments today, with RAS inhibitors used as supportive care.

Based on supportive pre-clinical data generated during 2022, we plan to initiate a Phase 2a study with setanaxib in about 20 patients with Alport syndrome in the second quarter of 2023. 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 for which the enrollment of a first patient was announced in September 2020.

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.

Our Product Candidate: Budenofalk for the Treatment of Autoimmune Hepatitis

We have exclusively in-licensed Budenofalk 3 mg oral capsules for the US market from Dr. Falk Pharma GmbH, or Falk Pharma. Budenofalk is a formulation of budesonide originally developed to treat Crohn’s disease. Our license covers all indications for the United States market, excluding orphan indications outside of liver targets.

Budenofalk has been tested in a large, randomized, controlled clinical trial in AIH patients and is approved for the treatment of AIH in several countries in Europe, but there has been no clinical development or regulatory approval in the United States. In addition, Budenofalk has been approved for the treatment of Crohn’s disease and acute episodes of collagenous colitis in several countries in Europe, but regulatory approval was never pursued in the United States. We therefore believe Budenofalk also has the potential to address AIH for patients in the United States. We have received orphan drug designation for the treatment of AIH using budesonide by the FDA. We have discussed the development plans with the FDA for AIH since 2020, but additional interaction is required before establishing any definitive clinical development plans. We are conducting additional investigations in preparation for FDA interactions during 2023 to address outstanding questions and assess the potential of seeking approval of Budenofalk for AIH in the United States through the Section 505(b)(2) approval pathway.

AIH Disease Background

AIH is a rare disease associated with chronic inflammation of the liver. Based on current knowledge of AIH’s pathophysiology, the origin of the autoimmune response is believed to be production of cytotoxic T-cells and B-cell derived autoantibodies directed towards liver cells or its components, resulting in inflammation of the liver cells that eventually destroys the cell and leads to fibrosis. AIH often presents as a slow progressing disease of the liver, leading to cirrhosis at variable rates with complications such as liver failure and liver cancer. Typical symptoms are fatigue, abdominal discomfort, jaundice, enlarged liver, skin rashes, joint pains and, in women, loss of menstruation. Some patients have no obvious symptoms and are diagnosed based on liver problems identified during routine blood tests. AIH is an orphan disease and based on its known prevalence rates, we estimate that there are approximately 50,000 to 80,000 patients in the United States. The annual incidence of AIH ranges from 0.1 to 1.9 cases per 100,000 in the United States. The disease is at least three times as common in women as in men and can occur at any time during life.

Current Treatments for AIH

There are currently no approved therapies for treatment of AIH in the United States. The standard of care includes immunosuppressive systemic corticosteroids, typically prednisone, alone or in combination with azathioprine. A common treatment strategy using systemic corticosteroids is to use a high-dose induction period followed by a lower-dose maintenance therapy. The clinical outcome target is to prevent development of cirrhosis or prevent progression if cirrhosis has occurred. Many patients respond well to standard of care and achieve disease remission, in which case the prognosis is favorable. However, up to 80% of treated patients report steroid-related side effects after two years and 15% discontinue treatment due to drug-related adverse events. Furthermore, 50% to 90% of patients relapse if treatment is stopped. In addition, the high risk of adverse events in some patient groups (where systemic steroid treatment may be contraindicated) such as patients with osteoporosis, hypertension, diabetes or underlying mental illness, results in non-treatment, which leads to an increased risk of cirrhosis. Given the high rates of standard-of-care treatment adverse events and high rates of relapse after discontinuation of standard-of-care treatment among AIH patients, there is a significant unmet need among AIH patients.

Our Solution: Budenofalk

Based on our current knowledge of AIH's pathophysiology, we believe that targeted exposure to budesonide in the liver may counteract the original autoimmune response that is believed to drive AIH, as well as the inflammation resulting from the damage to the liver cells. Budenofalk was studied in a randomized clinical trial and was observed to have greater clinical activity and fewer side effects compared to treatment with systemic corticosteroids, which may drive patient compliance and improve outcomes. We believe that Budenofalk has the potential to address the significant unmet medical need to improve outcomes for AIH patients for whom there are no currently approved therapies in the United States.

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 2022, Everest has paid us an aggregate of $13.0 million in regulatory milestones, and is required to pay us additional milestone payments of up to $95.0 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, STADA has paid the initial upfront payment 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. 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.

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 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 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.

TARPEYO was the first ever FDA approved therapy for the treatment of IgAN. In February 2023, the FDA 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 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) because of these risks. 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. FILSPARI was developed and is commercialized by Travere Therapeutics, Inc. (previously Retrophin Inc.).

We are aware that other companies are developing product candidates for IgAN, including product candidates in Phase 3 clinical development. Omeros Corporation is developing narsoplimab, a monoclonal antibody administered through intravenous infusion. Chinook Therapeutics, Inc. has initiated enrollment in a Phase 3 trial with an orally administered small molecule, atrasentan. Novartis AG is developing iptacopan (LNP023), an orally-administered small molecule and haves announced that they also started a Phase 3 trial, and finally Otsuka Holdings (US; originator Visterra, Inc.) has initiated a Phase 3 trial with sibeprenlimab (VIS649), an intravenous monoclonal antibody. Additional compounds are in earlier stages of development.

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 in Phase 3 clinical development by Cymabay Therapeutics Inc, and GENFIT SA. Intercept Pharmaceuticals, Inc, and Zydus Pharmaceuticals (USA) Inc. also have projects exploring PPAR agonists but are in Phase 2 development. Novartis AG is conducting Phase 3 development of linerixibat, a sodium-bile acid cotransport inhibitor, for 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 regards 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.

With regards 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 implementing legislation of EU Member States. The CTR is 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. If authorized, those 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. 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. This timeframe may be extended by the CHMP if it deems it necessary to address issues arising during the assessment process. 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 is identical to 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 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 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 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. It is anticipated that the EC will submit 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. Although general requirements for advertising and promotion of medicinal products are established under EU directives, 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, as approved by the competent 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. Direct-to-consumer advertising of prescription medicinal products is also 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 that might be 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. 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 our product candidates or a decision by a third-party payor to not cover our product candidates could reduce physician usage of the product candidates 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.

In December 2021 the EU Parliament adopted the HTA regulation which, when it enters into application in 2025, 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.

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 agree to offer 50% (increased to 70% as of January 1, 2019 pursuant to the Bipartisan Budget Act of 2018) 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. Further, prior to the US Supreme Court ruling on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. 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 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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 will 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. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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.

Brexit and the Regulatory Framework in the UK

Following the result of a referendum in 2016, the UK (UK) left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020 (the Transition Period) during which EU rules continued to apply. The UK and the EU have signed an EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU's relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice, or GMP, inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extended to procedures such as batch release certification.

Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as 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. As part of the TCA, the EU and the UK will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the EC. Since January 1, 2021, an applicant for a centralized procedure marketing authorization can no longer be established in the UK. Since this date, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures to obtain an MA to market products in the UK. Until 31 December 2023, the MHRA may rely on a decision taken by the EC on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing authorization; or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in EU Member States through decentralized and mutual recognition procedures to be granted in the UK or Great Britain. The MHRA has been updating various aspects of the regulatory regime for medicinal products in the UK. These include: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and facilitate patient access for innovative medicinal products; updates to the UK national approval procedure, introducing a 150-day objective for assessing applications for marketing authorizations in the UK, Great Britain and Northern Ireland and a rolling review process for marketing authorization applications (rather than a consolidated full dossier submission).

Orphan designation in Great Britain following Brexit is, unlike in the EU, not available pre-marketing authorization. Applications for orphan designation are made at the same time as an application for a marketing authorization. The criteria to be granted an orphan medicinal product designation or essentially identical to those in the EU but based on the prevalence of the condition in Great Britain. It is therefore possible that conditions that were or would have been designated as orphan conditions in Great Britain prior to the end of the Transition Period are or would no longer be and that conditions that were not or would not have been designated as orphan conditions in the EU will be designated as such 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.

The Retained EU Law (Revocation and Reform) Bill 2022, which is currently progressing through the Parliament of the UK and seeks to allow the Government of the UK to repeal or replace certain EU law that was incorporated into the law of the UK effective as of the end of the transition period, increases the likelihood of further regulatory divergence between the EU and UK, which could lead to further disruption in the trade of goods between the UK and EU.

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, and if approved, proposed sales, marketing and education programs of our product candidates. 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. On December 2, 2020, the Office of Inspector General, or OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 1, 2023. We continue to evaluate what effect, if any, the rule will have on our business;

- 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.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business, including HIPAA, as amended by HITECH, and their implementing regulations, as well as the California Consumer Privacy Act of 2018, or the CCPA, which became effective on January 1, 2020. The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. The California State Attorney General has commenced enforcement actions against violators as of July 1, 2020. Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA implemented additional obligations with respect to processing and storing personal information that took effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Many of the state laws differ from each other in significant ways and are often not preempted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

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, 2022, we had 178 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 10,344 square feet of office space at this location, under one lease agreement, and our lease for this location extends through November 2024. 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, 2022, 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, 2022:

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%	Biopharmaceutical 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 10,344 square feet, located in Stockholm, Sweden. The lease for this facility expires in 2024.

We have a total of five facilities worldwide owned or leased as of December 31, 2022, as set forth in the following table:

Facility location	Use	Approx. size (m^2)	Lease expiry
Sweden	Principal office	961	November 2024
France	Laboratory	155	July 2029
Switzerland	Office	526	August 2027
US	Office	502	October 2026
US	Office	169	July 2026

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 name TARPEYO under accelerated approval on December 15, 2021 and we reported commercial availability in the United States in January 2022. 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. 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 urine protein-to-creatinine ratio ≥1.5 gram/gram on July 15, 2022 and our licensee STADA announced commercial availability in Germany in September 2022. On February 1, 2023, the MHRA granted Conditional Marketing Authorization for Kinpeygo for the same indication as the EC.

TARPEYO was the first ever treatment on 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.

Nefecon has been granted orphan drug exclusivity in the United States and orphan market exclusivity by the EC and the MHRA.

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/3 clinical trial, in which we randomized the first patient in February 2022. Setanaxib will be administered to approximately 318 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 up to 150 investigational centers. 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. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in the first half of 2024, subject to recruitment rate, and will determine which dose of setanaxib will be used for the Phase 3 part of the 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, in order to explore setanaxib's use as a treatment approach in cancers with high levels of tumors associated fibroblasts, or CAFs.

In addition, we have in-licensed Budenofalk 3 mg oral capsules and intend to develop Budenofalk in the United States for the treatment of autoimmune hepatitis, or AIH, subject to regulatory feedback. We discussed development plans with the FDA for AIH during 2020 and have refined our clinical approach during 2021 and 2022 with a target to arrive at a definitive clinical development plan in 2023, subject to further interactions with KOLs and the FDA.

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 Kreos and, more recently, from revenue from sales of TARPEYO. Through December 31, 2022, 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, 2022 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, 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, 2022 and 2021, we had a net loss of SEK 412.3 million and SEK 509.5 million, respectively. As of December 31, 2022 and 2021, we had an accumulated loss of SEK 1,836.3 million and SEK 1,426.6 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 operating losses for the foreseeable future, and we expect our expenses to increase in connection with our ongoing development and commercialization activities.

In June 2019 and March 2022, we received upfront payments from Everest in connection with the execution and expansion of the license agreement, as discussed below under "—License Agreement with Everest." We do not expect to generate substantial revenue from product sales or otherwise unless and until we successfully complete clinical development and successfully commercialize Nefecon or our other product candidates. In addition, we expect to incur significant expenses 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, 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 2022, Everest has paid us an aggregate of $13 million in regulatory milestones and is obligated to pay us additional milestone payments of up to $95 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."

Initial Public Offering

In June 2020, we completed an initial public offering of our American Depositary Shares 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 in the US IPO 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.

ATM Facility

In July 2022, we entered into an Open Market Sale Agreement[SM], or the Sales Agreement, with Jefferies LLC, or 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. Any such sales, made through our sales agent can be made by any method that is deemed an "at-the-market offering" as defined in Rule 415 promulgated under the Securities Act, or in other transactions pursuant to an effective shelf registration statement on Form F-3. We agreed to pay Jefferies a commission of up to 3.0% of the gross proceeds of any sales of ADSs sold pursuant to the Sales Agreement. As of the date of this report, we have not sold any shares pursuant to the Sales Agreement.

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 year ended December 31, 2022. 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. Revenue for license agreements are 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, 2022, 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 for the foreseeable future as we:

- continue to develop and advance Nefecon, setanaxib, and any other product candidates;
- initiate and continue clinical development for Nefecon or its active ingredient budesonide in other potential indications, and setanaxib for PBC, head and neck cancer and Alport syndrome;
- seek regulatory approval for Nefecon, setanaxib and/or any product candidates that successfully complete clinical trials;
- establish a distribution infrastructure and scale-up external manufacturing to commercialize Nefecon and setanaxib, if approved;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- add clinical and scientific personnel, including personnel to support our product development and potential future commercialization efforts;
- 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 the COVID-19 pandemic, 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, 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, 2022, we had SEK 3,562.4 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, 2022 and 2021

	Year ended December 31,	
	2022	2021
	(In thousands of SEK)	
Net sales	802,879	229,347
Cost of sales	(15,201)	—
Gross profit	787,678	229,347
Operating expenses	(1,209,621)	(753,803)
Research and development expenses	(414,749)	(357,485)
Marketing and selling expenses	(515,190)	(179,603)
Administrative expenses	(259,469)	(210,630)
Other operating income	2,862	259
Other operating expenses	(23,074)	(6,344)
Operating loss	**(421,943)**	**(524,456)**
Financial income	50,195	20,336
Financial expenses	(37,669)	(9,253)
Loss before taxes	**(409,417)**	**(513,373)**
Income taxes	(2,851)	3,836
Net loss for the year attributable to shareholders	**(412,268)**	**(500,293)**
Non-controlling interest	—	(9,244)
Loss per share before and after dilution, SEK	(7.78)	(9.84)

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.

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.

Comparison of Years Ended December 31, 2021 and 2020

	Year ended December 31,	
	2021	2020
	(In thousands of SEK)	
Net sales	229,347	874
Operating expenses	(753,803)	(380,594)
Research and development	(357,485)	(241,371)
Administrative and selling	(390,232)	(141,724)
Other operating income	259	2,501
Other operating expenses	(6,344)	—
Operating loss	**(524,456)**	**(379,720)**
Financial income	20,336	547
Financial expenses	(9,253)	(56,978)
Loss before taxes	**(513,373)**	**(436,151)**
Income taxes	3,836	(360)
Net loss for the year attributable to shareholders	**(500,293)**	**(433,494)**
Non-controlling interest	(9,244)	(3,017)
Loss per share before and after dilution, SEK	(9.84)	(9.66)

Net Sales

Net sales increased SEK 228.5 million for the year ended December 31, 2021 compared to the year ended December 31, 2020. The increase was mainly due to the out-licensing of Nefecon for EU as part of the license agreement with STADA.

Research and Development Expenses

Research and development expenses increased by SEK 116.1 million for the year ended December 31, 2021 compared to the year ended December 31, 2020. The increase was primarily due to increased cost for the setanaxib clinical trials of SEK 66.3 million and CMC development of setanaxib of SEK 14.4 million. Additionally, we recorded an impairment charge of SEK 28.0 million regarding the SIIL contract, which originated from the Genkyotex acquisition. As per recent information from SIIL, the product development has not developed as planned, and the project is not expected to generate future cash flows.

Selling and Administrative Expenses

Administrative and selling expenses increased by SEK 248.5 million for the year ended December 31, 2021 compared to the twelve months ended December 31, 2020. The increase was primarily due to a SEK 105.4 million increase in third party consultant costs engaged in pre-commercialization preparations for TARPEYO in the United States and a SEK 46.7 million increase in personnel costs engaged in pre-commercial preparations for TARPEYO in the United States. Additionally, we had a SEK 18.7 million increase in costs for our administration in the United States and a SEK 23.6 million increase in costs in Sweden for administration and infrastructure to support the U.S commercialization readiness.

Other Operating Income

Other operating income decreased by SEK 2.2 million for the year ended December 31, 2021 compared to the year ended December 31, 2020, primarily due to disadvantageous exchange rate development on operating liabilities.

For the year ended December 31, 2021, other operating expenses increased to SEK 6.3 million. The increase in other operating expenses for the year ended December 31, 2021 was primarily related to a more disadvantageous exchange rate development on operating liabilities and change in value of the contingent consideration at fair value for Genkyotex SA. No other operating expenses were recognized for the year ended December 31, 2020.

Financial Income/(Expense)

Financial income increased by SEK 19.8 million for the year ended December 31, 2021 compared to the year ended December 31, 2020, primarily due to increased unrealized foreign currency transaction gains on cash accounts. Financial expense decreased by SEK 47.7 million for the year ended December 31, 2021 compared to the year ended December 31, 2020, primarily due to less unrealized foreign currency transaction losses on cash accounts.

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 and, more recently, from revenue from sales of TARPEYO. In 2019, we recognized revenue in connection with the execution of the license agreement with Everest, in 2021, we recognized revenue in connection with the execution of the license agreement with STADA, and in 2022, we recognized revenue in connection with the execution of the license agreement with Viatris and additionally we have during this period received payments resulting from the satisfaction of regulatory and clinical milestones under such 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. 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, 2022, 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, 2022 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 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. 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 is 9% per annum with a maturity of December 2025. The loan agreement has no financial covenants. Other than the Kreos Capital loan 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.

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, 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.

Comparison for the Years Ended December 31, 2021 and 2020

The table below summarizes our cash flows for the years ended December 31, 2021 and 2020.

	Year ended December 31,		
	2021	2020	Variance
	(In thousands of SEK)		
Cash and cash equivalents at beginning of the period	**996,304**	**753,540**	**242,764**
Net cash flows (used in) / from operating activities	(461,588)	(309,181)	(152,407)
Net cash flows (used in) / from investing activities	(24,340)	(172,607)	148,267
Net cash flows (used in) / from financing activities	435,162	768,558	333,396
Net increase (decrease) in cash	(50,766)	286,770	(337,536)
Exchange-rate difference in cash	9,969	(44,006)	53,975
Cash and cash equivalents at end of the period	**955,507**	**996,304**	**(40,797)**

Operating Activities

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.

During the year ended December 31, 2020, net cash used in operating activities was SEK 309.2 million, primarily resulting from our operating loss of SEK 379.7 million and negative net cash changes in our operating assets and liabilities of SEK 54.1 million. Net changes in our operating assets and liabilities for the year ended December 31, 2020 consisted mainly of a SEK 46.6 million increase in account receivables due to the timing of payments associated with the license agreement with Everest.

Investing Activities

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.

During the year ended December 31, 2020, net cash used for investing activities was SEK 172.6 million for the acquisition of shares in Genkyotex SA.

Financing Activities

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 draw down 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.

During the year ended December 31, 2020, net cash provided by financing activities was SEK 768.6 million, mainly consisting of net SEK 795.5 million from our IPO in the United States and SEK 59.3 million from exercise of warrants less SEK 82.1 million used for acquisition of shares in Genkyotex SA in a simplified public mandatory cash offer.

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, 2022 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 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 obligation primarily comprises our leased premises. The total lease obligations for 0-5 years were SEK 39.1 million as of December 31, 2022. The lease agreements for leased premises have terms ending from 2023 until 2026 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 is 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 is 9% per annum with a maturity to December 2025. The loan has no financial covenants. As of December 31, 2022, the amount we have drawn down on the loan facility was USD 75.0 million.

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 and Dr. Falk Pharma

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.

Additionally, pursuant to our agreement with Dr. Falk Pharma, we may incur future potential milestone payments totaling up to €37.0 million upon our achievement of specific regulatory and commercial milestones, as applicable and royalties on annual net sales of licensed products at a low- to mid-teens percentage, subject to reductions in certain circumstances, on annual net sales of licensed products. These royalty payments are subject to certain minimum annual dollar requirements in the amount of six to seven figures.

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, 2022 to December 31, 2022 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, 2020, 2021, and 2022, 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.

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. Ahead of the 2023 annual general meeting, the nomination committee has proposed that our board of directors shall comprise six members.

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, 2022:

Name	Age	Position
Elmar Schnee	63	Chairman of the Board of Directors
Hilde Furberg	64	Director
Diane Parks	70	Director
Molly Henderson	52	Director
Henrik Stenqvist	55	Director
Elisabeth Björk	61	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.

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 Manger/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, OncoZenge, Bio-Me, Herantis Pharma, and Sedana Medical. Ms. Furberg previously served on the board of directors of Tappin AS, 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 CTI Biopharma, TriSalus Life Sciences, Kura Oncology, Inc. 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.

Molly Henderson has served as a member of our board of directors since June 2020. Currently, Ms. Henderson is the Chief Financial and Business Officer at Phathom Pharmaceuticals (Nasdaq PHAT) since April 2022. Prior to that role, Ms. Henderson was Chief Financial Officer of UroGen Pharma LTD (Nasdaq URGN), from October 2020 to March 2022 and Chief Financial Officer, Executive Vice President and Corporate Secretary at Advaxis, Inc. from June 2018 to September 2020. Prior to serving at Advaxis, Inc., Ms. Henderson was Chief Financial Officer at Iovance Biotherapeutics, Inc. (formerly Lion Biotechnologies, Inc.) from June 2015 through August 2016. Ms. Henderson also served as the Chief Business and Financial Officer, Senior Vice President of VirtualScopics, Inc., a public company provider of imaging solutions to the pharmaceutical, biotechnology, and medical device industries, from May 2008 to August 2013, and as that company's Chief Financial Officer from May 2003 to May 2008. From 2013 to 2015, Ms. Henderson relocated to Europe, during which time she advised start-up companies in Switzerland. Earlier in her career, Ms. Henderson served as the Corporate Controller of Ultralife, Inc., a publicly-held provider of high performance lithium battery solutions. Prior to serving at Ultralife, Inc., Ms. Henderson was a Manager in the audit division of PricewaterhouseCoopers LLP. Ms. Henderson received her M.B.A. and B.S. degrees from the State University of New York at Buffalo.

We believe that Ms. Henderson is qualified to serve on our board of directors because of her 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. Currently, Dr. Bjork is the Senior Vice President and Global Head of late-phase development for Cardiovascular, Renal and Metabolism (CVRM) at AstraZeneca, and assumes overall accountability for development strategy and delivery across AstraZeneca's CVRM portfolio. 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, Chalmers Ventures, Rocket Pharmaceuticals, and Pharvaris NV.

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.

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, Finance Director at Astra Export & Trading and board member of MedCap AB. Mr. Stenqvist received his M.B.A. and bachelor's degree from the University of Linköping. Mr. Stenqvist previously served as a board member of MedCapAB, and is a current board member of Midsona AB.

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, 2022)

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	4	2	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, 2021 can be found in our Annual Report on Form 20-F for the year ended December 31, 2021, filed with the SEC on April 27, 2022.

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, 2022:

Name	Age	Position
Renée Aguiar-Lucander	60	Chief Executive Officer
Fredrik Johansson	45	Chief Financial Officer
Richard Philipson, M.D.	58	Chief Medical Officer
Andrew Udell	52	President, North America
Frank Bringstrup, M.D.	63	Vice President Regulatory Affairs

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.

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 has served as our Chief Medical Officer since July 2020. Dr. Philipson is a physician with 24 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 Member of the Royal College of Physicians and Fellow of the Faculty of Pharmaceutical Medicine.

Andrew Udell has served as our President, North America since May 2021. He previously served as Head of North America, Commercial from July 2020 to May 2021 and as Vice President, US Commercial from January 2019 to July 2020. Prior to joining us, from March 2017 to June 2018, he served as Vice President North America Commercial at NeuroDerm, LTD, a biotechnology company. Mr. Udell also served as the Principal at Andrew B. Udell Consulting LLC, a marketing consulting company, from May 2012 to January 2019. Prior to that, Mr. Udell held several sales and marketing positions in the pharmaceutical industry. Mr. Udell received his BSc from Lehigh University and his M.B.A. from the University of Connecticut.

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.

Jonathan A. Schur, J.D., has served as our Group General Counsel since October 2020. Prior to joining Calliditas, Mr. Schur was a Partner in the Life Sciences practice group at Goodwin Procter LLP, and before that a partner and co-managing partner of the Paris Office of Dechert LLP. Mr. Schur received his A.B. from Harvard College and his J.D. from Harvard Law School, and is a member of the New York Bar and a former member of the Paris Bar.

Sandra Frithiof has served as our Head of Human Resources since May 2020. She previously served as Head of Human Resources and COO at Ramberg Advokater. Prior to that, Ms. Frithiof held several human resource positions at Karolinska University Hospital, UTC, CGI and Manpower Group. Ms. Frithiof received a Bachelor’s Degree in Human Resource Management from Örebro University, Sweden.

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, 2022, the aggregate compensation accrued or paid to the members of our board of directors and executive officers serving during the year was SEK 41.6 million.

During and for the year ended December 31, 2022, our executive officers had performance-based compensation programs and amounts paid to provide pension and healthcare benefits.

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

Warrant Programs

We have established two warrant programs, as an incentive for our employees and consultants: the 2018/2022 Warrant Program, or the 2018 Program and the 2019/2022 Warrant Program, or the 2019 Program. We refer to the 2018 Program and the 2019 Program as the Programs. Warrants are issued by the board in accordance with authorizations given to it by our shareholders. Each warrant issued under the Programs entitle the holder to subscribe for shares at a specified exercise price during a specified subscription period. The material terms of the Programs are summarized below.

No further awards will be issued under either the 2018 Program or 2019 Program.

2018/2022 Warrant Program

In 2018, our shareholders approved the 2018 Program to permit the issuance of warrants to purchase up to 1,160,000 common shares to our certain employees and consultants. In March 2022, all 856,586 warrants were exercised.

2019/2022 Warrant Program

In 2019, our shareholders approved the 2019 Program to permit the issuance of warrants to purchase up to 1,160,000 common shares to certain of our employees and consultants. In December 2022, all 422,500 warrants were exercised.

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, 2022, options to purchase up to an aggregate of 1,371,666 common shares were outstanding. Eligible participants in the ESOP 2020 include our executive officers, employees and consultants. The ESOP 2020 Program is closed, 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 1,479,500 common shares were outstanding. Eligible participants in the ESOP 2021 include our executive officers, employees and consultants. We have initially reserved options to purchase up to a maximum of 1,500,000 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 2021 annual general meeting and the date of the 2022 annual general meeting to up to 40 employees or consultants of the Company. The maximum allocation per individual in each category shall be 400,000 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 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, 2022, options to purchase up to an aggregate of 1,101,000 common shares were outstanding. Eligible participants in the ESOP 2022 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 2022 annual general meeting and the date of the 2023 annual general meeting to up to 100 employees or consultants of the Company. 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 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.

LTIP 2019

On May 8, 2019, our shareholders approved the Board Long Term Incentive Program 2019, or the LTIP 2019, to permit the grant of performance-based share awards, or Share Awards, to certain of our board members. Pursuant to the terms of the LTIP 2019, 51,399 Share Awards were granted. In July 2022, all 51,399 share awards were exercised.

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. 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 2020, subject to the board member's continued service through the applicable vesting date. Share Awards granted under the LTIP 2020 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 2020, 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 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, 2022, 24,244 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, 2022, 40,706 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.

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)	12/12	—	4/4
Elisabeth Björk (from May 2022)	7/8	—	2/2
Hilde Furberg	12/12	7/7	—
Lennart Hansson (until May 2022)	4/4	2/2	2/2
Molly Henderson	12/12	5/7	—
Diane Parks	11/12	—	4/4
Henrik Stenqvist	4/8	2/5	—

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 Molly Henderson, 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 Molly Henderson 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 seven times in the course of 2022. At these meetings, the main points of discussion were review of the 2021 financial statements, Ernst & Young AB's 2021 audit report, 2022 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 2023 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 four times over the course of 2022. The main topics of discussion were management performance reviews, allocation of share-based incentive programs, and 2022 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 2022 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 2023 annual general meeting, the nomination committee consists of Patrick Sobocki (appointed by Stiftelsen Industrifonden), Jan Särlvik (appointed by Fjärde AP-fonden), 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 expect to voluntarily follow most 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;

- 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."

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 28, 2023 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 28, 2023. The percentage ownership information shown in the table is based upon 59,580,087 common shares outstanding as of February 28, 2023.

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 28, 2023. 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 LP[(1)]	6,260,311	10.5 %
Linc AB[(2)]	5,962,312	10.0 %
Stiftelsen Industrifonden [(3)]	3,324,035	5.6 %
Executive Officers and Directors:		
Renée Aguiar-Lucander[(4)]	643,000	1.1 %
Fredrik Johansson[(5)]	42,750	*
Richard Philipson, M.D.	—	—
Andrew Udell[(6)]	26,000	*
Frank Bringstrup, M.D.[(7)]	8,500	*
Elmar Schnee[(8)]	33,236	*
Hilde Furberg[(9)]	53,199	*
Diane Parks[(10)]	8,449	—
Molly Henderson[(11)]	100	*
Elisabeth Björk	—	—
Henrik Stenqvist[(12)]	10,000	*
All directors and executive officers as a group (11 persons)	825,234	1.4 %

* 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) Based on information provided by Linc AB in a Schedule 13G filed with the Securities and Exchange Commission on March 2, 2022. 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 3,380,440 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.

(5) Consists of 42,750 common shares.

(6) Consists of 26,000 common shares.

(7) Consists of 8,500 common shares.

(8) Consists of 33,236 common shares.

(9) Consists of 53,199 common shares.

(10) Consists of 8,449 common shares.

(11) Consists of 100 common shares.

(12) Consists of 10,000 common shares.

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 28, 2023, 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 28, 2023. 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, 2022, assuming that all of our common shares represented by ADSs are held by residents of the United States, we estimate that approximately 15.4% of our outstanding common shares were held in the United States by approximately 18 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, 2022, 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.

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.

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

Consolidated financial statements

The consolidated financial statements are included as part of this annual report, starting at page F-1.

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.

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.

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 granted by the company. 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 (such as interest income); or

- at least 50% of its gross assets (determined on the basis of a quarterly weighted average) is attributable to assets that produce passive income or are held for the production of passive income.

We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other entity treated as a corporation or partnership for US federal income tax purposes, the equity of which we own, directly or indirectly, 25% or more (by value).

Based on our analysis of our income, assets, activities and market capitalization for our taxable year ending December 31, 2022, we do not believe that we were a PFIC for our taxable year ending December 31, 2022. 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 becoming a PFIC for our current taxable year or any future taxable years. 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, a 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 do not intend to 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 stay in Sweden for six consecutive months 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 current 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 7.1 million and SEK (1.6) million for the years ended December 31, 2022 and 2021, 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 46.6 million and SEK 20.2 million for the years ended December 31, 2022 and 2021, respectively. These foreign currency translation 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, 2022, 2021 and 2020.

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 %

Currency Exposure 2020 ()%	Revenue	Operating expenses
USD	100 %	35 %
EUR	—	36 %
GBP	—	6 %
SEK	—	23 %

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 23.1 million, SEK 0.9 million and SEK 10.2 million for the years ended December 31, 2022, 2021 and 2020, respectively. A 10% stronger US dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 9.6 million for the year ended December 31, 2022, a negative impact on profit after tax and equity of approximately SEK 22.4 million for the year ended December 31, 2021 and a positive impact of SEK 10.0 million for and the year ended December 31, 2020.

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, 2022 and 2021, we had SEK 713.0 million and SEK 189.2 million in debt outstanding, respectively. As of December 31, 2020, we had no debt outstanding. 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. The loan has no financial covenants.

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.

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, 2022. 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.

With the exception of a previously identified material weakness regarding impairment of goodwill and other intangible assets, which has been remediated, based upon our evaluation as of December 31, 2022, our Chief Executive Officer and Chief Financial Officer have concluded that 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, 2022, 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.

Entity-Level Control Environment

The entity-level control environment did not adequately support the prevention or detection and correction of material misstatements. We identified deficiencies in four of the five components of the entity-level control environment, aggregating to material weaknesses in each component:

Control Environment – We did not adequately maintain an environment that sufficiently stressed the importance of internal controls and the emphasis placed on them in determining the company's policies, processes, and organizational structure. We did not have adequate discipline, structure, and training within the company to influence the control consciousness of the company's personnel. We did not have sufficient oversight over the company's financial reporting process and internal control environment, nor did we sufficiently analyze control deficiencies to identify trends and root causes and evaluate whether modification of certain policies, communications, training or controls was necessary.

Control Activities – We did not sufficiently design, implement, and maintain control activities at the transaction level that mitigate the risk of material misstatement in our financial reporting, resulting in the transaction-level material weaknesses described below. We did not develop policies and procedures at a sufficient level of precision to support the operating effectiveness of the controls, nor did we sufficiently emphasize the need to retain the required documentation to demonstrate and ensure that controls consistently operated at a sufficient level of precision to prevent and detect potential errors.

Information and Communication – We did not design and implement sufficient procedures, as part of the aforementioned control activities, to validate the completeness and accuracy of underlying data used in the performance of controls over accounting transactions and disclosures.

Monitoring – We did not allocate sufficient and qualified resources to design and execute effective monitoring of the company's internal controls to ascertain if the components of internal control were present and functioning. In addition, we did not perform effective monitoring over the timely remediation of identified control deficiencies, including deficiencies related to segregation of duties.

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 journal entry approvals and processing; 2) share-based payments; 3) income taxes; and 4) the completeness of certain underlying key sources of data used to perform control procedures.

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 occurrence of milestone revenue, cash receipts, and management review of gross-to-net models.

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, authorization levels, and disbursements; and 2) the completeness of certain accounts payable and expense accruals.

Payroll

We did not appropriately document the execution of the controls over the recording of payroll and related expenses. Specifically, we did not adequately design or execute controls over certain aspects of payroll processing related to master data changes, payroll revisions, payroll processing, and management remuneration.

IT Processes

We did not adequately design and implement controls that address the IT risks of certain applications used in the company's business processes. Specifically, we did not adequately execute controls over 1) review and consideration of IT risks residing at service organization; 2) access management procedures; 3) application change management procedures; and 4) timeliness of segregation of duties access monitoring procedures.

Remediation Plan

We have initiated a remediation plan that includes steps to increase dedicated resources, improve reporting processes, and enhance related supporting technology. To that end, we have hired a dedicated US-based Internal Controls leader with risk management and Sarbanes Oxley experience, provided a first wave of training on SOX and how to properly execute and evidence control performance, and the importance of a strong internal control environment. We implemented a new solution for documenting our risks-related controls and their assertions to facilitate tracking and trend analysis of internal control deficiencies to support timely remediation. We have retained an outsourced team to perform independent testing of our internal controls throughout the year. We are committed to implement a robust 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 remediation process further includes, but is not limited to:

- Augmenting and hiring additional knowledgeable and qualified information technology, accounting and finance resources and professionals;
- Implementing a new payroll system across the organization to help address system limitations inherent within the current solution in Sweden;
- Enhancing the robustness and effectiveness of our IT systems and control environment;
- Further develop and improve the remediation plan for each of the material weaknesses, specifically enhancing related policies and process documentation, implementing new and/or re-designing existing controls, and improving the skills of the process owners;
- Evaluating the completeness and appropriateness of the remediation plan, and specifically verifying it addresses all the material weaknesses, both at the entity- and at the transaction-level, across all material locations and across all relevant departments;
- Implementing the remediation plan, and specifically training the process owners, evaluating the adoption of the revised policies and procedures, and monitoring the results;
- Increase the frequency and independent testing of the design and operating effectiveness of controls to help remediate internal control deficiencies quicker.

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, 2022, has been audited by Ernst & Young AB, an independent public accounting firm. Their report is included on page F-5.

D. CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

The previously identified material weakness related to the impairment of goodwill and other intangible assets has been remediated. Except for the remediation of this material weakness 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, 2022, 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, both Molly Henderson 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 2021 and 2022. Our accountants billed the following fees to us for professional services in each of those fiscal years:

Fees	Year Ended December 31, 2022	2021
	(in thousands of SEK)	
Audit Fees	13,369	6,235
Audit-Related Fees	3,370	2,105
Tax Fees	—	73
All Other Fees	—	—
Total	**16,739**	**8,413**

"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 2022 and 2021, "Audit-Related Fees" also include fees billed for assurance and audit-related services regarding our public offerings on Nasdaq.

"Tax Fees" are the aggregate fees billed for professional services rendered by the principal accountant for tax compliance, tax advice and tax planning related services.

"All Other Fees" are any additional amounts billed for products and services provided by the principal accountant. No other fees were paid to Ernst & Young AB for the fiscal years ended December 31, 2022 or 2021.

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 expect to voluntarily follow most 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;
- 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.

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

		Incorporated by Reference Schedule/			
Exhibit	**Description**	**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 2019	Form F-1	333-238244	10.6	05/14/2020
4.7#	Board Long Term Incentive Program 2020	Form F-1	333-252436	10.6	01/26/2021
4.8#	Board Long Term Incentive Program 2021	Form 20-F	001-39308	4.8	04/27/2022
4.9#*	Board Long Term Incentive Program 2022				
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				
4.15#*	ESOP 2022 United States Sub-Plan				
4.16#	Employment Agreement, by and between the Registrant and Renée Aguiar-Lucander, dated May 1, 2017	Form F-1	333-238244	10.8	05/14/2020
4.17#	Employment Agreement, by and between the Registrant and Fredrik Johansson, dated August 1, 2017	Form F-1	333-238244	10.10	05/14/2020
4.18#	Employment Agreement, by and between the Registrant and Frank Bringstrup, dated February 1, 2019	Form F-1	333-238244	10.11	05/14/2020
4.19#	Employment Agreement, by and between the Registrant and Andrew B. Udell, dated March 1, 2019	Form F-1	333-238244	10.12	05/14/2020
4.20#	Employment Agreement, by and between the Registrant and Katayoun Welin-Berger, dated September 17, 2019	Form F-1	333-252436	10.13	01/26/2021
4.21#	Employment Agreement, by and between the Registrant and Richard Philipson, dated March 26, 2020	Form F-1	333-252436	10.14	01/26/2021
4.22	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
4.23	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
4.24	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
4.25	Open Market Sale Agreement℠, dated June 28, 2022, by and between and between Calliditas Therapeutics AB and Jefferies LLC	Form F-3	333-265881	1.2	06/28/2022
4.26*†+	License Agreement between the Registrant and Viatris Pharmaceuticals Japan Inc., dated December 12, 2022				
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				

Exhibit	Description	Incorporated by Reference Schedule/ Form	File Number	Exhibit	File Date
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				
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				
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 26, 2023

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 26, 2023 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, 2022 the Group's revenues from product sales were SEK 375,515 thousands, and as stated in Notes 1 and 3, revenue from the sale of goods is calculated net of deductions including actual and estimated rebates to public payors and provisions for potential returns and prompt payment discounts. These estimates of variable consideration are affected by judgments made by management. A description of the judgements on which revenue recognition is based is provided in Note 2.

Auditing management's estimate of variable consideration was complex because the calculation involves subjective management assumptions about expected future events, including rebates to public payors, return rates, and prompt payment discounts. Changes in these assumptions can have a material effect on the amount of revenue recognized.

How We Addressed the Matter in Our Audit

To test the estimate of variable consideration, our audit procedures included, among others, evaluating management's methodology and significant assumptions, and performing analytical procedures to compare the estimates of the rebate distributions between different payor categories, expected future returns and prompt payment discounts, against actual results where available. 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. In addition, we involved our government pricing subject matter professionals to assist in evaluating management's methodology and calculations used to measure government rebates.

Valuation of intangible assets

Description of the matter

Intangible assets, including goodwill, amount to SEK 483,841 thousand as of December 31, 2022. As explained in Note 1, Note 2 and Note 15 of the consolidated financial statements, the Company performs an impairment assessment of intangible assets not yet available for use and goodwill, on an annual basis or when there is an indication that an asset may be impaired. The Company's evaluation of the carrying value 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, taking into account the development risk. Changes in assumptions used by management could have a significant impact on the recoverable amount.

The audit of the valuation of intangible assets was complex, due to the significant judgments made by management to estimate the recoverable amount, including assumptions related to the likely 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 valuation of intangible assets, which included, among others, evaluating management's methodology, 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 so doing, we compared these inputs to third-party statistical data for the clinical indications targeted and for other development projects within the industry.

With the assistance of our valuation specialists, we evaluated the discount rates used, by preparing independent estimates based on market and peer company observable data and comparing to those used by management.

/s/ Ernst & Young AB

We have served as the Company's auditor since 2004.

Stockholm, Sweden

April 26, 2023

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, 2022, 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, 2022, 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 in controls related to the Entity-level Control Environment, Financial Statement Close and Reporting Process, Net Sales, Accounts Payable, Accrued Expenses and Operating Expenses, Payroll, and IT Processes.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), consolidated statements of financial position of the Company as of December 31, 2022 and 2021, 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, 2022, 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 2022 consolidated financial statements, and this report does not affect our report dated April 26, 2023, 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

We have served as the Company's auditor since 2004.

Stockholm, Sweden

April 26, 2023

GROUP

Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31, 2022	2021	2020
Net sales	*3*	802,879	229,347	874
Cost of sales		(15,201)	—	—
Gross profit		**787,678**	**229,347**	**874**
Research and development expenses	*7,8,9,10*	(414,749)	(357,485)	(241,371)
Marketing and selling expenses	*7,8,9,10*	(515,190)	(179,603)	(38,964)
Administrative expenses	*6,7,8,9,10*	(259,469)	(210,630)	(102,760)
Other operating income	*4*	2,862	259	2,501
Other operating expenses	*5*	(23,074)	(6,344)	—
Operating loss	*7*	**(421,943)**	**(524,456)**	**(379,720)**
Financial income	*11*	50,195	20,336	547
Financial expenses	*12*	(37,669)	(9,253)	(56,978)
Loss before income tax		**(409,417)**	**(513,373)**	**(436,151)**
Income tax expense	*13*	(2,851)	3,836	(360)
Loss for the year		**(412,268)**	**(509,537)**	**(436,511)**
Attributable to:				
Equity holders of the Parent Company		(412,268)	(500,293)	(433,494)
Non-controlling interests		—	(9,244)	(3,017)
		(412,268)	**(509,537)**	**(436,511)**
Loss per share				
Before and after dilution to ordinary equity holders of the Parent Company	*14*	(7.78)	(9.84)	(9.66)

GROUP

Consolidated Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31, 2022	2021	2020
Loss for the year		**(412,268)**	**(509,537)**	**(436,511)**
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*	36,287	(20,111)	(9,352)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		**36,287**	**(20,111)**	**(9,352)**
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:				
Remeasurement gain on defined benefit plans	*28*	2,763	1,993	1,216
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods		**2,763**	**1,993**	**1,216**
Other comprehensive income/(loss) for the year		**39,050**	**(18,118)**	**(8,137)**
Total comprehensive loss for the year		**(373,218)**	**(527,655)**	**(444,648)**
Attributable to:				
Equity holders of the Parent Company		(373,218)	(519,189)	(438,343)
Non-controlling interests		—	(8,466)	(6,305)
		(373,218)	**(527,655)**	**(444,648)**

GROUP

Consolidated Statements of Financial Position

(SEK in thousands)	Note	December 31, 2022	2021
ASSETS			
Non-current assets			
Intangible assets	*15*	483,841	399,418
Equipment	*16*	7,468	6,309
Right-of-use assets	*8*	24,452	33,300
Non-current financial assets	*17,19,33*	11,210	3,915
Deferred tax assets	*18*	13,799	4,196
Total non-current assets		**540,770**	**447,138**
Current assets			
Inventories	*21*	3,647	889
Accounts receivable	*20*	78,703	—
Other current assets	*19*	10,018	11,343
Prepaid expenses and accrued income	*22*	70,741	45,032
Cash	*23*	1,249,094	955,507
Total current assets		**1,412,204**	**1,012,772**
TOTAL ASSETS		**1,952,973**	**1,459,910**
EQUITY AND LIABILITIES			
Equity	*25*		
Share capital		2,383	2,094
Additional paid-in capital		2,590,890	2,459,741
Reserves		9,307	(26,979)
Retained earnings including net loss for the year		(1,836,317)	(1,426,574)
Equity attributable to equity holders of the Parent Company		**766,264**	**1,008,281**
Non-current liabilities			
Provisions	*26*	11,792	14,530
Contingent consideration	*27*	75,880	54,399
Pension liabilities	*28*	884	3,182
Deferred tax liabilities	*18*	39,752	30,856
Non-current interest-bearing liabilities	*20*	713,030	189,164
Non-current lease liabilities	*8,19*	15,792	24,052
Other non-current liabilities	*19,29*	4,350	—
Total non-current liabilities		**861,479**	**316,183**
Current liabilities			
Accounts payable	*19,20*	160,404	67,971
Current tax liabilities		5,684	1,221
Other current liabilities	*8,19*	22,697	12,702
Accrued expenses and deferred revenue	*30*	136,446	53,553
Total current liabilities		**325,231**	**135,446**
TOTAL EQUITY AND LIABILITIES		**1,952,973**	**1,459,910**

GROUP

Consolidated Statements of Changes in 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, 2020		**1,548**	**1,274,664**	**(45)**	**(488,096)**	**788,071**	**—**	**788,071**
Loss for the year		—	—	—	(433,494)	(433,494)	(3,017)	(436,511)
Other comprehensive income/(loss) for the year		—	—	(6,045)	1,196	(4,849)	(3,288)	(8,137)
Total comprehensive loss for the year		**—**	**—**	**(6,045)**	**(432,298)**	**(438,343)**	**(6,305)**	**(444,648)**
Transactions with owners:								
New share issue		397	890,990	—	—	891,388	—	891,388
Costs attributable to new share issue		—	(97,686)	—	—	(97,686)	—	(97,686)
Exercise of warrants		52	59,199	—	—	59,251	—	59,251
Share-based payments	*10*	—	6,012	—	—	6,012	—	6,012
Non-controlling interests from business combinations		—	—	—	—	—	136,084	136,084
Purchase of non-controlling interests		—	—	—	1,798	1,798	(83,970)	(82,172)
Total transactions with owners		**449**	**858,516**	**—**	**1,798**	**860,763**	**52,114**	**912,877**
Closing equity December 31, 2020	*10,25*	**1,998**	**2,133,179**	**(6,090)**	**(918,596)**	**1,210,491**	**45,809**	**1,256,300**
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)**	**316,980**	**(37,343)**	**279,637**
Closing equity December 31, 2021	*10,25*	**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 income/(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	1,025	**2,383**	**2,590,890**	**9,307**	**(1,836,317)**	**766,264**	**—**	**766,264**

GROUP

Consolidated Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31, 2022	2021	2020
Operating activities				
Operating loss		(421,943)	(524,456)	(379,720)
Adjustments for non-cash items	*23*	61,260	66,676	15,465
Interest received		3,553	102	1,912
Interest paid		(35,252)	(5,432)	(393)
Income taxes paid		(7,392)	(3,949)	(528)
Cash flow used in operating activities before changes in working capital		**(399,774)**	**(467,058)**	**(363,264)**
Cash flow from changes in working capital				
Changes in inventory		(2,758)	(949)	—
Changes in operating receivables		(91,878)	(11,712)	8,033
Changes in operating liabilities		183,056	18,131	46,050
Cash flow used in operating activities		**(311,354)**	**(461,588)**	**(309,181)**
Investing activities				
Acquisition of a subsidiary, net of cash acquired		—	—	(172,602)
Purchase of equipment	*16*	(2,512)	(6,588)	—
Investments in non-current financial assets	*17*	(2,633)	(1,686)	(5)
Purchase of intangible assets	*15*	—	(16,066)	—
Cash flow used in investing activities		**(5,144)**	**(24,340)**	**(172,607)**
Financing activities				
New share issue		—	324,000	891,388
Costs attributable to new share issue		—	(20,909)	(95,937)
Issuance of treasury shares		236	—	—
Repurchase of treasury shares		(236)	—	—
Exercise of warrants		95,121	—	59,251
Purchase of non-controlling interests		—	(49,303)	(82,172)
Contribution from non-controlling interests		—	2,282	—
New borrowings	*20*	491,745	199,524	—
Costs attributable to new loans		(1,260)	(14,858)	—
Repayment of lease liabilities		(9,615)	(5,575)	(3,972)
Cash flow from financing activities		**575,990**	**435,162**	**768,558**
Net increase/(decrease) in cash		**259,493**	**(50,766)**	**286,770**
Cash at beginning of the year		**955,507**	**996,304**	**753,540**
Exchange-rate difference in cash		34,094	9,969	(44,006)
Cash at the end of the year	*23*	**1,249,094**	**955,507**	**996,304**

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, 2022, 2021 and 2020, respectively.

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, 2022, 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 25, 2023.

Note 1 Significant Accounting Policies

Basis for Preparation

These consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) published by the International Accounting Standards Board (IASB).

The accounting policies stated below have, unless otherwise stated, been applied consistently over all periods presented in the consolidated financial statements. The Group's accounting policies have been applied consistently by the Group's companies. The consolidated financial statements provide comparative information in respect of the previous period and an additional comparative period.

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).

Basis for Valuation and Current versus Non-Current Classification

The consolidated financial statements have been prepared on a historical cost basis, except for certain financial assets (including derivative financial instrument) and contingent consideration that have been measured at fair value through profit or loss.

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.

Basis for Consolidation

The consolidated financial statements comprise the financial statements of the Parent Company and its subsidiaries as of December 31, 2022. Control is achieved when the Parent Company has control over the investee, the Parent Company is exposed to or has rights to variable returns from its involvement in the investee, and the Parent Company has the ability to use its power over the investee to affect the amount of the investor's returns, which normally means that the Parent Company owns more than half of the number of votes for all of the shares and participations.

The Group re-assesses whether or not it controls an investee if facts and circumstances indicate that there are changes of the control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date the Group gains control until the date the Group ceases to control the subsidiary.

All subsidiaries are consolidated using the acquisition method. The cost of an acquisition is measured as the fair value of assets that have been provided as payment along with any liabilities taken over or which have arisen at the acquisition date. With the acquisition method, the fair value of acquired identifiable assets, assumed liabilities and contingent liabilities in a business combination, regardless of the scope of any non-controlling interest, are measured at fair value as of the acquisition date. Any surplus arising from the difference between cost and fair value of identifiable acquired assets, liabilities and contingent liabilities is recognized as goodwill. If the cost amount is less than the fair value of the acquired net assets, it is recognized in the consolidated statements of income.

Subsidiaries that were acquired during the financial year are included in the consolidated financial statements as soon as the controlling interest has been transferred to the Group. Subsidiaries that were disposed during the financial year are included in the consolidated financial statements up until the date when the controlling interest no longer exists.

For each business combination, the Group elects whether to measure the non-controlling interests in the acquiree at fair value or at the proportionate share of the acquiree's identifiable net assets. Acquisition-related costs are expensed as incurred and included in administrative and selling expenses in the consolidated statements of income.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

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, 2022 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.

Revenue

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 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 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 remuneration as well as variable remuneration in the form of regulatory and commercial milestones, and sales-based royalties. Variable remuneration (for example, attributable to future regulatory milestones) are initially considered constrained, as there is 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.

Royalty Revenue

Calliditas is entitled to royalties on sold goods, as per agreement. Revenue recognition is based on royalty reports received, which are based on actual net sales statistics of the licensee. Accrued royalty revenue is recognized on the balance sheet under prepaid expenses and accrued income.

Financial Income

Financial income consists of interest income and foreign exchange gains. Interest income is recognized in accordance with the effective interest method. Effective interest is the interest that discounts estimated future receipts and payments during a financial instrument's anticipated duration to the financial assets or liability's recognized net value. The calculation contains all costs included in the effective interest paid by the parties to the contract, transaction costs and all other premiums and discounts. Dividends received are recognized when the right to receive a dividend has been established. Foreign exchange gains and losses are netted.

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.

Employee Benefits

Short-term benefits

Current employee benefits such as salaries, social security costs, vacation pay and bonuses are expensed during the period in which employees perform the service.

Pensions

The Group has both defined-contribution and defined-benefit pension plans, and most employees are covered by and recognized in the defined-contribution pension plans. Employees in France and Switzerland are covered by defined-benefit pension plans. All other employees were covered by defined-contribution pension plans. See Note 27 Pension Liabilities for more information.

Defined-contribution pension plans

A defined-contribution pension plan is a pension plan according to which the Group pays fixed premiums to a separate legal entity. The Group does not have any legal or informal obligation to pay further premiums if this legal entity does not have sufficient assets to pay the full remuneration to employees corresponding to their service during the current or previous periods. The Group therefore has no further risk. The Group's obligations relating to fees for defined-contribution plans are expensed in profit or loss as they are accrued due to the employee performing services for the Group over a period.

Defined-benefit pension plans

In defined-benefit plans, the pension is determined as a percentage of the pensionable final salary, based on the employee's length of service and average final salary. The Group is responsible for ensuring that the established benefits are paid out. The defined-benefit pension obligations are recognized in the consolidated statements of financial position as the net total of the estimated present value of the obligations and the fair value of the plan assets, which are recognized as a provision or a non-current financial receivable. For defined-benefit plans, pension expense and commitments are calculated using the applicable principles of IAS 19. This calculation is performed at least annually by independent actuaries. The Group's obligations are measured at the present value of expected future payments.

Actuarial gains and losses may arise in connection with the determination of the present value of the obligations and the fair value of plan assets. These arise either because the fair value differs from the previous assumption, or the assumptions change. Actuarial gains and losses are recognized in the consolidated statements of comprehensive income in the period in which they arise. Interest expense, less the estimated return on plan assets, is classified as a financial expense. Other cost items in the pension expense are charged to operating profit.

Severance pay

An expense for remuneration in connection with termination of employment of personnel is recognized only if the Group is committed, without any realistic possibility of withdrawal, by a formal detailed plan to eliminate a position in advance of when that position would normally expire. When remuneration is paid as an offer to encourage voluntary termination of employment, the cost is recognized if it is probable that the offer will be accepted and the number of employees that will accept the offer can be reliably estimated.

Share-based payments

Share-based payments in the Group refers to option programs and performance-based share award programs, which are regulated by equity instruments. In cases where the fair value of the instrument exceeds what the employee paid, the difference is recognized as a personnel cost. The fair value of options is determined at the grant date using the Black-Scholes model for pricing of options. The valuation of the performance share awards is based on a discounted model with Monte Carlo simulation of the share price's development for the share-related parts and with estimated probabilities for the outcome of the market conditions. The cost is recognized, together with a corresponding increase in equity, during the period in which the service conditions are met, up to and including, the date on which the employees concerned are fully eligible for compensation.

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 resolved.

Leases

Lessee

The Group assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

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 estimated lease term, which currently is two to four 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 19 Financial and Non-Financial Assets and Liabilities).

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.

Financial Expenses

Financial expenses mainly consist of interest expenses, realized and unrealized losses on foreign exchange derivative instruments and unrealized foreign exchange losses. Foreign exchange gains and losses are netted.

Taxes

Income tax comprises current tax and deferred tax. Income tax is recognized in net profit for the year, except when the underlying transaction is recognized in other comprehensive income or equity with the related tax effect recognized in other comprehensive income and in equity. Current tax is the tax that is to be paid or received in the current year, with the application of the tax rates that have been enacted or substantively enacted by the end of the reporting period. Current tax also includes adjustments of current tax attributable to prior periods.

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.

Deferred tax assets on deductible temporary differences and loss carryforwards are recognized only to the extent that it is probable that it will be possible to utilize these, or to the extent that there are temporary differences which these can be utilized to offset. A provision for deferred tax assets will be recognized when it is no longer deemed probable that they can be utilized.

Intangible Assets

Intangible assets in the Group consist of licenses and similar rights and goodwill.

Licenses and similar rights

Intangible assets with a finite useful life are recognized at initial recognition at cost less accumulated amortization and any accumulated impairment losses. Intangible assets with finite lives are amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. When determining the amortized amount of the assets, the residual value of the asset is taken into account, when applicable.

Goodwill

Goodwill arising in a business combination comprises the difference between the cost of the business combination and the fair value of identifiable assets acquired, liabilities assumed, and any contingent liabilities recognized at the acquisition date. Goodwill on business combinations is included in intangible assets and measured at cost less any accumulated impairment losses. Goodwill is allocated to the cash-generating units, which is the full Group, and tested annually for impairment requirement, or whenever there is any indication of impairment. There is no amortization of goodwill and impairment of goodwill is not reversed.

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

Amortization of the intangible assets begins when the asset can be used, that is, when it is in the place and in the condition required to be able to use it in the manner intended by the Group’s management.

The Group's expected finite useful life is:
– Licenses and similar rights – 6-15 years

Until full market approval from regulatory authorities has been granted, amortization of "Licenses and Similar Rights" will not commence. As market approval has not yet been obtained, no other costs have been capitalized. Following market approval from regulatory authorities, "Licenses and Similar Rights" will be amortized on a straight-line basis over the expected useful life. Until a market approval of the product has been obtained, the asset is assessed for impairment at least once a year, and when there is an indication that the asset may be impaired.

Equipment

Equipment is recognized in the consolidated statement of financial position at cost less accumulated depreciation and impairment. Such cost includes the cost price and expenses directly attributable to the asset. Repairs and maintenance costs are expensed as incurred, while expenses for improvements are recognized as investments and added to the cost of the assets.

An item of equipment and any significant part initially recognized is derecognized upon disposal (i.e., at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of income when the asset is derecognized.

Depreciation

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

The residual values, useful lives, and methods of depreciation of equipment are reviewed at each financial year and adjusted prospectively, if appropriate. If there is an indication that an asset needs to be impaired, the asset is written down to its recoverable amount if this is lower than the carrying amount. The recoverable amount corresponds to the highest of net realizable value and value in use.

Impairment of Non-Financial Assets

Goodwill and intangible assets not yet available for use, are not amortized but the Group assesses for impairment at each reporting date, and when there is an indication that an asset may be impaired. Equipment that is depreciated is assessed for impairment whenever events or changes in circumstances indicate that the carrying amount is not recoverable.

An impairment loss is made by the amount by which the asset's carrying amount exceeds its recoverable amount. An asset's recoverable amount is the higher of an asset's or cash generating units' ("CGU") fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or CGU exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs of disposal, recent market transactions are taken into account. If no such transactions can be identified, an appropriate valuation model is used. These calculations are corroborated by valuation multiples, quoted share prices for publicly traded companies or other available fair value indicators.

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. Impairment losses of continuing operations are recognized in the statement of income in expense categories consistent with the function of the impaired asset. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years.

Financial Assets and Financial Liabilities

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity. Financial instruments are classified at initial recognition, including on the basis of the purpose for which the instrument was acquired and managed. This classification determines the valuation of the instruments.

Initial recognition and measurement of financial assets

The Group's financial assets consist of non-current financial assets, accounts receivable and cash, which are recognized at amortized cost.

The instruments are classified into:

– Amortized cost, or
– Fair value through profit or loss

Financial assets at amortized cost are initially measured at fair value with the addition of transaction costs. Following the initial recognition, the assets are measured at amortized cost less a provision for losses on expected credit losses. Assets classified at amortized cost are held according to the business model to collect contractual cash flows that are only payments of capital amount and interest on the outstanding capital amount.

Initial recognition and measurement of financial liabilities

The Group's financial liabilities consist of contingent consideration, non-current interest-bearing liabilities, other non-current liabilities, lease liabilities, accounts payable and other current liabilities, all of which, except contingent consideration, are recognized as amortized cost. Contingent consideration is recognized at fair value through profit or loss.

The instruments are classified into:
– Amortized cost, or
– Fair value through profit or loss

Financial liabilities at amortized costs are initially measured at fair value, net of transaction costs. Subsequently periods are measured at amortized cost using the effective interest (EIR) method. Financial liabilities classified at fair value are measured both initially and in subsequent periods 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.

Recognition and derecognition

A financial asset or financial liability is recognized in the consolidated statement of financial position when the Group becomes a party in accordance with the contractual terms of the instrument. Debt is recognized when the counterparty has performed and a contractual obligation exists to pay, even if an invoice has not yet been received.

A financial asset is derecognized from the consolidated statement of financial position when the rights in the agreement are realized, expire or the Group loses control of them. A financial liability is derecognized from the consolidated statement of financial position when the contractual obligation is fulfilled or otherwise extinguished. The same applies to part of a financial asset or financial liability.

Gains and losses from derecognition from the consolidated statement of financial position are recorded in the consolidated statement of income.

A financial asset and financial liability are offset and recognized with a net amount in the consolidated statement of financial position only when there is a legal right to set off the amounts and that there is an intention to settle the items with a net amount or to simultaneously realize the asset and settle the debt.

Impairment of financial assets

The Group's impairment model is based on expected credit losses and takes into account forward-looking information. The valuation of expected credit losses takes into account any collateral and other credit enhancements in the form of guarantees. See Note 20 Financial Risks for information on considerations relating to accounts receivable and deposits.

Inventory

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. By continuously monitoring inventory, we ensure that it is dispatched based on its shelf life and moving average basis. When necessary, impairment of inventory is performed within the frame of normal business operations and is recognized in costs of goods sold.

Accounts Receivable

Accounts receivable are reported at amortized cost. A provision for expected credit losses is recorded based on the Group's forward looking expected credit losses (ECL). An analysis of expected credit losses is performed, taking into account historical, current and forward looking factors. The effect of recognition of the provision amount is reported in the statement of income.

Cash

Cash is entirely comprised of cash at banks.

Equity

Common shares, other contributed capital and retained earnings are classified as equity. Financial instruments that meet the criteria for classification as equity are recognized as equity even if the financial instrument is legally structured as a liability. Transaction costs that are directly attributable to the issue of new shares or options are recognized net after tax in equity as a deduction from the issue proceeds.

When Calliditas shares are repurchased, the amount of the consideration paid is recognized as a deduction from equity. Repurchased shares are classified as treasury shares and are presented as a deduction from total equity. When treasury shares are sold or subsequently reissued, the amount received is recognized as an increase in equity and the resulting surplus or deficit on the transaction is transferred to or from Additional Paid-in Capital.

Option Program

The Group has issued an option program which constitutes share-based payments. 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.

Provisions

A provision differs from other liabilities in that there is uncertainty about the time of payment or the amount of the amount to settle the provision. A provision is recognized in the statement of financial position when there is an existing legal or informal obligation arising from past events, and it is likely that an outflow of financial resources will be required to settle the obligation and a reliable estimate of the amount can be made. The amount recognized is the best estimate of what is required to settle the existing obligation on the balance sheet date. Where the effect of when payment is made in time is significant, provisions are calculated by discounting the expected future cash flow.

Contingent Liabilities

A contingent liability is disclosed when there is a possible commitment originating from events that have occurred and whose occurrence is confirmed by one or several uncertain future events. An obligation arising from past events whose existence will be confirmed by the occurrence or non-occurrence of one or more uncertain future events is not recognized as a liability or provision.

Foreign Currency

Transactions in foreign currency

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.

Translation from foreign operations

Assets and liabilities in foreign operations are translated from the functional currency of the operations to the Group's 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.

Earnings per Share

The calculation of earnings per share is based on the Group's net loss for the year and on the weighted-average number of common shares outstanding during the year. In calculating earnings per share after dilution, earnings and the average number of shares are adjusted for the dilutive effects of potential common shares. Earnings per share is not adjusted for any dilution that results in a profit per share after dilution that is higher than profit per share before dilution, or loss per share that is lower than loss per share before dilution.

Cash Flow

The consolidated statement of cash flows is prepared in accordance with the indirect method. The recognized cash flow includes only transactions that involve inflows and outflows, divided into operating activities, investing activities and financing activities. Cash flows from inflows and outflows are recognized at gross amounts, except for transactions comprising large inflows and outflows that pertain to items that are traded quickly and have short terms.

Segment Information

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 NA Enterprises Inc. The non-current assets are located in Sweden, the U.S.,France and Switzerland.

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.

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, 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.

Specifically, the significant accounting judgments and estimates within revenue recognition include determining which promises within each contract 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 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 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 determined estimates are recorded for 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 is reviewed and adjusted on no less than a quarterly basis.

Intangible Assets

The Group's intangible assets are essentially attributable to the Group acquiring the rights to the NOX platform, as well as goodwill in connection with the acquisition of Genkyotex SA. As well as to the previous in-licensing agreement of Budenofalk 3mg oral capsule from the German pharmaceutical company Dr Falk Pharma GmbH. 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. See below and Note 15 Intangible Assets and Impairment Testing.

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, in accordance with the policy described in Note 1 Significant Accounting Policies. 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, see Note 15 Intangible Assets and Impairment Testing. As of December 31, 2022, the Group's goodwill amounted to SEK 45,784 and other intangible assets amounted to SEK 438,057. There is no impairment for the year ended December 31, 2022.

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 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, 2022, 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.

Allowance for Expected Credit Losses for Accounts Receivable

Management makes allowance for expected credit losses for accounts receivable equal 12 months. 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.

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.

Assumptions for The Valuation of Pension Benefits

The valuation of pension commitments and pension expenses is based on the actuarial assumptions specified in Note 28 Pension Liabilities.

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 Revenue from Contracts with Customers

The Group’s revenues in 2022 primarily consisted of net sales of TARPEYO in the U.S., milestone fees from STADA for the conditional approval and commercialization of Kinpeygo in Europe and the milestone fee from Viatris to register and commercialize Nefecon for the treatment of IgA nephropathy (IgAN) in Japan. In addition, net sales also consisted of the milestone fee from Everest Medicines for the extension of the license agreement for South Korea.

The recognition of revenue is associated with significant accounting judgments and estimates, for additional information see Note 2.

Set out below is the Group's revenue from contracts with customers:

Type of goods or service	Year Ended December 31, 2022	2021	2020
Product sales	375,515	—	—
Outlicensing of product	421,689	225,252	—
Royalty income	2,287	—	—
Performance of certain regulatory services	3,387	4,095	—
Provision of drugs	—	—	874
Total	**802,879**	**229,347**	**874**

Geographical markets	Year Ended December 31, 2022	2021	2020
USA	372,247	—	—
Europe*	143,955	201,878	—
Asia	286,677	27,469	874
Total	**802,879**	**229,347**	**874**

** No net sales was recorded in Sweden in 2022, 2021 and 2020, respectively.*

Revenue from major customers	Year Ended December 31, 2022	2021	2020
Customer A	372,247	—	—
Customer B	80,643	27,469	874
Customer C	143,955	201,879	—
Customer D	206,034	—	—
Total	**802,879**	**229,348**	**874**

As of December 31, 2022, the total liability for expected returns and rebates amounts to SEK 24,294, which are recognized in other current liabilities and accrued expenses and deferred revenue. In addition, there are no other performance obligations. No liability for expected returns and rebates was recorded as of December 31, 2021.

Contract assets comprise of accrued royalties and amounts to SEK 2,287 as of December 31, 2022. No contract assets were recorded December 31, 2021. Changes in contract asset balances are entirely attributable to the ordinary operations of the Group where sales have commenced during the year. Contract liabilities comprises of accrued rebates on sales and amounts to SEK 15,849 as of December 31, 2022 and deferred revenue amounts to SEK 3,387 as of December 31, 2021. Opening balance comprise prepaid income which has been recognized as revenue during the year.

Note 4 Other Operating Income

	Year Ended December 31, 2022	2021	2020
Exchange rate differences	—	149	2,501
Pass through costs	439	—	—
Net gains on disposal of equipment	—	110	—
Other income	2,423	—	—
Total	**2,862**	**259**	**2,501**

Note 5 Other Operating Expenses

	Year Ended December 31,		
	2022	2021	2020
Exchange rate differences	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	—
Total	**23,074**	**6,344**	**—**

Note 6 Auditors' Fee

	Year Ended December 31,		
	2022	2021	2020
EY			
Audit services	13,369	6,235	4,449
Other audit activities	3,370	2,105	3,774
Tax advice	—	73	—
Total	**16,739**	**8,413**	**8,223**
KPMG			
Audit services	—	472	102
Other audit activities	—	1,178	2,552
Total	**—**	**1,650**	**2,654**
Other auditors			
Audit services	—	471	102
Other audit activities	—	79	—
Total	**—**	**550**	**102**
Total Audit Fee	**16,739**	**10,613**	**10,979**

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 audit 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,		
	2022	2021	2020
Raw materials and consumables	3,179	—	—
Other external expenses	939,566	549,079	311,329
Personnel costs	248,952	164,206	68,943
Depreciation on equipment's and right-of-use assets	12,913	34,433	2,823
Other operating expenses	23,074	6,344	—
Total	**1,227,684**	**754,062**	**383,095**

Note 8 Leases

	December 31,	
	2022	2021
Right-of-use assets		
Opening balance	37,198	9,595
Additional agreements	—	34,944
Revaluation agreements	(474)	—
Termination of agreement	—	(7,625)
Exchange differences	3,485	284
Closing balance	**40,209**	**37,198**
Depreciation		
Opening balance	(3,898)	(4,351)
Depreciation	(10,807)	(5,711)
Revaluation agreements	47	—
Termination of agreement	—	6,456
Exchange differences	(1,099)	(292)
Closing balance	**(15,757)**	**(3,898)**
Net book value	**24,452**	**33,300**

Depreciation on right-of-use assets is included in the consolidated statements of income under Research and development expenses amounted to SEK 1,073, SEK 997 and SEK 165 in 2022, 2021 and 2020, respectively, under Marketing and selling expenses amounted to SEK 3,743, SEK 1,522 and SEK - in 2022, 2021 and 2020, respectively, and under Administrative expenses amounted to SEK 5,991, SEK 3,192 and SEK 2,621 in 2022, 2021 and 2020, respectively.

	December 31,	
Lease liabilities	2022	2021
Non-current lease liabilities	15,792	24,052
Current lease liabilities	10,374	9,591
Total	**26,165**	**33,642**

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	2022	2021
<12 months	16,467	11,909
1-2 years	12,613	11,231
>2 years	10,053	16,256
	39,133	**39,396**

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 2023 until 2026 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,		
	2022	2021	2020
Interest expenses attributable to lease liabilities	1,604	590	388
Expenses attributable to short-term lease	—	633	731
Expenses attributable to leasing agreements with low value	214	146	103
Expenses attributable to variable lease payments that are not included in lease liabilities	303	446	344
Expenses attributable to lease depreciation	10,807	5,711	2,786
Total expensed during the year	**12,928**	**7,526**	**4,352**
This year's lease payments in the Group	13,231	6,659	4,930

Note 9 Employees and Personnel Costs

Average Number of Employees

	Year Ended December 31,					
	2022		2021		2020	
	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.
Parent Company						
Sweden	45	33 %	29	40 %	16	44 %
	45	**33 %**	**29**	**40 %**	**16**	**44 %**
Subsidiaries						
France	2	—	3	26 %	—	—
Switzerland	6	53 %	6	47 %	2	50 %
United States	33	52 %	18	62 %	5	100 %
	41	**51 %**	**27**	**55 %**	**7**	**86 %**
Total for the Group	**86**	**41 %**	**56**	**47 %**	**23**	**57 %**

Wages and Salaries, Pension Costs and Social Security Costs to the Board, Executive Management and Other Employees

	Year Ended December 31,		
Wages and Salaries	**2022**	**2021**	**2020**
Parent Company			
Board and Executive Management[1)]	33,471	27,792	19,211
Other employees	52,126	33,370	15,598
Subsidiaries			
Board and Executive Management	14,493	4,983	3,184
Other employees	90,055	57,452	11,615
Total	**190,145**	**123,597**	**49,608**

[1)] Executive Management includes the Board, CEO and other executive management.

	Year Ended December 31,		
Social Security Costs and Pension Costs	**2022**	**2021**	**2020**
Parent Company			
Pension costs for the Board and Executive Management	2,167	1,785	1,748
Pension costs to other employees	6,582	4,084	1,666
Social security costs	17,393	17,088	12,330
Subsidiaries			
Pension costs for the Board and Executive Management	616	167	129
Pension costs to other employees	2,647	928	506
Social security costs	6,484	8,596	225
Total	**35,889**	**32,648**	**16,604**

Gender Distribution Among the Board and Executive Management

	Year Ended December 31,		
	2022	**2021**	**2020**
Percentage of women on the Board	67 %	60 %	60 %
Percentage of men on the Board	33 %	40 %	40 %
Percentage of women among other executive management	38 %	33 %	33 %
Percentage of men among other executive management	62 %	67 %	67 %

Disclosures Regarding Total Remuneration of The Board and Executive Management

	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						
Hilde Furberg	413	—	—	—	239	651
Diane Parks	490	—	—	—	239	729
Lennart Hansson (until May, 2022)	200	—	—	—	33	233
Molly Henderson	590	—	—	—	227	817
Henrik Stenqvist (from May, 2022)	275	—	—	—	74	349
Elisabeth Björk (from May, 2022)	188	—	—	—	74	261
Executive Management						
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
Diane Parks	421	—	—	—	162	583
Molly Henderson	539	—	—	—	124	663
Executive Management						
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**

	Year Ended December 31, 2020					
	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
Chairman of the Board						
Elmar Schnee	834	—	—	—	310	1,144
Board members						
Thomas Eklund (until June, 2022)	72	—	—	—	43	115
Hilde Furberg	273	—	—	—	106	379
Lennart Hansson	281	—	—	—	106	387
Bengt Julander (until June, 2022)	58	—	—	—	—	58
Diane Parks	379	—	—	—	106	485
Molly Henderson (from June, 2022)	345	—	—	—	37	382
Executive Management						
CEO, Renée Aguiar-Lucander	3,401	678	1,357	—	1,094	6,530
Other executive management (5 people)	9,816	1,198	1,760	472	2,018	15,264
of which relates to subsidiaries	*2,547*	*129*	*636*	—	—	*3,312*
Total	**15,459**	**1,876**	**3,117**	**472**	**3,820**	**24,744**

Other Remuneration

Other remuneration comprises of fees for services rendered to the Parent Company. Management services purchased from Cordcom Consultants KB amounted to SEK –, SEK – and SEK 472 in 2022, 2021 and 2020, respectively, and relates to the functions of a Head of Communications and Investor Relations that were outsourced to this entity.

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, Vice President Operations, Group General Counsel and Head of Human Resources.

Pensions

All pension commitments are defined-contribution plans for executive management, as well as board members. The guidelines shall apply to 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 2022 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.

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.

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, 2021**	**Change**	**December 31, 2021**	**Change**	**December 31, 2022**
Renée Aguiar-Lucander, CEO	225,000	71,000	296,000	295,000	591,000
Other executive management	415,000	120,000	535,000	520,000	1,055,000
Other employees and consultants	449,000	1,009,000	1,458,000	848,166	2,306,166
Total	**1,089,000**	**1,200,000**	**2,289,000**	**1,663,166**	**3,952,166**

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	Exercised 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 %	836,500
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	145.05	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 %	500,000
ESOP 2021:2	September 29, 2021	September 29, 2024	25.72	109.38	47.50 %	329,500
ESOP 2021:3	March 17, 2022	March 17, 2025	27.64	93.77	43.84 %	650,000
ESOP 2022:1	September 27, 2022	September 27, 2025	26.57	94.66	45.14 %	1,101,000
						3,952,166

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 5,000,000 warrants 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,		
	2022	2021	2020
Share-based payments	34,549	24,737	5,304
Provisions attributable to changes in social security costs (Share-based payments)	234	9,992	3,164
Total	**34,783**	**34,729**	**8,468**

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 2019	Share Awards Outstanding as of				
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
Elmar Schnee, Chairman of the Board	23,236	—	23,236	(23,236)	—
Thomas Eklund, Board member (until June, 2020)	2,816	—	2,816	(2,816)	—
Hilde Furberg, Board member	8,449	—	8,449	(8,449)	—
Lennart Hansson, Board member (until May, 2022)	8,449	—	8,449	(8,449)	—
Diane Parks, Board member	8,449	—	8,449	(8,449)	—
Total	**51,399**	**—**	**51,399**	**(51,399)**	**—**

Board LTIP 2020	Share Awards Outstanding as of				
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
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	—	4,327	(1,443)	2,884
Diane Parks, Board member	4,327	—	4,327	—	4,327
Molly Hendersson, Board member	4,327	—	4,327	—	4,327
Total	**31,371**	**—**	**31,371**	**(1,443)**	**29,928**

Board LTIP 2021	Share Awards Outstanding as of				
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
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, 2022)	—	4,086	4,086	(2,724)	1,362
Diane Parks, Board member	—	4,086	4,086	—	4,086
Molly Henderson, Board member	—	4,086	4,086	—	4,086
Total	**—**	**26,968**	**26,968**	**(2,724)**	**24,244**

Board LTIP 2022	Share Awards Outstanding as of				
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
Elmar Schnee, Chairman of the Board	—	—	—	13,926	13,926
Hilde Furberg, Board member	—	—	—	5,356	5,356
Diane Parks, Board member	—	—	—	5,356	5,356
Molly Hendersson, Board member	—	—	—	5,356	5,356
Henrik Stenqvist, Board member	—	—	—	5,356	5,356
Elisabeth Björk, Board member	—	—	—	5,356	5,356
Total	**—**	**—**	**—**	**40,706**	**40,706**

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 2019	June 1, 2022	22.49	51,399
Board LTIP 2020	July 1, 2023	33.97	29,928
Board LTIP 2021	July 1, 2024	62.95	24,244
Board LTIP 2022	July 1, 2025	51.54	40,706

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,		
	2022	2021	2020
Share-based payments	1,531	876	267
Provisions attributable to changes in social security costs (Share-based payments)	(1,614)	297	207
Total	**(83)**	**1,173**	**474**

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.

For the programs initiated in 2018 and 2019, the observation period was short for the underlying share and the volatility was then based on the observation period with a discount as it normally decreases as the share's history becomes longer. The risk-free interest rate is at the same level as Swedish government bonds with a corresponding term. Dividends are assumed to amount to zero during the period until the date of expiration.

	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, 2021	1,089,000	120.94	82,770	—	1,279,086	74.37
Granted	1,331,000	133.48	26,968	—	—	—
Forfeited	(131,000)	121.78	—	—	—	—
Outstanding as of December 31, 2021	**2,289,000**	**128.18**	**109,738**	**—**	**1,279,086**	**74.37**
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**	**—**	**—**	**—**
Weighted average share price at the date of exercise	—	—	102.06	—	91.45	—

Note 11 Financial Income

	Year Ended December 31,		
	2022	2021	2020
Interest income under the effective interest method	3,553	102	547
Exchange rate differences	46,642	20,234	—
Total	**50,195**	**20,336**	**547**

Note 12 Financial Expenses

	Year Ended December 31,		
	2022	2021	2020
Interest on lease liabilities	(1,604)	(590)	(388)
Other interest expenses under the effective interest method	(31,191)	(6,518)	(5)
Exchange rate differences	—	—	(53,267)
Changes in FX options measured at fair value	—	—	(3,318)
Other financial expenses	(4,874)	(2,145)	—
Total	**(37,669)**	**(9,253)**	**(56,978)**

Note 13 Income Tax Expense

	Year Ended December 31,		
	2022	2021	2020
Current income taxes	(11,539)	(4,581)	(1,035)
Deferred tax	8,688	8,417	675
Income tax expense recognized in the consolidated statements of income	**(2,851)**	**3,836**	**(360)**

	Year Ended December 31,		
Reconciliation of effective tax rate	2022	2021	2020
Accounting loss before income tax	(409,417)	(513,373)	(436,151)
Tax in accordance with applicable tax rate in Sweden 20.6% (20.6%,21.4)%	84,340	105,755	93,336
Tax effect of:			
Effect of other tax rates for foreign subsidiaries	(11,857)	11,481	680
Tax attributable to unrecognized deferred tax assets for tax losses carried forward	(64,150)	(101,785)	(91,725)
Non-deductible expenses	(11,184)	(11,615)	(2,652)
Non-taxable income	—	—	1
Income tax expense recognized in the consolidated statements of income	**(2,851)**	**3,836**	**(360)**
At the effective income tax rate	**(1)%**	**1 %**	**—**

The Group has costs attributable to new share issue amounted to SEK-, SEK 20,909 and SEK 97,686 in 2022, 2021 and 2020, respectively, which are recognized directly against equity. These costs are deductible for tax purposes.

The Group has SEK 3,562,440 and SEK 3,200,911 of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position as of December 31, 2022 and 2021, respectively. The tax losses carried forward are allocated between Sweden of SEK 1,597,989, France of SEK 1,194,206 and Switzerland of SEK 770,245, 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.

Note 14 Earnings per Share

	Year Ended December 31,		
Loss per share before and after dilution	2022	2021	2020
Net loss for the year attributable to equity holders of the Parent Company	(412,268)	(500,293)	(433,494)
Weighted-average number of common shares outstanding	53,022,550	50,829,255	44,873,448
Loss per share before and after dilution	**(7.78)**	**(9.84)**	**(9.66)**

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 – 2022. 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 3,952,166 shares and for issued share awards with entitlement to receive 94,878 shares, since the Group is in a loss position in 2022, 2021 and 2020, respectively.

For disclosures regarding the number of outstanding shares, refer to Note 25 Equity.

Note 15 Intangible Assets and Impairment Testing

	December 31, 2022	2021
Licenses and similar rights		
Cost at opening balance	390,166	380,836
Acquisition for the year	—	16,066
Exchange differences on translation	78,545	(6,736)
Cost at closing balance	**468,711**	**390,166**
Impairment		
Cost at opening balance	(27,975)	—
Impairment	—	(27,975)
Exchange differences on translation	(2,679)	—
Accumulated impairment at closing balance	**(30,654)**	**(27,975)**
Goodwill		
Cost at opening balance	37,227	37,989
Exchange differences on translation	8,557	(762)
Cost at closing balance	**45,784**	**37,227**
Net book value	**483,841**	**399,418**

Intangible assets consist of licenses and similar rights of SEK 438,057 and goodwill of SEK 45,784 as of December 31, 2022.

Intangible assets are mainly from the acquisition of the NOX platform and associated goodwill. The net book value of the NOX platform amounts to SEK 405,925 as of December 31, 2022. 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.

Impairment Testing of Intangible Assets

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, 2022, the Group's goodwill amounted to SEK 45,784. There is no impairment for the year ended December 31, 2022.

The following table shows the discount rate used before tax:

	Year Ended December 31,	
Parameter, %	**2022**	**2021**
Discount rate	12.0	11.0

Intangible assets, not yet available for use

These significantly consist of the NOX platform and Budenofalk 3 mg oral capsule, which are tested, at least, annually for impairment requirement. The technology and the rights were reviewed for impairment individually. The assessment of the value of the technology and the rights is based on the fair value less cost of disposals of each individual asset. 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:

	Year Ended December 31,	
Parameter, %	**2022**	**2021**
Discount rate NOX platform	12.0	17.7
Discount rate Budenofalk 3 mg oral capsule	12.0	12.4

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.

Note 16 Equipment

	December 31,	
	2022	**2021**
Cost at opening balance	7,073	214
Acquisition for the year	2,512	6,588
Disposal for the year	—	(118)
Exchange differences	1,582	389
Cost at closing balance	**11,167**	**7,073**
Depreciation at opening balance	(764)	(51)
Depreciation for the year	(2,106)	(465)
Disposal for the year	—	51
Exchange differences	(830)	(299)
Depreciation at closing balance	**(3,700)**	**(764)**
Net book value	**7,468**	**6,309**

Depreciation on equipment is included in the consolidated statement of income under Research and development expenses amounted to SEK 579, SEK 59 and SEK – in 2022, 2021 and 2020, respectively, under Marketing and selling expenses amounted to SEK 806, SEK 176 and SEK – in 2022, 2021 and 2020, respectively and under Administrative expenses amounted to SEK 721, SEK 230 and SEK 37 in 2022, 2021 and 2020, respectively.

Note 17 Non-Current Financial Assets

	December 31,	
	2022	2021
Cost at opening balance	3,915	2,225
Additional acquisition	7,064	1,686
Exchange differences	231	4
Net book value	**11,210**	**3,915**

Non-current financial assets comprise of bank guarantees/deposits amounted to SEK 6,851 and SEK 3,915 as of December 31, 2022 and 2021, respectively and other non-current receivables amounted to SEK 4,359 as of December 31, 2022, and no other non-current receivables were recognized as of December 31, 2021.

Note 18 Deferred Tax Assets and Deferred Tax Liabilities

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 items net value	382	—	382
Liabilities	3,218	—	3,218
Personnel-related items	10,654	—	10,654
Tax loss carried forward	17,037	—	17,037
Other items	311	—	311
Total	**31,601**	**(57,555)**	**(25,953)**
Offsetting	(17,803)	17,803	—
Tax assets/liabilities, net	**13,799**	**(39,752)**	**(25,953)**

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 items net value	270	68	44	382
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)**	**(25,953)**

Deferred tax assets and liabilities as of December 31, 2021	Deferred Tax Assets	Deferred Tax Liabilities	Net
Intangible assets	—	(46,175)	(46,175)
Tangible assets	—	(238)	(238)
Lease items net value	270	—	270
Personnel-related items	4,141	—	4,141
Tax loss carried forward	15,319	—	15,319
Other items	23	—	23
Total	**19,753**	**(46,413)**	**(26,661)**
Offsetting	(15,557)	15,557	—
Tax assets/liabilities, net	**4,196**	**(30,856)**	**(26,661)**

Tax losses carried forward of SEK 15,319 have been recognized as deferred tax assets in the statement of financial position as of December 31, 2021 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, 2021	Cost at Opening Balance	Recognized in Profit or Loss	Exchange Differences	Cost at Closing Balance
Intangible assets	(47,120)	—	945	(46,175)
Tangible assets	—	(226)	(12)	(238)
Lease items net value	—	256	14	270
Personnel-related items	596	3,304	240	4,140
Tax loss carried forward	9,666	5,065	588	15,319
Other items	4	18	1	23
Total	**(36,854)**	**8,417**	**1,776**	**(26,661)**

Note 19 Financial and Non-Financial Assets and Liabilities

Financial and non-financial assets and liabilities as of December 31, 2022

	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
Accounts receivable	—	78,703	—	78,703
Prepaid expenses and 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 interest-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 and non-financial assets and liabilities as of December 31, 2021

	Financial Assets Measured at Fair Value through Profit or Loss	Financial Assets Measured at at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Assets				
Non-current financial assets	—	3,915	—	3,915
Cash	—	955,507	—	955,507
	—	**959,422**	**—**	**959,422**

	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	54,399	—	—	54,399
Non-current interest-bearing liabilities	—	189,164	—	189,164
Non-current lease liabilities	—	24,052	—	24,052
Accounts payable	—	67,971	—	67,971
Other current liabilities	—	9,591	3,111	12,702
Accrued expenses and deferred revenue	—	25,168	28,385	53,553
	54,399	**315,946**	**31,496**	**401,841**

Financial liabilities valued through profit or loss constitutes of contingent consideration of SEK 75,880 and SEK 54,399 as of December 31, 2022 and 2021, respectively. The fair value of contingent consideration is measured at Level 3 of the fair value hierarchy.

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

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 and liquidity 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.

Days past due, but not impaired, receivables on the closing balance is given below. Of accounts receivable net, SEK 71,825 is to an individual major customer as of December 31, 2022.

	December 31,	
Accounts receivable	**2022**	**2021**
Gross accounts receivable	79,873	—
Provisions, expected credit losses	(1,170)	—
Net accounts receivable	**78,703**	**—**
Maturity structure accounts receivable		
Accounts receivable, not yet due	79,873	—
Provisions, expected credit losses	(1,170)	—
Net book value	**78,703**	**—**
Provisions for expected credit losses		
Opening balance, expected credit loss provisions	—	—
This years provisions	(1,170)	—
Closing balance, expected credit loss provisions	**(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.

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, 2022 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 sales and 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 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 %

Currency exposure 2020 (%)	Revenue	Operating expenses
USD	100 %	35 %
EUR	—	36 %
GBP	—	6 %
SEK	—	23 %

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 23,132, SEK 909 and SEK 10,247 in 2022, 2021 and 2020, 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 9 624, SEK 22,402 and pos. SEK 9,979 in 2022, 2021 and 2020, respectively.

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 48,771 and SEK 18,270 as of December 31, 2022 and 2021, respectively. A 10% stronger Swedish Krona against the U.S. dollar would have a positive impact on equity of approximately SEK 4,877 and SEK 1,827 as of December 31, 2022 and 2021, respectively. Translation against Euros amounted to SEK -322,135 and SEK -93,814 as of December 31, 2022 and 2021, respectively. A 10% stronger Swedish Krona against Euros would have a negative impact on equity of approximately SEK 32,214 and SEK 9,381 as of December 31, 2022 and 2021, 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 19,377 and SEK 29,236 as of December 31, 2022 and 2021, respectively, and in U.S. dollars SEK 80,655 and SEK 10,707 in Euros as of December 31, 2022 and 2021, 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 1,938 and SEK 2,924 as of December 31, 2022 and 2021, respectively. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 8,065 and SEK 1,071 as of December 31, 2022 and 2021. 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, 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, 2021		
Maturity analysis	**<6 months**	**6-12 months**	**2-5 years**
Contingent consideration	—	—	54,399
Non-current interest-bearing liabilities	—	—	189,164
Non-current lease liabilities	—	—	24,052
Accounts payable	67,971	—	—
Other current liabilities	7,906	4,796	—
Accrued expenses	47,753	5,800	—

Non-current interest-bearing liabilities

	December 31,	
	2022	**2021**
Opening balance	189,164	—
New borrowings, net	491,745	199,524
Transaction costs paid	(1,260)	(14,858)
Interest expense	4,874	2,145
Exchange difference on translation	28,507	2,353
Closing balance	**713,030**	**189,164**

In July 2021, Calliditas 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. Draw down of the first USD 25 million tranche was made in 2021. Draw down of the second tranche of USD 25 million was made in June 2022 and draw down of the third and final USD 25 million tranche was made December 2022. The interest rate on the loan is 9 % per annum with a maturity to December 2025, which is recognized in Financial expenses. The loan has no financial covenants.

Note 21 Inventories

	December 31,	
	2022	2021
Raw materials	1,855	889
Work in progress	937	—
Finished goods	855	—
Total	**3,647**	**889**

Inventories recognized as cost of sales amounted to SEK 3,179 in 2022. No inventories were recognized as cost of sales in 2021 and 2020, respectively. No write-downs of inventories have occurred.

Note 22 Prepaid Expenses and Accrued Income

	December 31,	
	2022	2021
Accrued royalties	2,287	—
Prepaid insurance premiums	9,148	10,813
Prepaid interest costs	3,693	—
Prepaid expenses for research and development	45,454	27,888
Prepaid expenses for marketing and selling	8,194	—
Other prepaid expenses	1,964	6,331
Total	**70,741**	**45,032**

Note 23 Cash

	December 31,	
	2022	2021
Cash at Banks	1,249,094	955,507
Total	**1,249,094**	**955,507**

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,		
	2022	2021	2020
Depreciations and impairments	12,913	34,433	2,823
Chage in Provisions	(3,346)	5,856	6,634
Share-based payments	35,791	21,960	6,012
Cange in Contingent consideration	15,941	4,470	—
Other items	(39)	(43)	(4)
Total	**61,260**	**66,676**	**15,465**

Reconciliation of liabilities from financing activities

	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**

	January 1, 2021	Cash-Flow	Non-Cash Items	December 31, 2021
Non-current interest-bearing liabilities	—	184,667	4,497	189,164
Lease liabilities	4,786	(5,575)	34,431	33,642
	4,786	**179,092**	**38,928**	**222,806**

Note 24 Group Companies

Company	Principal Activities	Country of Incorporation	% Equity Interest 2022	2021	2020
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 %	—
Calliditas Therapeutics France SAS	Research and development of pharmaceuticals	France	100 %	100 %	86.2 %
Calliditas Therapeutics Suisse SA	Research and development of pharmaceuticals	Switzerland	100 %	100 %	86.2 %

Note 25 Equity

	Year Ended December 31, 2022	2021	2020
Total registered shares at the beginning of the year	52,341,584	49,941,584	38,707,638
New share issue*	—	2,400,000	9,937,446
Exercise of warrants	1,322,985	—	1,296,500
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**	**52,341,584**	**49,941,584**
Shares			
Ordinary shares	59,580,087	52,341,584	49,941,584
Total	**59,580,087**	**52,341,584**	**49,941,584**
- of which shares are held by Calliditas	*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**	**52,341,584**	**49,941,584**

Share Capital	December 31, 2022	2021	2020
Opening balance	2,094	1,998	1,548
New share issue*	—	96	397
Exercise of warrants	53	—	52
Issuance of treasury shares	236	—	—
Closing balance	**2,383**	**2,094**	**1,998**

* *Initial public offering on The Nasdaq Global Select Market in the United States in June 2020 and the following exercise of the partial over-allotment option from the IPO in July 2020.*
* *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, with the exception of treasury shares held by Calliditas. The quotient value is SEK 0.04 per share.

Transactions in Treasury Shares

Since 2020, Calliditas has had ordinary shares, in the form of American Depositary Shares (“ADSs”), listed in the United States on The Nasdaq Global Select Market. In 2022 Calliditas has implemented and launched an At-The-Market program (“ATM Program”). The purpose of the ATM Program is to efficiently and cost-effectively raise capital, if necessary, in the U.S. market and to ensure delivery of shares to be sold under the company’s ATM Program.

In 2022, 5,908,018 series C shares were issued, which were repurchased and converted to ordinary shares by Calliditas. These transactions are in accordance with the granting mandate. In 2022, no shares were sold in the ATM Program.

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, 2022	2021	2020
Opening balance	(26,979)	(6,090)	(45)
Change of the year	36,286	(20,889)	(6,045)
Closing balance	**9,307**	**(26,979)**	**(6,090)**

Note 26 Provisions

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**

Provisions as of December 31, 2021	Social Security Costs on Share-Based Payment	Other Provisions	Provisions, net
Opening balance	4,972	1,419	6,391
Provisions for the year	8,112	—	8,112
Exchange differences	—	27	27
Total	**13,084**	**1,446**	**14,530**

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 share awards are used.

Note 27 Contingent Consideration

	December 31,	
	2022	2021
Opening balance	54,399	48,969
Change for the year	15,942	4,470
Exchange differences	5,539	960
Net book value	**75,880**	**54,399**

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 12.0 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 20.8% and 15.21% as of December 31, 2022 and 2021, respectively. A 10% higher probability of success in the clinical trials would have a negative impact on profit after tax of approximately SEK 7,588 and SEK 5,440 as of December 31, 2022 and 2021, 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

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	**2022**	**2021**
Switzerland	(789)	(3,071)
France	(94)	(111)
Total	**(884)**	**(3,182)**

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, 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 statement of consolidated operations	**(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 items of 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)**

	Defined Benefit Plan Obligation (Switzerland)	Defined Benefit Plan Obligation (France)	Fair Value of Plan Assets (Switzerland)	Employee Benefit Obligations
January 1, 2021	**(19,193)**	**(172)**	**11,069**	**(8,296)**
Service costs	(2,165)	(13)	—	(2,178)
Interest expense	(17)	—	10	(7)
Curtailment*	12,011	—	(7,805)	4,206
Employee contribution	—	—	704	704
Subtotal included in the statement of consolidated operations	**9,829**	**(13)**	**(7,091)**	**2,725**
Amounts paid/received	291	—	(291)	—
Return on assets (excluding interest expenses)	—	—	64	64
Actuarial gains/(losses) related to changes in demographic assumptions	349	77	—	426
Actuarial gains/(losses) related to changes in financial assumptions	1,120	—	—	1,120
Other actuarial gains/(losses)	360	—	—	360
Subtotal included in other items of comprehensive income	**1,829**	**77**	**64**	**1,970**
Employer contributions	—	—	704	704
Currency translation effect	(698)	(3)	416	(285)
December 31, 2021	**(7,942)**	**(111)**	**4,871**	**(3,182)**

**The change in the Curtailment refer to retirement obligation settlement connected to the departure of senior management member of Switzerland employees.*

	December 31,	
Distribution by Plan Assets (Switzerland)	**2022**	**2021**
Cash	137	205
Bonds	3,048	2,801
Mortgage loans	655	667
Shares	126	92
Real estate	901	760
Other investments	372	346
Total	**5,238**	**4,871**

Of the plan assets above, SEK 3,048 and SEK 2,801 as of December 31, 2022 and 2021, 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	**2022**	**2021**
Swiss pension plan		
Discount rate	2.30 %	0.35 %
Mortality table	LPP 2020 generation	LPP 2020 generation
Salary revaluation rate	1.00 %	1.00 %
Retirement pension inflation rate	0.50 %	0.50 %
Deposit rate on savings accounts	1.00 %	1.00 %
Turnover rate	10.00 %	10.00 %
Remaining life expectancy after retirement	18.6 years	22.3 years
Retirement age	65 years	65 years

	December 31,	
Sensitivity Analysis	**2022**	**2021**
Pension commitments under current assumptions for Swiss pension plans	6,027	7,942
Discount rate , -0,5%	6,615	8,904
Discount rate , +0,5%	5,518	7,130
Retirement pension inflation rate, -0,5%	5,797	7,575
Retirement pension inflation rate, +0,5%	6,281	8,353
Salary revaluation rate, -0,5%	5,927	7,792
Salary revaluation rate, +0,5%	6,131	8,100

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 813 and SEK 555 in 2022 and 2021, respectively. The weighted average maturity of the obligation is an estimated 18.6 and 22.3 years in 2022 and 2021, respectively.

Note 29 Other Non-Current Liabilities

	December 31,	
	2022	2021
Opening balance	—	—
Additional liabilities	4,350	—
Closing balance	**4,350**	**—**

Additional liabilities are related to advance payments from customers.

Note 30 Accrued Expenses and Deferred Revenue

	December 31,	
	2022	2021
Vacation pay liabilities	8,310	6,107
Accrued salaries and Board fees	28,186	16,786
Social security costs	7,065	5,492
Deferred revenue	—	3,387
Accrued rebates on sales	15,849	—
Accrued expenses for royalty	12,023	—
Accrued expenses for research and development	34,637	4,230
Accrued expenses for marketing and selling	21,543	1,242
Accrued expenses for administration	8,832	16,309
Total	**136,446**	**53,553**

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 Change of presentation of expenses

From January 1, 2022, Calliditas has switched to presenting marketing and selling expenses separately from administrative expenses. The purpose of the change is to provide more relevant information about the Group's and the Parent Company's financial results and follow the practice in the industry for a company in commercial stage. The change constitutes a voluntary change and is applied with full retroactivity.

	Year Ended December 31,			Year Ended December 31,		
	2021	Re-classification	2021	2020	Re-classification	2020
Net sales	229,347	—	229,347	874	—	874
Operating expenses						
Research and development expenses	(357,485)	—	(357,485)	(241,371)	—	(241,371)
Marketing and selling expenses	—	(179,603)	(179,603)	—	(38,964)	(38,964)
Administrative expenses	(390,232)	179,603	(210,629)	(141,724)	38,964	(102,760)
Other operating income/expenses	(6,085)	—	(6,085)	2,501	—	2,501
Operating loss	**(524,456)**	**—**	**(524,456)**	**(379,720)**	**—**	**(379,720)**
Net financial income/(expenses)	11,083	—	11,083	(56,431)	—	(56,431)
Loss before income tax	**(513,373)**	**—**	**(513,373)**	**(436,151)**	**—**	**(436,151)**
Income tax	3,836	—	3,836	(360)	—	(360)
Loss for the year	**(509,537)**	**—**	**(509,537)**	**(436,511)**	**—**	**(436,511)**

Note 33 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 in the future. 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.

The Group has pledged assets amounted to SEK 6,859 and SEK 3,915 as of December 31, 2022 and 2021, respectively, which consist of restricted bank accounts and lease deposits. The assets are pledged for the benefit of certain lessors and other suppliers. The Group has no other obligations.

Note 34 Events After the Reporting Period

In March 2023, Calliditas announced positive topline results from the global, randomized, double-blind, placebo-controlled Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon (TARPEYO®/Kinpeygo® (budesonide) delayed release capsules) versus placebo in patients with primary IgA nephropathy (IgAN). The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in estimated glomerular filtration rate (eGFR) over the two-year period of 9-months of treatment with Nefecon or placebo and 15-months of follow-up off drug and the eGFR benefit was observed across the entire study population, irrespective of urine protein-to-creatinine ratio (UPCR) baseline, which the company believes supports a regulatory filing for full approval in the study population. The UPCR reductions observed were durable, reflecting a long-lasting treatment effect during the 15- month follow-up period off treatment.

Exhibit 1.1

Articles of Association

Articles of Association of Calliditas Therapeutics AB. Reg. no. 556659-9766.

Adopted at the annual general meeting held on 19 May 2022.

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 710,000 and not more than SEK 2,840,000. The number of shares shall be not less than 17,750,000 and not more than 71,000,000.

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 § 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.

12 § Financial year

The company's financial year shall be the calendar year.

13 § 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).

14 § 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.

Exhibit 2.4

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 19, 2022. 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 March 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 five 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 2022 annual general meeting held on May 19, 2022, our shareholders resolved that for the period until the 2022 annual general meeting, our board of directors would be authorized to, at one or several occasions, increase our share capital by issuing new shares. Such share issue resolution may be made with or without deviation from the

shareholders' preferential rights, where payment for new share can be made in cash, contribution in kind, debt conversion or in accordance with certain other conditions. The authorization may only be utilized to the extent that it corresponds to a dilution of not more than 15% of the total number of outstanding shares outstanding as per the time of the annual general meeting. The authorization was proposed by the board of directors to increase its financial flexibility. Should the board of directors resolve on an issue with deviation from the shareholders' preferential rights, the reason for such deviation shall be to finance an acquisition, to procure capital to finance the continued development of projects or to commercialize our products. Ahead of the 2023 annual general meeting, a similar proposal for authorization to the board of directors has been proposed.

Any share issue under the authorization must be made at market terms and conditions. The subscription price will be determined by the board of directors. Any new shares issued on the basis of the authorization will rank pari passu with our existing shares.

On the date of the 2022 annual general meeting, we had 53,172,170 shares outstanding. As such, under the authorization, the board of directors is authorized to issue up to 7,975,825 new shares, of which 5,908,018 new shares have been issued as a result of the creation and conversion of C-shares to common shares in 2022.

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 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.

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 some cases, 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 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 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 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 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

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

company's website no later than two weeks after the meeting.	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 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 Depository 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.

Exhibit 4.9

Board LTIP 2022 in Calliditas Therapeutics AB (publ)

GRANT NOTICE & AGREEMENT

On 19 May 2022, the annual general meeting in Calliditas Therapeutics AB (publ) (the "**Company**") resolved to introduce a long-term performance-based incentive program for members of the Board of Directors ("**Board LTIP 2022**").

In summary, the resolution entails that the members of the Board of Directors (each a "**Participant**") are granted share awards (the "**Share Awards**") which entitle the Participant to receive a corresponding number of shares in the Company over a three-year vesting period (1/3 vesting at the end of each term), provided that the Participant is still a member of the Board of Directors on such date and to the extent that certain performance vesting requirements, based on the Company's share price development, are met. The Share Awards are granted free of charge and each vested Share Award entitles the Participant to one share in the Company without any compensation being payable.

The Share Awards may not be transferred or pledged.

On this day, _____ 2022, you have, under Board LTIP 2022, been allocated _____ Share Awards, entitling you to a corresponding number of shares in the Company, subject to the above and the detailed terms set out in "Terms for Board LTIP 2022 in Calliditas Therapeutics AB (publ)".

Your vested Share Awards will be exercised automatically on the day falling immediately after the date of, whichever is earliest, (i) the annual general meeting 2025 or (ii) 1 July 2025 (the "**Vesting Date**"), and the vesting result will be confirmed and communicated to you by the Company as soon as practically possible after the Vesting Date.

By signing this Grant Notice & Agreement, you hereby confirm

i) that you have read, understood and accepted the above information,
ii) that you have read, understood and accepted the "Terms for Board LTIP 2022 in Calliditas Therapeutics AB (publ)",
iii) that you have read, understood and accepted the information under "Personal data" on the next page of this Grant Notice & Agreement,
iv) that you accept the receipt of the above said number of Share Awards (in accordance with the above said terms and conditions), and
v) that you understand and accept that all tax and currency risks and effects for you related to your participation in Board LTIP 2022 are your responsibility.

_____
Place and date

_____
Signature

_____
Clarification of signature

Please complete, sign and return this Grant Notice & Agreement by scanned copy to Fredrik.Johansson@calliditas.com by no later than _____ 2022.

Personal data

Personal data submitted to the Company, e.g. contact details and personal identity number, or otherwise registered in connection with the administration of Board LTIP 2022, is processed by the Company, as data controller, for the administration of the program. The processing of personal data is necessary for the Company in order to fulfill the agreement concerning Board LTIP 2022 and to enable the Company to fulfill its statutory obligations. If you do not provide the requested personal data to the Company, you may not participate in the program.

Personal data may, for specified purposes, sometimes be disclosed to other companies within the Company's group, to banks or to companies with which the Company cooperates, within and outside the EU/EEA. Should personal data be transferred outside the EU/EEA, it will be conducted in accordance with suitable safeguards approved by the EU. You may, at any time, request further information regarding such transfer and request copies of agreements or other safeguards used by the Company for such transfer. In certain situations the Company is also obligated by law to disclose data, e.g. to the Swedish Tax Agency.

Requests for information on the personal data being processed by the Company, erasure of personal data, limitations to the processing of personal data, data portability, or rectification of personal data may be directed to the Company's CFO, who you may also contact if you desire any further information regarding the Company's processing of personal data. Should you wish to register a complaint regarding the Company's processing of personal data you may contact the Swedish Data Protection Authority in its capacity of supervisory authority.

Personal data is only kept for as long as it is necessary for the administration of Board LTIP 2022 or as long as it is required for the Company to fulfill its statutory obligations.

Address to the Company's CFO: Fredrik.Johansson@calliditas.com

TERMS FOR BOARD LTIP 2022 IN CALLIDITAS THERAPEUTICS AB (PUBL)

1. Background and scope of Board LTIP 2022

At the annual general meeting in Calliditas Therapeutics AB (publ), Reg. No 556659-9766 (the "Company" or "Calliditas"), held on 19 May 2022 (the "Annual General Meeting"), it was resolved to introduce a performance-based, long-term incentive program for board members in the Company ("Board LTIP 2022"). As part of Board LTIP 2022, the Company will therefore grant share awards subject to performance vesting ("Share Awards") that entitle to not more than 50,000 shares in Calliditas in total, in accordance with these terms and conditions (the "T&C's").

2. Entitlement to Share Awards

The number of Share Awards that shall be granted to each participant shall equal the below amount for the respective participant divided by the volume-weighted average price of the Calliditas Therapeutics share on Nasdaq Stockholm for the 10 trading days preceding the date the Share Awards are allocated.

The Share Awards under Board LTIP 2022 shall be awarded in accordance with the following:

- Share Awards calculated based on SEK 1,300,000 to the chairman of the Board of Directors; and
- Share Awards calculated based on SEK 500,000 to each of Diane Parks, Hilde Furberg, Molly Henderson, Henrik Stenqvist and Elisabeth Björk.

A board member that is entitled to or is a holder of Share Awards shall be referred to as the "Participant".

3. Performance Vesting

3.1 The Share Awards are subject to performance vesting based on the development of the Calliditas share price over a certain period, as set out in the following. The development of the share price will be measured based on the volume-weighted average price of the Company's share on Nasdaq Stockholm for the 10 trading days immediately preceding the date the Share Awards are allocated (the "First Reference Price") and the 10 trading days immediately preceding the Vesting Date, as defined below (the "Second Reference Price"). In the event the price of the Company's share has thereby increased by more than 60 percent, 100 percent of the Share Awards will vest and 33 percent of such Share Awards will vest should the share price increase by 20 percent. In the event of an increase of the share price of between 20 and 60 percent, vesting of the Share Awards will occur linearly. Should the increase be less than 20 percent, no vesting will occur.

Example of performance conditions:

Share price increase, percent (Second Reference Price compared to First Reference Price)	Percentage of Share Awards Vested
20.0%	33.0%
40.0%*	66.5%*
>60.0%	100.0%

**In the event of an increase of the share price of between 20 and 60 percent, vesting of the Share Awards will occur linearly.*

3.2 The terms under the heading "Vesting in exceptional cases and in case of transactions" provides that Share Awards will vest in their entirety in certain cases.

4. Exercise of Share Awards

4.1 Vested Share Awards will be exercised automatically on the date of, whichever is earliest, (i) the annual general meeting 2025 or (ii) 1 July 2025 (the "Vesting Date"), subject to that Share Awards which have vested pursuant to Clause 7.3 may instead be exercised from and including the day of vesting.

4.2 Each vested Share Award entitles the Participant to receive one share in Calliditas without any compensation being payable provided that the Participant is still a board member of Calliditas at the relevant time of vesting. The Share Awards shall vest gradually over approximately three years, corresponding to three terms up to the Vesting Date, where each term equals the period from one annual general meeting up until the day falling immediately prior to the next annual general meeting or the Vesting Date, as applicable (each such period a "Term"). The Share Awards shall vest by 1/3 at the end of each Term. The requirement that the Participant shall be a Board member of Calliditas at the relevant time of vesting shall not apply if the Share Awards have vested in accordance with what is stated in items 7.2–7.3 below. For clarity, if the Participant is not a board member and was not a board member of Calliditas on the relevant time of vesting, and if the aforementioned exceptions do not apply, the Share Awards will not be exercisable.

5. Automatic exercise and lapse

Vested Share Awards will be exercised automatically on the day set out in Clause 4.1, and on the same day all unvested Share Awards will lapse.

6. Transferability

The Share Awards may not be transferred and vested Share Awards may only be exercised by the Participant or, in the event of the death of the Participant, by the Participant's estate (Sw. *dödsbo*), heirs (Sw. *arvtagare*) or beneficiaries (Sw. *testamentstagare*). For the avoidance of doubt, in each case exercise of the Share Awards will be automatic in accordance with these T&C's and neither the Participant nor its estate, heirs or beneficiaries need to take any action.

7. General clause on leaving the Board

7.1 A Share Award which has not vested will lapse automatically on the date on which a Participant is no longer a Board member of Calliditas, whether or not such resignation is voluntary, unless the reason for resignation is one listed in item 7.2(i)–(ii) below.

Leaving in exceptional cases and in case of transactions

7.2 Notwithstanding the above, if a Participant ceases to be a Board member of Calliditas (also if this occurs during the first Term (i.e. up until the day of the annual general meeting 2023)) for any of the following reasons:

(i) death;

(ii) permanent illness or incapacity or disability;

allocated Share Awards will not lapse. Instead, the number of Share Awards allocated to the Participant will in such situation be reduced on a monthly pro rata basis for the period from the date when the application for the Board member's resignation is filed with the Swedish Companies Registration Office (the "Resignation Date") up until the day falling immediately prior to the Vesting Date. Further, all remaining Share Awards after such reduction will vest in accordance with what is stated in item 3.1 above, except that the allocated Share Awards will vest based on the development of the Calliditas share price over the period from the date the Share Awards are allocated up to and including the Resignation Date. The development of the share price will in such case be measured based on the volume-weighted average share price 10 trading days immediately preceding the date the Share Awards are allocated and 10 trading days immediately preceding the Resignation Date.

7.3 In the event any party (an "Overtaking Entity"), alone or together with subsidiaries, has become the owner of more than 90 percent of all outstanding shares in the Company ("Take-Over"), a sale of substantially all assets ("Asset Sale") or a merger where the Company is not the surviving entity ("Merger") has been completed, all Share Awards will vest in their entirety upon the day of completion of such transaction.

8. Re-purchase

Following a Take-Over, Asset Sale or Merger, the Company, or the surviving entity in case of a Merger, shall have the right by a written communication to that effect, to re-purchase all Share Awards from the Participants for market value. The right to re-purchase Share Awards shall in such cases encompass all Share Awards.

9. Merger

9.1 In the event that the general meeting, in accordance with Chapter 23 Section 15 of the Swedish Companies Act, approve – or all shareholders, in accordance with paragraph four of aforementioned provision, signs – a merger plan, whereby the Company shall be absorbed by another company, whereby the Company shall be absorbed by a parent company, exercise of Share Awards may not thereafter be made.

9.2 Not later than in the immediate adjacent to the Board of Directors' resolution to convene a general meeting that shall resolve upon merger pursuant to what is stated above, or if the merger plan shall be signed by all shareholders, not later than six weeks prior to such signing, notice shall be given to the Participant in respect of the intent to execute a merger of the Company. The notice shall be given by the Board of Directors in the manner set out in item 14 below. The notice shall state the principal terms of the merger plan and remind the Participant that exercise of Share Awards may not be made after a final decision regarding a merger has been made or a merger plan has been signed, in accordance with what is stated in 9.1 above.

9.3 In the event that a merger has been effectuated in pursuance of such decisions as referred to in item 9.1 above, the Participant shall, in exchange for the Participant's Share Awards and unless the Share Awards have been re-purchased in accordance with item 8 above, have a right to receive shares in the absorbing company upon exercise of Share Awards. The right to receive shares in the absorbing company in the event of a merger shall however not prevail if the Participant has a right to have his or her Share Awards re-purchased by the absorbing company for cash consideration pursuant to the terms set out in the merger plan.

10. Partition

10.1 In the event that the general meeting, in accordance with Chapter 24 Section 17 of the Swedish Companies Act, approves – or all shareholders, in accordance with paragraph four of aforementioned provision, signs – a partition plan, whereby the Company shall be dissolved without liquidation, exercise of Share Awards may not thereafter be made.

10.2 Not later than in the immediate adjacent to the Board of Directors' resolution to convene a general meeting that shall resolve upon partition pursuant to what is

stated above, or if the partition plan shall be signed by all shareholders, not later than six weeks prior to such signing, notice shall be given to Participants in respect of the intent to execute a partition of the Company. The notice shall be given by the Board of Directors in the manner set out in section 14 below. The notice shall state the principal terms of the partition plan and remind the Participant that exercise of Share Awards may not be made after a final decision regarding partition has been made or a partition plan has been signed, in accordance with what is stated above.

10.3 In the event of a forthcoming partition, the value of the Participant's Share Awards shall be unaffected.

11. Liquidation

11.1 In the event it is resolved that the Company shall enter into liquidation in accordance with Chapter 25 of the Swedish Companies Act, regardless of the grounds for such liquidation, exercise of Share Awards may not thereafter be made. The right to exercise the Share Awards shall also terminate if the Company is declared bankrupt. The right to exercise the Share Awards shall terminate in conjunction with the resolution to liquidate the Company, regardless of whether such resolution has entered into effect (*Sw.* vunnit laga kraft), or in conjunction with the declaration of bankruptcy.

11.2 Not later than in the immediate adjacent to the Board of Directors' resolution to convene a general meeting that shall resolve whether the Company shall be placed into liquidation in accordance with what is stated in 11.1 above, notice shall be given to the Participant in respect of the intended liquidation. The notice shall be given by the Board of Directors of the Company in the manner set out in section 14 below. The notice shall state that exercise of Share Awards may not be made following the adoption of a resolution by the general meeting that the Company shall enter into liquidation.

11.3 Should a liquidation be effected, all Share Awards shall lapse.

12. Discontinued merger or partition or terminated liquidation

Notwithstanding the provisions set forth in items 9.1, 10.1 and 11.1 above, stating that exercise of Share Awards may not be made following the approval of a Merger, partition or resolution of entering into liquidation or declaration of bankruptcy, the right to exercise Share Awards shall be re-instated in circumstances where the merger or partition, respectively, is discontinued or the liquidation or declaration of bankruptcy has been terminated.

13. Recalculation terms

The provisions in item 8 (a)–(j) in the terms and conditions for the warrants issued to ensure the delivery of shares upon exercise of Share Awards, Appendix 1, shall

constitute an integral part of the T&C's and what is stated in regards to warrants in item 8 (a)–(j) in Appendix 1 shall prevail *mutatis mutandis* to Share Awards. Items 8 (a)–(j) in Appendix 1 *inter alia* states that the number of shares to which each warrant entitles may be recalculated. In case of a conflict between the terms of the T&C's and Appendix 1, the terms of the T&C's shall prevail.

14. Notices

Notices to be given to a Participant pursuant to the T&C's shall be sent via registered letter, courier or e-mail to the Participant's address or e-mail address that is known to the Company. The notice shall be deemed received by the Participant at the earlier of

i) the date when the Participant signs a certificate of receipt,

ii) the date when the Participant otherwise confirms receipt, and

iii) in case of a notice sent by registered letter, on the date occurring five days after the date when the notice was sent by the Company.

15. Force Majeure

15.1 In respect to actions by the Company, the Company cannot be made liable for loss resulting from Swedish or foreign legislation, Swedish or foreign governmental actions, acts of war, terrorism, strikes, blockades, boycotts, lockouts or other similar circumstances. The reservation in respect to strikes, blockades, boycotts and lockouts shall apply even if the Company is itself the subject of such action.

15.2 In the event the Company, fully or partially, is prevented from taking actions due to circumstances mentioned in item 15.1 above, the actions may be postponed until the obstacle is removed. If the Company due to such circumstance is prevented from making or receiving payments, the Company or the Participant shall not be required to pay interest.

16. Applicable law and dispute

16.1 Swedish law shall apply on the T&C's. Any dispute shall be finally settled by arbitration in accordance with the rules for expedited arbitration of the Arbitration Institute of Stockholm Chamber Commerce. The seat of arbitration shall be Stockholm, Sweden. The language of the arbitration shall be English. Written evidence may however be provided in the Swedish or English language.

16.2 All arbitral proceedings conducted pursuant to Clause 16.1, all information disclosed and all documents submitted or issued by or on behalf of any of the disputing Parties or the arbitrators in any such proceedings as well as all decisions and awards made or declared in the course of any such proceedings shall be kept strictly confidential and may not be used for any other purpose than these proceedings or the enforcement of any such decision or award nor be disclosed to any third party without the prior written consent of the party to which the information relates or, as regards to a decision or award, the prior written consent of all the other disputing parties.

Resolution on the introduction of a long-term incentive program for the company's management and key personnel (item 18)

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 2022**") in accordance with items 18a – 18b below.

The resolutions under items 18a – 18b below are proposed to be conditional upon each other. Should the majority requirement for item 18b 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 18c below and resolutions under items 18a and 18c shall then be conditional upon each other.

ESOP 2022 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 18a)

The rationale for the proposal

ESOP 2022 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 currently the company are launching TARPEYO in the United States. When recruiting experienced commercial personnel in the United States and other key employees in the United States and Europe it will be important for Calliditas Therapeutics to be able to offer attractive compensation terms. A competitive equity-based incentive program will be a key component in order to be able to attract and retain highly skilled and experienced individuals as Calliditas Therapeutics launches TARPEYO in the United States.

The Board of Directors of Calliditas Therapeutics believes that ESOP 2022 will fortify the alignment of the interests of the participants and the interests of the shareholders. ESOP 2022 is adapted to the current position and needs of Calliditas Therapeutics. The Board of Directors is of the opinion that ESOP 2022 will increase and strengthen the participants' dedication to Calliditas Therapeutics' operations, improve company loyalty and that ESOP 2022 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 2022 and the date of the annual general meeting 2023 (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, significant 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 100 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 2022 and the date of the annual general meeting 2023. The maximum number of Options that may be allocated to the participants under ESOP 2022 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 2022, 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 2022 no longer serve their purpose.

Preparation of the proposal

ESOP 2022 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 2022 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 2022 is 2,000,000 which corresponds to a dilution of approximately 3.6 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 9.4 percent on a fully diluted basis.

The dilution is expected to have a marginal effect on the company's key performance indicator "Earnings (loss) per share".

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 2022 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 100.0, an annual increase in the share price of 15 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 16.2 million per year before tax. The average annual social security costs over the vesting period are estimated to approximately a total of SEK 10.9 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 2022 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 18b 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 2022 will be fully covered and will hence not affect the company's cash flow.

The total cost of ESOP 2022, including all social security costs, is estimated to amount to approximately SEK 81.3 million under the above assumptions.

The costs associated with ESOP 2022 are expected to have a marginal effect on the company's key performance indicator "Expenses relating to R&D/operating expenses".

Delivery of shares under ESOP 2022

In order to ensure the delivery of shares under ESOP 2022 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 18b below.

Proposal regarding issue of warrants (item 18b)

In order to ensure the delivery of shares under ESOP 2022, and 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, 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 2022. 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 18c)

Should the majority requirement for item 18b above not be met, the Board of Directors proposes that the annual general meeting resolves that ESOP 2022 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.

be entitled to acquire and transfer shares of Calliditas Therapeutics to the participants.

Majority requirements

Resolution in accordance with item 18b 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 2022, 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 2022. 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 2022. 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 2027.

Exhibit 4.15

CALLIDITAS THERAPEUTICS AB

ESOP 2022

UNITED STATES SUB-PLAN

1. PURPOSE; DEFINITIONS

The purpose of the ESOP 2022 United States Sub-Plan (the "Sub-Plan") is to establish certain rules and limitations applicable to Options granted under the T&C's to Employees and Consultants who are or are expected to become United States residents or otherwise subject to the federal tax laws of the United States ("US Co-workers"). The T&C's and this Sub-Plan are complementary to each other and shall, with respect to Options granted to US Co-Workers, be read and deemed as one. In the event of any contradiction, whether explicit or implied, between the provisions of this Sub-Plan and the T&C's, the provisions of this Sub-Plan shall prevail with respect to Options granted to US Co-Workers.

For purposes of the Sub-Plan, the following initially capitalized words and phrases will be defined as set forth below, unless the context clearly requires a different meaning. Any capitalized terms not defined below will have the meanings given to them as forth in the T&C's.

(a) "Code" means the Internal Revenue Code of 1986, as amended. Any reference to a section of the Code herein will be a reference to any successor or amended section of the Code and will include the Treasury Regulations and other legally binding guidance promulgated thereunder.

(b) "Company" means Calliditas Therapeutics AB (publ), reg. no 556659-9766.

(c) "Consultant" means any natural person, including an advisor, engaged by the Company or Subsidiary to render bona fide services to such entity, provided the services (i) are not in connection with the offer or sale of securities in a capital-raising transaction, and (ii) do not directly promote or maintain a market for the Company's securities, in each case, within the meaning of Form S-8 promulgated under the Securities Act, and provided further, that a Consultant will include only those persons to whom the issuance of Shares may be registered under Form S-8 promulgated under the Securities Act.

(d) "Employee" means a person who is engaged by the Company or Subsidiary of the Company as an employee.

(e) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(f) "Fair Market Value" means, as of any date, the value of a Share determined as follows:

(i) If the Company's Shares are listed on Nasdaq Stockholm or any other established stock exchange or a national market system, the Fair Market Value shall be the volume weighted average price of the Company's

Shares on Nasdaq Stockholm (or such other exchange or quotation system on which the Shares are then listed) for the ten (10) trading days preceding the date of determination, as reported in such source as the Board of Directors deems reliable;

(ii) In the absence of an established market for the Shares, the Fair Market Value thereof shall be determined in good faith by the Board of Directors in a manner as set forth in Section 409A of the Code and the Treasury Regulations promulgated thereunder.

(g) "Incentive Stock Option" means any Option granted that by its terms qualifies and is otherwise intended to qualify as an incentive stock option within the meaning of Code Section 422 and the regulations promulgated thereunder.

(h) "Non-Qualified Stock Option" means any Option that is not an Incentive Stock Option.

(i) "Securities Act" means the Securities Act of 1933, as amended.

(j) "Shares" means shares of the Company's Common Stock.

(k) "Subsidiary" means a "subsidiary corporation," whether now or hereafter existing, as defined in Code Section 424(f).

(l) "T&C's" means the terms and conditions of the ESOP 2022.

2. SHARES SUBJECT TO THE PLAN

(a) Shares Subject to the Sub-Plan. No more than 2,000,000 Shares shall be available for Options granted under the Sub-Plan. For avoidance of doubt, Shares may be issued under either the T&C's or the Sub-Plan, but the aggregate number of Shares issued under both shall not exceed 2,000,000 Shares.

3. ELIGIBILITY

(a) Employees and Consultants are eligible to be granted Options under the Sub-Plan.

4. OPTIONS

(a) General. Any Option granted under the Sub-Plan will be in such form as the Board of Directors may at the time of such grant approve. No Incentive Stock Options may be granted under the Sub-Plan and all Options granted to US Co-workers under the Sub-Plan will be classified as Non-Qualified Stock Options.

The Grant Notice and Agreement evidencing any Option will incorporate the following terms and conditions and will contain such additional terms and conditions, not inconsistent with the T&C's, as the Board of Directors deems appropriate in its sole and absolute discretion:

(b) Exercise Price. The Exercise Price per Share purchasable under any Option granted under the Sub-Plan will be determined by the Board of Directors and will not be less than 115[1]% of the Fair Market Value per Share on the date of the grant.

(c) Option Term. Notwithstanding anything in the T&C's to the contrary, no Option granted under the Sub-Plan will be exercisable more than one (1) year following the date on which such Option becomes exercisable consistent with the T&C's and in no event later than ten (10) years following the date of the grant.

(d) Exercisability. Options will vest and be exercisable at such time or times and subject to such terms and conditions as determined by the Board of Directors as permitted by the T&C's.

(e) Tax Withholding. The Board of Directors, in its sole discretion and pursuant to such procedures as it may specify from time to time, may permit a US Employee to satisfy such tax withholding obligation, in whole or in part by such methods as the Board of Directors shall determine, including, without limitation, (i) paying cash, (ii) selling a sufficient number of Shares otherwise deliverable to the US Co-worker through such means as the Board of Directors may determine in its sole discretion (whether through a broker or otherwise) equal to the amount required to be withheld, or (iii) any combination of the foregoing methods of payment. The amount of the withholding requirement will be deemed to include any amount which the Board of Directors agrees may be withheld at the time the election is made, not to exceed the amount determined by using the maximum federal, state or local marginal income tax rates applicable to the Employee with respect to the Option on the date that the amount of tax to be withheld is to be determined or such greater amount as the Board of Directors may determine if such amount would not have adverse accounting consequences, as the Board of Directors determines in its sole discretion. The fair market value of the Shares to be withheld or delivered will be determined as of the date that the taxes are required to be withheld.

(f) Option Adjustments. Any adjustments to the number of Shares subject to an Option and the applicable exercise price that are prescribed by Section 8 of the T&C's shall be done only to the extent permitted by, and in a manner that complies with, Section 409A of the Code.

5. AMENDMENTS AND TERMINATION

(a) The Board of Directors may amend, alter or discontinue this Sub-Plan at any time, provided that the Company will obtain shareholder approval of any amendment necessary and desirable to comply with applicable laws.

[1] For US tax purposes, this can be no less than 100 percent.

6. GENERAL PROVISIONS

(a) The Board of Directors may require each US Co-worker to represent to and agree with the Company in writing that the US Co-worker is acquiring securities of the Company for investment purposes and without a view to distribution thereof and as to such other matters as the Board of Directors believes are appropriate.

(b) Shares shall not be issued hereunder unless, in the judgment of counsel for the Company, the issuance complies with the requirements of any stock exchange or quotation system on which the Shares are then listed or quoted, the Securities Act of 1933, the Exchange Act, all rules and regulations promulgated thereunder and all other applicable laws.

(c) All Shares or other securities delivered under the Sub-Plan will be subject to such share-transfer orders and other restrictions as the Board of Directors may deem advisable under the rules, regulations, and other requirements of any stock exchange upon which the Shares are then listed and any applicable laws, and the Board of Directors may cause a legend or legends to apply to any such Shares to make appropriate reference to such restrictions.

(d) No Option or any right with respect thereto shall be assignable, transferable, or given as collateral to any third party whatsoever by operation of law or otherwise, except by will or by the laws of descent and distribution. During the lifetime of the US Co-worker, all of such US Co-worker's rights to purchase Shares upon the exercise of any Option shall be exercisable only by the US Co-worker.

7. EFFECTIVE DATE

(a) The T&C's has become effective on [DATE] and this Sub-Plan will become effective on the date that it is adopted by the Board of Directors.

8. TERM OF T&C'S

(a) The Sub-Plan will continue in effect until the earlier of: (i) its termination in accordance with Section 5, (ii) all Shares available for issuance in respect of Options under the T&C's have been granted, vested and exercised (if applicable), or (iii) the lapse of ten years from the date that the T&C's is adopted by the Board of Directors.

9. INVALID PROVISIONS

(a) In the event that any provision of this Sub-Plan is found to be invalid or otherwise unenforceable under any applicable law, such invalidity or unenforceability will not be construed as rendering any other provisions contained herein as invalid or unenforceable, and all such other provisions will be given full force and effect to the same extent as though the invalid or unenforceable provision was not contained herein.

Exhibit 4.26

EXECUTION VERSION

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 "[***]".

LICENSE AGREEMENT

between

CALLIDITAS THERAPEUTICS AB (PUBL)

and

VIATRIS PHARMACEUTICALS JAPAN INC.

TABLE OF CONTENTS

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 "[***]".

THIS LICENSE AGREEMENT (this "**Agreement**") is entered into on December 12, 2022 (the "**Effective Date**") and made by and between:

(1) **Calliditas Therapeutics AB (publ)**, corp. reg. no. 556659-9766, with its principal office and address at D5, Kungsbron 1, SE-111 22 Stockholm, Sweden ("**Calliditas**") and

(2) **Viatris Pharmaceuticals Japan Inc.**, a company organized and existing under the laws of Japan, with its principal office and address at Holland Hills Mori Tower, 5-11-2 Toranomon Minato-ku, Tokyo 105-0001, Japan ("**Licensee**").

Calliditas and Licensee are hereinafter collectively referred to as the "**Parties**" and individually a "**Party**."

1. BACKGROUND INFORMATION

1.1 Calliditas has developed a pharmaceutical product known as Nefecon®, which consists of a patented oral formulation of budesonide with targeted release to the small intestine.

1.2 Licensee is engaged in the research, development and commercialization of pharmaceutical products.

1.3 Calliditas Controls the Licensed Patents and related Know-How (each capitalized term as defined below).

1.4 Licensee wishes to acquire license rights under the Licensed Technology for the development and commercialization of Licensed Product in the Field in the Territory (each capitalized term as defined below) and to purchase Licensed Product in bulk from Calliditas for resale, and Calliditas is willing to grant such rights and sell such Licensed Product, all in accordance with the provisions of this Agreement.

1.5 In view of the above, the Parties agree as follows:

2. DEFINITIONS

In this Agreement:

2.1 "**4 mg Capsule**" has the meaning given to it Section 5.3.

2.2 "**Acquirer**" means, collectively, with respect to a Change of Control of a Party, the third-party referenced in the definition of Change of Control and such third-party's Affiliates, determined as of immediately prior to the closing of such Change of Control.

2.3 "**Additional Indication**" has the meaning given to it in Section 4.3.

2.4 "**Adjusted Net Sales**" means Net Sales for a relevant period, less deductions for [***].

2.5 "**Affiliate**" means, in relation to a Party, (a) an organization which directly or indirectly controls a Party; (b) an organization which is directly or indirectly controlled by a Party; or (c) an organization which is controlled, directly or indirectly, by the ultimate parent company of a Party. "**Control**" (and its cognates) is defined for the purposes of (a) to (c) above as owning more than fifty percent

(50%) of the voting stock of a company or having otherwise the power to determine the financial and the operating policies of or to appoint principal management body or senior management of an organization.

2.6 "**Applicable Laws**" means applicable federal, national, foreign, supranational, state, provincial or local or administrative statute, law, ordinance, rule, code or regulation or orders, injunctions, decrees of any court, administrative agency or similar authority.

2.7 "**Approval**" or "**Approved**" means, in respect of Licensed Product, approval or having been approved, respectively, by a Competent Authority permitting commercial use of Licensed Product in the Field in the Territory, including without limitation any accelerated or conditional approval.

2.8 "**Approved Supplier**" has the meaning given to it in Section 10.2.

2.9 "**Arising Product IP**" has the meaning given to it in Section 14.1.

2.10 "**Authorized Generic**" means a generic version of a product with identical formulation to a Licensed Product but to be packaged, marketed and promoted without a brand name or under a different name than the name(s) used for Licensed Product.

2.11 "**Change of Control**" means, with respect to a Party, (a) a merger or consolidation involving such Party, as a result of which a third-party acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the combined voting power of the outstanding securities or other ownership interests of the surviving entity immediately after such merger, reorganization or consolidation, (b) a transaction or series of related transactions in which a third-party, together with its Affiliates (determined as of immediately prior to the closing of the first such transaction), becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities or other ownership interests of such Party, or (c) the sale or other transfer to a third-party of all or substantially all of (i) such Party's and its controlled Affiliates' assets, or (ii) with respect to Calliditas, its global assets related to the Licensed Product. Notwithstanding the foregoing, (i) the issuance or sale of securities for a Party's first public offering, (ii) transaction or series of transactions effected for the primary purpose of financing the operations of a Party including the issuance or sale of securities for financing purposes less than a controlling interest, [***] or (iii) changing the form or jurisdiction of organization of a Party, will not be deemed a "Change in Control" for purposes of this Agreement.

2.12 "**Commercialization Plan**" has the meaning given to it in Section 9.2.

2.13 "**Commercially Reasonable Efforts**" means [***].

2.14 "**Commercial Supply Agreement**" has the meaning given to it in Section 10.5.

2.15 "**Competent Authority**" means any governmental authority responsible for granting or recommending Approval for a pharmaceutical product, including the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan, the Food and Drug Administration (FDA) in the US, European Medicine Agency (EMA) and the National Medical Products Administration (NMPA) in China.

2.16 "**Competing Activities**" has the meaning given to it in Section 6.1.

2.17 "**Competing Product**" means any pharmaceutical product (other than Licensed Product) which is either: [***].

2.18 "**Confidential Information**" has the meaning given to it in Section 24.2.

2.19 "**Control**" means with respect to any intellectual property right or other intangible property, that a Party or one of its Affiliates owns or has a right to use such intellectual property right or intangible property and is entitled to grant access to or a license or sublicense of such right or property for a specified scope, use and territory without breaching the terms of any agreement or other arrangement with a third party and without materially increasing its financial obligations to a third-party (other than those assumed by the beneficiary of such grant), in each case subject to Section 5.

2.20 "**Development Plan**" has the meaning given to it in Section 8.2.

2.21 "**Disclosing Party**" has the meaning given to it in Section 24.1.

2.22 "**Dossier**" means the documents filed by Calliditas with Competent Authorities in the United States, China or the European Union for the purpose of obtaining and maintaining an authorization to conduct clinical trials regarding Licensed Product or for the purpose of obtaining and maintaining an Approval for Licensed Product. "**Dossier**" shall be deemed to include documents filed by licensees of Calliditas with Competent Authorities for such purposes, but only if and to the extent such documents are specifically identified and requested by Licensee and are within Calliditas' Control.

2.23 "**EU**" means the organization of member states as it may be constituted from time to time, which as of the Effective Date consists of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

2.24 "**Exclusivity Period**" means [***].

2.25 "**Field**" means (a) IgAN, and (b) any Additional Indications which are added to the Field in accordance with Section 4.

2.26 "**First Commercial Sale**" means the first arm's length commercial sale of Licensed Product by Licensee or an Affiliate or permitted sublicensee to a third-party for end use in the Territory after the grant of an Approval for Licensed Product in the Territory. For the avoidance of doubt, supply of Licensed Product (a) without charge or at a price not exceeding cost, if supplied (b) as samples or to patients for compassionate use, named patient use, clinical trials or other similar purposes, shall not be considered a First Commercial Sale.

2.27 "**Governmental Authority**" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof, or (c) any supranational body.

2.28 "**IgAN**" shall mean IgA nephropathy.

2.29 "**Improvements**" means any improvements, refinements, enhancements or modifications of the Licensed Technology, including any inventions, know-how, results, data, materials, process and other information related to the composition of matter or formulation of, or method of making or using Licensed Product.

2.30 "**Indication**" means each disease, disorder, medical condition or patient population that a pharmaceutical product is intended to treat, prevent, cure, diagnose, or ameliorate, or that is the subject of a clinical trial, the data and results of which clinical trial (if successful) are intended to be used to support a regulatory submission seeking Approval to use such pharmaceutical product with labeling within the indications section of the label relevant to usage in such disease, disorder, medical condition or patient population. "**Indicated for**" has a correlative meaning.

2.31 "**Infringement Claim**" has the meaning given to it in Section 18.1.

2.32 "**IMPs**" means Licensed Product and/or placebos of Licensed Product to be used in clinical trials as investigational medicinal products, to be either provided as primary packed bright stock in the commercial primary packaging used by Calliditas or as bulk.

2.33 "**IMP Supply Agreement**" has the meaning given to it in Section 10.4.

2.34 "**IND**" means an investigational new drug application or similar application which is required to commence clinical trials in humans of a pharmaceutical product submitted to a Competent Authority.

2.35 "**Indemnified Party**" has the meaning given to it in Section 22.3.

2.36 "**Indemnitees**" has the meaning given to it in Section 22.1.

2.37 "**Initial Royalty Term**" has the meaning given to it in Section 11.3.2.

2.38 "**JSC**" has the meaning given to it in Section 7.1.

2.39 "**Know-How**" means scientific, technical and other information that is not in the public domain, including proprietary concepts, data, designs, developments, discoveries, ideas, inventions, processes, research materials, research results, and techniques (whether or not patentable or copyrightable), which is Controlled by Calliditas or its Affiliates as of the Effective Date or during the Term, and which is necessary or reasonably useful for Licensee's development or commercialization of Licensed Product in the Field in the Territory.

2.40 "**Licensed Patent(s)**" means: (i) all patent applications and patents that are Controlled by Calliditas or its Affiliates as of the Effective Date or during the Term, which (a) claim the composition of matter or formulation of, or method of making or using, Licensed Product, and (b) have been or can be applied for or granted in the Territory. Licensed Patents granted or published as of the Effective Date are listed in Appendix 1, which Appendix shall be updated from time to time by Calliditas or upon request by Licensee, and Licensed Patents shall include any and all patents and patent applications in the Territory issuing or claiming priority from therefrom, including all continuations, continuations-in-part, divisions, extensions, registrations, reissues, renewals, and revalidations thereof.

2.41 "**Licensed Product**" means Calliditas' proprietary formulation of budesonide, including as described in Appendix 2, [***].

2.42 "**Licensed Technology**" means the Licensed Patents and the Know-How.

2.43 "**Losses**" has the meaning given to it in Section 22.1.

2.44 "**Major Market**" means any one or more of the following: [***].

2.45 "**Milestone Event**" has the meaning given to it in Section 11.2.1.

2.46 "**Milestone Payment**" has the meaning given to it in Section 11.2.1.

2.47 "**NDA**" means new drug application, i.e., an application for Approval by a Competent Authority permitting commercial use of a pharmaceutical product in an Indication in the Field in the Territory.

2.48 "**NHI**" means the National Health Insurance in Japan.

2.49 "**Net Sales**" means [***].

2.50 "**New Data**" means, in respect of Licensed Product, all data, information, or results generated in the performance of any preclinical studies (including pharmacological and toxicological studies), clinical studies, or chemistry, manufacturing, control and analytical studies in respect of Licensed Product conducted by or on behalf of Licensee or its Affiliates in the course of carrying out the development and commercialization of Licensed Product in accordance with this Agreement.

2.51 [***].

2.52 "**Post-Manufacturing Processing**" means the processing of Licensed Product after delivery to Licensee or its delegate by Calliditas under the Supply Agreements, including packaging, labeling, testing and warehousing.

2.53 "**Product Data**" means in respect of Licensed Product, all data, information or results generated in the performance of any clinical studies, preclinical studies (including pharmacological and toxicological studies) or chemistry, manufacturing, control and analytical studies in respect of Licensed Product conducted by or on behalf of Calliditas or its Affiliates before the Effective Date or during the Term and included in a Dossier.

2.54 "**Prosecution**" has the meaning given to it in Section 16.1.

2.55 "**Qualifying Supply Failure**" has the meaning given to it in Section 10.9.

2.56 "**Recipient**" has the meaning given to it in Section 24.1.

2.57 "**Regulatory Documentation**" has the meaning given to it in Section 8.8.

2.58 "**Regulatory Exclusivity**" means, with respect to Licensed Product in the Territory, any exclusive marketing right, data protection or other exclusive right, other than a patent right, conferred by any Competent Authority or otherwise under Applicable Laws with respect to Licensed Product in the Territory, including new drug exclusivity, new Indication or use exclusivity, pediatric exclusivity or orphan drug exclusivity.

2.59 "**Regulatory Plan**" has the meaning given to it in Section 8.7.

2.60 "**Pharmacovigilance Agreement**" has the meaning given to it in Section 8.12.

2.61 "**Phase II Clinical Trial**" means a clinical trial of Licensed Product conducted in patients with the disease or condition under study to evaluate the effectiveness of Licensed Product, in a manner that is generally consistent with 21 CFR § 312.21(b), as amended (or its successor regulation), or equivalent law or regulation in regulatory jurisdictions outside the U.S.

2.62 "**Senior Executives**" means the CEO of Calliditas and the JANZ Regional President of Licensee.

2.63 "**Supply Agreements**" means the IMP Supply Agreement and the Commercial Supply Agreement.

2.64 "**Supply Failure**" has the meaning given to it in Section 10.8.

2.65 "**Term**" has the meaning given to it in Section 26.1.

2.66 "**Territory**" means Japan.

2.67 "**Territory Development Activities**" has the meaning given to it in Section 8.1.

2.68 "**Territory Dossier**" means the documents filed by or on behalf of Licensee, its Affiliates or permitted sublicensees with Competent Authorities in the Territory for the purpose of obtaining and maintaining an authorization to conduct clinical trials regarding Licensed Product or for the purpose of obtaining and maintaining an Approval for Licensed Product in the Territory.

2.69 "**Third-Party License**" has the meaning given to it in Section 11.5.

2.70 "**TLFs**" has the meaning give to it in Section 26.3.

2.71 "**Trademark(s)**" has the meaning given to it in Section 20.2.

2.72 "**USD**" means the United States Dollar.

3. GRANT OF RIGHTS; SUBLICENSING

3.1 Subject to the terms and conditions of this Agreement, Calliditas hereby grants to Licensee an exclusive (also in relation to Calliditas and its Affiliates), royalty-bearing, non-transferrable (except as set forth in Section 28.1), sublicensable (subject to Section 3.5 below) right and license, under the Licensed Technology, to research, use and have used, develop and have developed, improve and have improved, import and have imported, distribute and have distributed, purchase for resale, sell and have sold, and otherwise commercialize the Licensed Product in the Field in the Territory (including packaging, labeling, and testing), provided that Licensee is granted no right to, and shall not, modify the Licensed Product, except if (a) necessary for the Approval of the Licensed Product in the Field in the Territory, or (b) the development program for such modification of the Licensed Product is included in a Development Plan reviewed and recommended by the JSC. Licensee may, under the license granted by this Section 3.1, conduct its permitted activities with respect to research, development, improvements, purchase for resale, and Post-Manufacturing Processing, both within and outside of the Territory, though Licensed Product may be commercialized, distributed and sold by Licensee only within the Territory.

3.2 In the event that, during the Term, Calliditas is granted or publishes an application for a patent Controlled by Calliditas that claims the composition of matter or formulation of, or method of making

or using, Licensed Product, it shall notify Licensee of such grant or publication. In such a case, or should Licensee notify Calliditas of a patent or published patent application Controlled by Calliditas with such claims, Appendix 1 shall be updated to include such patent or patent application. Notwithstanding any provision of this Agreement to the contrary, Licensed Patents for jurisdictions other than the Territory shall be included in the license grant under Section 3.1 solely for the purposes of applying for a counterpart patent in the Territory to the extent permitted under Section 16 and conducting the permitted activities under Sections 3.1 and 3.4 and the Supply Agreements.

3.3 Further, subject to the terms and conditions of this Agreement, Calliditas hereby grants to Licensee an exclusive (also in relation to Calliditas and its Affiliates), non-transferrable (except as set forth in Section 28.1), sublicensable (subject to Section 3.5 below) right and license to use and reference the Dossier and the Product Data, in each case, Controlled by Calliditas or its Affiliates, solely for the purpose of obtaining relevant Approvals for Licensed Product in the Field in the Territory. The right of use and reference concerning portions of the Dossier containing manufacturing trade secrets proprietary to Calliditas shall be exercised in a manner that preserves the confidentiality of such trade secrets, even as to Licensee, without limitation on the provisions of the Supply Agreements.

3.4 Notwithstanding the foregoing, Calliditas and its Affiliates retain the rights to develop and have developed, and manufacture and have manufactured Licensed Product and its active pharmaceutical ingredient in the Territory but solely for use outside the Territory, and (without limitation on the provisions of the Supply Agreements) the exclusive right to manufacture and have manufactured Licensed Product for use in the Territory. For the avoidance of doubt, the Supply Agreements will include rights for Licensee to conduct Post-Manufacturing Processing, inside and outside the Territory.

3.5 Licensee shall be entitled to grant sublicenses of its rights under this Agreement to its Affiliates (however, only for as long as they remain Affiliates of Licensee) upon written notice to Calliditas, and to other third parties with the prior written consent of Calliditas, which shall not be unreasonably conditioned, delayed or denied, in each case provided that:

(a) [***];

(b) [***];

(c) [***];

(d) within [***] after the grant of any sublicense, Licensee shall provide to Calliditas a true copy of such sublicense; the Licensee may redact information not pertaining to the Licensee's obligations under this Agreement, such as information on products other than Licensed Product, or sensitive business information of the sublicensee that do not pertain to Licensee's obligations under this Agreement; and

(e) Licensee shall be responsible for any breach of the sublicense by the sublicensee, as if the breach had been that of Licensee under this Agreement, and Licensee shall indemnify Calliditas against any claims, costs, damages, expenses, or losses that are awarded against or suffered by Calliditas as a result of any such breach by the sublicensee, all pursuant to Section 22.

3.6 Notwithstanding anything to the contrary, Licensee shall have the right to engage subcontractors to perform services for Licensee, its Affiliates, and its permitted sublicensees in the course of its or their development and/or commercialization of Licensed Product in the Field and Territory; provided that [***].

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 "[***]".

3.7 Know-How Transfer.

(a) Beginning promptly after the Effective Date, Calliditas will provide to Licensee, in the format in which it is held by Calliditas or its Affiliates, access to or copies of Know-How in the possession of Calliditas or its Affiliates that is necessary or reasonably useful for Licensee to engage in the activities provided for and perform its obligations under this Agreement, provided that no information relating to manufacture of Licensed Product shall be required to be provided pursuant to this Section 3.7. The disclosure of such Know-How shall be made on a timely basis, so that Licensee's activities are not delayed; in particular, documents held by Calliditas or its Affiliates shall be provided no later than [***] after the date specified by decision of the JSC. Licensee will honor and not seek to circumvent any restrictions on the disclosure of the Know-How arising from obligations imposed on Calliditas by any applicable regulatory agency, such as blinding agreements. In the event such obligations prevent Calliditas from transferring some part of the Know-How to Licensee, Calliditas shall (i) transfer all aspects of the Know-How which are not covered by such obligations as described in this Section 3.7, and (ii) transfer all aspects of the Know-How which are covered by such obligations as soon as possible in compliance with Calliditas' legal and regulatory obligations. For the avoidance of doubt, Licensee acknowledges and agrees that Know-How shall be deemed to be Confidential Information and Licensee shall only disclose the Know-How to its employees, contractors, agents and sublicensees who have a bona fide reason to use and access the Know-How and that such Know-How shall be kept in strict confidence.

(b) During the Term, Calliditas shall provide to Licensee full and prompt disclosure, through the JSC or otherwise upon request of Licensee for good cause shown, of any Know-How (excluding Know-How relating to manufacture of Licensed Product) that becomes Controlled by and into the possession of Calliditas or any of its Affiliates after the Effective Date and that is necessary or reasonably useful for Licensee to conduct its activities or exercise its rights as contemplated hereunder, in the format in which it is held by Calliditas or its Affiliates.

(c) If necessary or reasonably useful for further permitted development or commercialization of Licensed Product in the Territory, and solely on request of Licensee, Calliditas shall in the ordinary course of business (and subject to the availability of personnel) re-arrange, re-format, compile, correct, or otherwise undertake secondary review of any Know-How to be provided by Calliditas to Licensee hereunder so that it is sufficiently understandable and useable for a reasonable third-party in the position of Licensee. In the event that Licensee properly identifies any additional Know-How (excluding Know-How relating to manufacture of Licensed Product) required to be provided by Calliditas and that has not been provided, Licensee may provide notice to Calliditas and Calliditas shall provide such Know-How to Licensee as soon as practicable, but no later than [***].

(d) During the Term of the Agreement, Calliditas shall provide such further reasonable consultation and assistance in the ordinary course of business (and subject to the availability of personnel) to Licensee as reasonably requested by Licensee in order to perfect the transfer set forth in Section 3.7(a).

(e) Licensee shall, promptly after Licensee or its Affiliates has come into the possession of the same, provide to Calliditas a summary report of the topline results in any clinical trial(s) conducted by Licensee and, upon Calliditas' reasonable request, any further data and information arising from clinical trial(s) conducted by Licensee or other development activities in connection with Licensed Product. Licensee shall further disclose to Calliditas through the JSC, or otherwise upon request by Licensee, all newly-arisen know-how within the Arising Product IP.

(f) All documentation required to be provided by Calliditas to Licensee under this Agreement may be provided in English. It shall be the responsibility of Licensee to have any such

documentation translated into Japanese at Licensee's expense to the extent required for use in the Territory or to the extent preferred by Licensee.

(g) Calliditas shall not be obligated to provide information relating to [***], unless such disclosure is required for Calliditas to meet its obligations or Licensee to exercise its rights under Sections 3.1, 3.3, 3.4, 8.7, 10, and 22.2 of this Agreement or the Supply Agreements. Disclosures requested by Licensee for the purposes of complying with disclosure requirements of a Governmental Authority may be made by Calliditas through direct disclosure on a confidential basis (even as to Licensee) to such Governmental Authority, if acceptable to the Governmental Authority, or to a designated representative of Licensee (such as a contract manufacturer) who enters into a confidentiality agreement with Calliditas reasonably acceptable to Calliditas. If disclosure to Licensee is necessary, Licensee agrees that such information shall be deemed to be Confidential Information and to disclose such information strictly on a need-to-know basis.

3.8 Calliditas hereby grants to Licensee an exclusive license to market an Authorized Generic version of a Licensed Product in the Territory, provided that Licensee agrees that [***].

3.9 Except for the license and option expressly granted under Section 3 and Section 4, Calliditas reserves all its rights in Licensed Product, the Licensed Technology, the Dossier, and the Product Data. Without prejudice to the generality of the foregoing, Calliditas grants no rights to any intellectual property other than the Licensed Technology and reserves all rights under the Licensed Technology outside the Field (but subject to Section 4) and the Territory.

3.10 All rights and licenses granted under or pursuant to this Agreement from Calliditas to Licensee are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, United States Code (the "**U.S. Bankruptcy Code**") or any non-U.S. equivalent thereof, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code.

4. OPTION TO EXTEND THE FIELD

4.1 If and when Calliditas decides, in its sole discretion, to initiate, or to authorize a third-party to initiate, a registrational clinical study to develop and pursue another Indication for Licensed Product [***], or to develop and commercialize Licensed Product in another Indication using intellectual property and/or rights of reference Controlled by Calliditas (each, an "**Other Indication**"), Calliditas shall promptly give Licensee written notice thereof, together with a global development plan describing Calliditas' plan for the development of Licensed Product in such Indication. For the avoidance of doubt, an expansion of the Indication or an Additional Indication (as defined below), [***], shall be deemed included in the pre-existing license for such Indication or Additional Indication, without negotiation or additional cost to Licensee.

4.2 Subject to the terms and conditions of this Agreement, Licensee shall have an exclusive option to extend the Field in the Territory to also include Other Indication(s) in the Field. If Licensee wishes to exercise the option granted in this Section 4.2, Licensee shall give written notice thereof to Calliditas within [***] after Calliditas' notice in accordance with this Section 4.2.

4.3 If Licensee timely exercises the option granted in Section 4.2 above, the additional Indication covered by such option shall thereafter be included in the definition of Field and referred to as an "**Additional Indication**." If Licensee chooses not to exercise its option or if Licensee does not give such notice within the time stipulated, the exclusive option in Section 4.2 shall lapse. Notwithstanding the failure of Licensee to exercise the option granted in Section 4.2 above, Calliditas shall not, and shall not authorize

a third-party to, directly or indirectly develop or commercialize in the Territory: (i) a Licensed Product for the Additional Indication or an Other Indication; or (ii) a Competing Product (including conducting any clinical trial other than as permitted by this Agreement to support a regulatory submission seeking approval from a Competent Authority for the Territory of [***].

5. THIRD-PARTY INTELLECTUAL PROPERTY RIGHTS

5.1 If there is a Change of Control of a Party during the Term, such Party will be deemed not to Control any patents, patent applications, know-how or other intellectual property rights owned or controlled (prior to the closing of such Change of Control or at any time thereafter) by the Acquirer of such Party, unless such Party (a) has in-licensed any such intellectual property rights from the Acquirer prior to the closing of such Change of Control, and (b) Controls such intellectual property rights.

5.2 Calliditas will be deemed not to Control any patents, patent applications, know-how or other intellectual property rights owned or controlled by Calliditas' licensees for Licensed Product (other than Licensee), including intellectual property rights relating to Additional Indications or Licensed Product, unless (a) such licensees have granted Calliditas sublicensable rights under such intellectual property rights, and (b) Licensee agrees in writing to accept such a sublicense and assume and comply with any applicable restriction or obligation imposed by such licensees, including any payments due to such licensees to the extent attributable or properly allocated (in Calliditas' reasonable discretion) to the Territory or otherwise triggered by the grant of such sublicense to Licensee.

5.3 In the event that, after the Effective Date, (a) Calliditas or its Affiliates acquire any patents, patent applications, know-how or other intellectual property rights (other than those subject to Section 5.2), or (b) an entity (other than an Acquirer) becomes an Affiliate of Calliditas, which entity owns or controls patents, patent applications, know-how or other intellectual property rights; and in each case of (a) and (b), (i) such intellectual property rights would constitute Licensed Technology if deemed to be Controlled by Calliditas or its Affiliates, and (ii) Calliditas or its Affiliate or such entity owes payments or is subject to other restrictions or obligations in respect of such intellectual property rights, Calliditas shall notify Licensee of the existence of such restrictions or obligations. Licensee shall have the right to decline a license under the applicable intellectual property rights or, if Licensee so notifies Calliditas within [***] after receipt of the notice from Calliditas, take such license, provided that if Licensee elects to take such a license, Licensee will be obliged to pay Calliditas [***] by reason of Licensee's use of such intellectual property rights, [***], and to enter into a separate agreement with Calliditas or its Affiliates sufficient to enable Calliditas and its Affiliates to comply with the applicable restrictions or obligations owed with respect to Licensee's use of such intellectual property rights in the Territory. Unless and until the Licensee elects to take such a license and executes such separate agreement with Calliditas or its Affiliates, the relevant intellectual property rights shall be deemed not to be Controlled by Calliditas or its Affiliates and shall be excluded from the definitions of "**Licensed Patents**", "**Know-How**" and "**Licensed Technology**" for all purposes. Subject to the foregoing, [***].

6. COMPETING PRODUCTS

6.1 During the Term of this Agreement, Licensee shall not, either by itself or with an Affiliate or a third-party: [***] (the "**Competing Activities**"). Licensee shall notify Calliditas promptly if it commences any Competing Activities in the Territory, by itself or with an Affiliate or third-party. [***].

6.2 For the avoidance of doubt, any alleged breach of this Section 6 shall be escalated to the Senior Executives. The Senior Executives shall meet within [***] and attempt to resolve the matter in good faith. If the Senior Executives do not reach agreement on such matter within [***] after their first meeting,

Calliditas may give notice of its intention to terminate this Agreement pursuant to Section 26.2.1, but with a non-extendable cure period reduced to [***].

7. JOINT STEERING COMMITTEE

7.1 Within [***] after the Effective Date, Calliditas and Licensee shall form a joint steering committee (the "**JSC**"), which will be comprised of an equal number of representatives from Calliditas and Licensee. No later than [***] after the Effective Date, each Party shall designate up to [***] representatives to serve on the JSC, identifying one (1) of its representatives to act as co-chair, representing that Party. In addition, each Party shall designate a project leader or alliance manager to act as the primary day-to-day contact for that Party in relation to activities under this Agreement, who shall not be a JSC representative but may attend the JSC meetings and bring issues to the JSC's attention. Each Party may from time to time change its representatives on the JSC or the project leader or alliance manager by notifying the other Party with the name of its new representative, project leader or alliance manager. The JSC shall continue to exist until the Parties mutually agree to dissolve it.

7.2 The JSC shall be responsible for overseeing the development and commercialization of Licensed Product in the Field in the Territory, serve as a forum for information exchange for the development and commercialization of Licensed Product outside the Territory (solely if and to the extent relevant for development or commercialization of Licensed Product in the Territory), and monitor and provide overall strategic oversight of the activities under this Agreement. The JSC's responsibilities include the following:

(a) discuss the overall strategy regarding Approval of Licensed Product in the Territory;

(b) review and recommend the Development Plan, Regulatory Plan, and Commercialization Plan, and any modifications and variations thereto proposed or requested by a Party;

(c) coordinate the activities of the Parties pursuant to the Development Plan, Regulatory Plan, and Commercialization Plan;

(d) monitor the progress of the activities carried out in accordance with the Development Plan, Regulatory Plan, and Commercialization Plan;

(e) discuss the state of the markets for Licensed Product in the Territory, including opportunities and issues concerning the commercialization of Licensed Product;

(f) discuss the marketing and promotional strategy, product positioning and key marketing messages;

(g) discuss corporate communications regarding Licensed Product in the Territory with respect to any recall or material safety event in relation to Licensed Product;

(h) discuss responsibilities and strategy in relation to filing, prosecution and maintenance of any potential Arising Product IP;

(i) discuss any matters relating to the supply of Licensed Product for the Territory which may be escalated to the JSC as provided in the Supply Agreements; and

(j) perform such other functions as are expressly delegated to it under this Agreement or as the Parties agree in writing.

7.3 The JSC shall have an organizational meeting by telephone or video conference promptly after its members are selected and shall thereafter meet (either in person or by telephone or video conference) on a regular basis and at least once [***]. In the event that an issue arises which requires the attention of the JSC prior to the next regularly scheduled JSC meeting, a JSC meeting may be held prior to the next regularly scheduled JSC meeting with the mutual consent of the Parties, and neither Party will unreasonably withhold or delay its consent to hold any such additional JSC meeting. Each Party shall bear all travel and related costs or expenses for its representatives' attendance at the JSC's meetings. At each meeting of the JSC, Licensee shall provide the JSC with an update regarding the work performed by or on behalf of itself with respect to the development and commercialization of Licensed Product in the Territory since the last meeting. Either Party may invite, at its cost and expense, subject matter experts or other relevant personnel to attend any meeting of the JSC, provided that such participants are bound under written obligations of confidentiality and non-use no less protective of the Parties' Confidential Information than those set forth in this Agreement.

7.4 The quorum for a meeting of the JSC shall be [***] individuals, [***] representing each Party. No valid meeting of the JSC may be held unless a quorum is present and all Parties have received not less than [***] notice of the meeting or otherwise waived, in writing, such notice period for the applicable meeting.

7.5 A representative of Licensee shall act as the secretary for each meeting. Minutes shall be kept at all meetings of the JSC and such minutes shall be circulated for approval within [***] after the meeting.

7.6 The Parties shall follow the recommendations of the JSC, subject to the conflict resolution framework set forth in this Section 7.6. The JSC shall endeavor to make recommendations by consensus. If the JSC identifies a matter which is causing or is reasonably expected to give rise to conflict between the Parties, the matter may, at the request of either Party, be referred to the Senior Executives for resolution. The Senior Executives shall meet within [***] and attempt to resolve the matter in good faith. If the Senior Executives do not reach agreement on such matter within [***] after the date on which the matter is referred to them, then such matter shall be resolved in accordance with the following:

(a) [***] shall have final decision-making authority with regard to [***];

(b) [***] shall have the final decision-making authority with respect to [***].

(c) [***] shall have the final decision-making authority with respect to matters [***] or the decision-making procedures in the Supply Agreements, if applicable.

7.7 Neither Party may exercise its decision-making authority under Section 7.6 in a manner that is contrary to this Agreement or would require the other Party to perform an act that would violate any Applicable Laws. In particular, the final decision-making authority granted to [***]. The JSC's authority shall be limited to those matters expressly delegated to it in this Agreement, and such decisions shall be made by consensus or escalated as described in Section 7.6. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. In addition, the JSC shall have no right, power or authority: (a) to interpret, modify, amend, or waive compliance with any provision of, or any right or remedy under, this

Agreement; (b) to determine whether or not a Party has complied with any of its obligations under this Agreement; (c) to determine any issue in a manner that would conflict with the express terms of this Agreement; or (d) to make any decision or approve any matter that is expressly stated to require the mutual agreement or mutual written agreement of the Parties or the written consent or written approval of a Party or of both Parties.

8. DEVELOPMENT

8.1 Licensee shall use Commercially Reasonable Efforts to develop Licensed Product in the Field in the Territory and to obtain, support, and maintain Approval and [***] of Licensed Product in the Field in the Territory ("**Territory Development Activities**"), at its sole cost and expense. Licensee shall perform all Territory Development Activities (a) in good scientific and clinical manner, (b) in compliance with Applicable Laws, and (c) within the scope of the license granted to Licensee hereunder. For the avoidance of doubt, Territory Development Activities shall not include activities directed towards modifications of the composition or specifications of, or the manufacturing, testing and release methods for, the Licensed Product, other than the development by or for the Licensee and at the Licensee's expense of any analytic or testing procedures that are required for the Approval or commercialization of the Licensed Product in the Territory.

8.2 As soon as reasonably possible, but no later than [***], Licensee shall prepare, and submit to the JSC for its review and recommendation, a plan for the Territory Development Activities, which describes in reasonable detail the planned activities and timelines for the Territory Development Activities (the "**Development Plan**"); provided that, should Licensee be unable to provide the Development Plan by such time by reason of a failure on the part of Calliditas to timely provide any duly-requested Know How, the time for the submission of the Development Plan to the JSC shall be adjusted accordingly by the JSC to reflect the reasonable time required to complete the Development Plan. Any Territory Development Activities conducted by Licensee under this Agreement on Licensed Product shall be conducted pursuant to the Development Plan. The Development Plan shall be focused on efficiently obtaining Approval for Licensed Product in the Field in the Territory. [***], Licensee shall submit to the JSC a report on the implementation of the Development Plan, describing in reasonable detail (a) the past, current, and projected activities taken or planned to be taken by Licensee in accordance with the Development Plan, at a level of detail reasonably sufficient to enable Calliditas to determine Licensee's compliance with its diligence obligations, and (b) any modifications of the Development Plan. Licensee will consider in good faith any comments from Calliditas on the Development Plan, such comments to be made through the JSC.

8.3 Licensee shall be responsible for conducting all development activities including clinical trials with respect to Licensed Product in the Territory that are required for obtaining or maintaining Approval and [***] of Licensed Product in the Field in the Territory. Licensee shall be responsible for all of its costs and expenses for the Territory Development Activities, and for any costs and expenses of Calliditas and its Affiliates that Licensee has committed to pay or reimburse in the Development Plan.

8.4 Licensee shall not, without the express written consent of Calliditas, modify the Licensed Product in a manner which [***].

8.5 Notwithstanding any other provision of this Agreement, Licensee (and its Affiliates and third parties authorized or assisted by Licensee) shall not [***].

8.6 Licensee shall maintain complete, current and accurate records of all Territory Development Activities, and all data and other information resulting from such activities. Such records shall fully and properly reflect all work performed and results achieved in the performance of such activities

in good scientific manner appropriate for regulatory and patent purposes. Each Party shall keep the other Party reasonably informed through the JSC regarding the progress of the development and any interactions with Competent Authorities in the Territory and outside the Territory.

8.7 Licensee shall be responsible for formulating and implementing a regulatory plan in connection with the Territory Development Activities (the "**Regulatory Plan**"), which shall include: [***]. Any regulatory activities conducted by Licensee under this Agreement on Licensed Product shall be conducted pursuant to the Regulatory Plan. Calliditas shall provide all information within its Control and any consultation, in each case as is reasonably necessary for Licensee to respond to inquiries from PMDA or other applicable Governmental Authorities in the Territory, including, without limitation, information and consultation regarding clinical studies conducted by Calliditas, its Affiliates and licensees, such information to be provided either to Licensee or, if necessary to preserve the confidentiality of manufacturing procedures and other trade secrets and allowed under Applicable Laws, to the applicable Governmental Authority.

8.8 Licensee shall be the marketing authorization holder for Licensed Product in the Field in the Territory. Licensee shall be responsible, [***], for preparing all submissions, documents or other correspondence submitted to Competent Authorities with respect to Licensed Product in the Field in the Territory (collectively, the "**Regulatory Documentation**"). Calliditas shall have the right to review and comment on all substantive Regulatory Documentation prepared by Licensee, and Licensee shall reasonably consider Calliditas' comments in good faith with respect to such Regulatory Documentation. Licensee shall promptly notify Calliditas of all material questions or inquiries as well as any material correspondence that it receives or plans to submit to a Competent Authority in the Territory and shall promptly provide Calliditas with a full copy (which may be wholly or partly in electronic form) of the same. Promptly following receipt of any Approval or other decision on Regulatory Documentation from a Competent Authority relating to Licensed Product, Licensee also shall furnish Calliditas with copies of the same. Upon Licensee's reasonable request and in the ordinary course of business (and subject to the availability of personnel), Calliditas will cooperate to assist Licensee in its efforts to timely prepare and submit any Regulatory Documentation and complete other activities under the Regulatory Plan to obtain, support, or maintain Approvals for Licensed Product, including preclinical packages, IND and NDA filings. In addition, Calliditas shall make its regulatory personnel reasonably available to Licensee for consultation between the regulatory teams of the Parties, and Licensee shall reimburse Calliditas for the documented out-of-pocket expenses reasonably incurred in connection with travel and accommodation as requested by Licensee for Calliditas to provide such consultation. Copies of any Approval or other decision on Regulatory Documentation that are in Japanese shall be submitted to Calliditas with an English translation, and Regulatory Documentation prepared in Japanese and submitted to Calliditas for review shall be submitted with an English language translation or synopsis sufficient to permit Calliditas to comment thereon; such translations or synopses shall be prepared [***].

8.9 In addition, [***] of post-Approval stability studies, Regulatory Documentation (updates, annual review/reports), product maintenance (continued process verification, new supplier assessments), in each case either (i) as requested by [***] by notice or as required by Competent Authority in the Territory but not by Competent Authorities outside the Territory, or (ii) on a pro rata basis if required by Competent Authorities both in and outside the Territory.

8.10 Licensee shall not, and shall cause its Affiliates and third-party sublicensees not to, take any action in connection with preparing, filing, obtaining and maintaining (a) Approval for Licensed Product outside the Territory, and (b) the [***] or orphan status (where applicable) for Licensed Product outside the Territory. Calliditas shall not, and shall cause its Affiliates and licensees (other than Licensee) not to, take any action in connection with preparing, filing, obtaining and maintaining (a) Approval for

Licensed Product in the Territory, and (b) the [***] or orphan status (where applicable) for Licensed Product in the Territory.

8.11 Licensee shall provide Calliditas with reasonable advance notice, including relevant documentation, of all substantive meetings with the Competent Authorities in the Territory pertaining to Licensed Product, or with as much advance notice as practicable under the circumstances. Licensee otherwise shall use Commercially Reasonable Efforts to permit Calliditas to have, at Calliditas' expense, [***] of Calliditas attend, solely as non-participating observers, substantive meetings with the Competent Authorities within the Territory pertaining to Licensed Product; provided, however, that if required by the Competent Authority or Licensee and not requested by Calliditas, a representative of Calliditas shall attend such meeting and Calliditas' costs and expenses associated with such attendance shall be [***]. Licensee shall promptly furnish Calliditas with relevant pre-meeting documentation and copies of minutes of all meetings with a Competent Authority in the Territory relating to Licensed Product, accompanied by an English translation or synopsis [***].

8.12 As promptly as practicable following the execution of a Supply Agreements for clinical or commercial supply of Licensed Product, but in no event later than [***] thereafter (or such longer period as may be mutually agreed by the Parties), Licensee and Calliditas will negotiate and agree upon safety data exchange procedures in a separate pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") and Licensee shall not in any event sell or administer a Licensed Product to any human prior to the execution of the Pharmacovigilance Agreement. Such agreement will describe the coordination of collection, investigation, reporting, and exchange of information concerning adverse events or any other safety problem of any significance, procedures for participation in the global safety database, and product quality and product complaints involving adverse events, sufficient to permit each Party and its Affiliates and partners or (sub-)licensees to comply with its legal obligations. The safety data exchange procedures will be promptly updated if required by changes in legal requirements. In the event of any conflict or inconsistency between this Agreement and the Pharmacovigilance Agreement with respect to: (a) safety-related matters, the Pharmacovigilance Agreement shall prevail; and (b) any other matter, this Agreement shall prevail. Unless otherwise agreed by the Parties, Calliditas shall be responsible, itself or through a designee, for maintaining any required global safety database with respect to Licensed Product.

9. COMMERCIALIZATION

9.1 Licensee shall be solely responsible for the commercialization of Licensed Product in the Field in the Territory, [***]. Licensee shall use Commercially Reasonable Efforts to (a) no later than [***] after having obtained Approval of Licensed Product in the Field in the Territory, establish an appropriately sized and qualified marketing and sales organization, supported by a previously-organized medical affairs team, for commercialization of Licensed Product, and (b) commercialize Licensed Product in the Field in the Territory no later than [***] after NHI pricing for Licensed Product in the Field in the Territory, provided that such period of [***] will be extended if, and for so long as, there is a shortage of supplies of Licensed Product and such shortage was not caused by Licensee.

9.2 No later than [***] prior to the anticipated First Commercial Sale of Licensed Product, Licensee shall provide to Calliditas, through the JSC, an initial commercialization plan which represents the preliminary projections of Licensee regarding the commercialization of Licensed Product in the Territory (the "**Commercialization Plan**"). At least [***], Licensee shall propose to the JSC changes, revisions and updates to the Commercialization Plan, provided that any material changes proposed by Licensee and presented to the JSC shall be reasonable and based on a rationale provided in reasonable detail to the JSC when proposed, and the Parties shall discuss any such proposal in good faith, acting reasonably.

Licensee shall have final decision-making authority with regard to the Commercialization Plan, any modifications or variations thereto, and the implementation thereof.

9.3 Licensee shall commercialize Licensed Product in the Field in the Territory in accordance with the then-current Commercialization Plan. Licensee exercise its rights under this Agreement and perform its obligations under the Commercialization Plan (a) in good professional manner and in conformity with good distribution practices, and (b) in compliance with Applicable Laws.

9.4 Starting no later than [***] prior to the anticipated First Commercial Sale of Licensed Product, Licensee shall from time to time (but no less frequently than [***]) provide Calliditas with a written report that summarizes the commercialization activities performed during such time period, including a sales forecast of each Licensed Product and planned commercialization activities for the subsequent [***] period. Such reports shall cover subject matter at a level of detail reasonably sufficient to enable Calliditas to determine Licensee's compliance with its diligence obligations.

9.5 As between the Parties, each Party shall be solely responsible for booking sales of Licensed Product sold in its territory. Each Party may warehouse Licensed Product both inside and outside of such Party's territory, provided that any sales with respect to Licensed Product occur and are booked in such Party's territory. As between the Parties, each Party shall be solely responsible for handling all returns of Licensed Product sold in its territory, as well as all aspects of Licensed Product, logistics, inventory, order processing, invoicing and collection, and distribution of Licensed Product sold in such territory.

9.6 Subject to Applicable Laws, neither Party shall engage in any advertising or promotional activities relating to Licensed Product directed primarily to customers or other buyers or users of Licensed Product located outside of its territory or accept orders for Licensed Product from or sell Licensed Product into such other Party's territory for its own account, and, if a Party receives any order for Licensed Product in the other Party's territory, it shall refer such orders to the other Party, to the extent it is not prohibited from doing so under Applicable Laws. Each Party shall use Commercially Reasonable Efforts to monitor and prevent exports of Licensed Product from its own territory for commercialization in the other Party's territory using methods permitted under Applicable Laws that are commonly used in the industry for such purpose (if any), and shall promptly inform the other Party of any such exports of Licensed Product from its territory, and any actions taken to prevent such exports. Each Party agrees to use Commercially Reasonable Efforts as permitted by Applicable Laws to take reasonable actions requested in writing by the other Party to prevent exports of Licensed Product from its territory for commercialization in the other Party's territory.

10. SUPPLY OF LICENSED PRODUCT BY CALLIDITAS

10.1 Calliditas has advised Licensee and Licensee accepts that Calliditas has IMP and commercial supplies of Licensed Product manufactured for Calliditas by an Approved Supplier. Calliditas has entered into supply agreements with such Approved Supplier and has made arrangements with other suppliers concerning the supply of active pharmaceutical ingredients, and other product components.

10.2 Calliditas shall supply IMP and commercial supplies of Licensed Product only from [***], in each case (a), (b), and (c), compliant with all Applicable Laws, including cGMP, and accredited by Competent Authority in the Territory as a foreign manufacturer of pharmaceuticals (any, an "**Approved Supplier**"). At Licensee's request, Calliditas shall provide Licensee with copies of such accreditation and other appropriate documentation relating thereto, as may be necessary or convenient for Licensee to import, distribute, develop, and/or commercialize (as applicable) the IMP and Licensed Product in the Territory.

10.3 If Calliditas plans to add or change Approved Supplier(s):

10.3.1 Calliditas will: (i) provide prompt notification of such plans to Licensee and will provide Licensee with such information and cooperation as Licensee may request to facilitate Licensee's efforts to obtain any permissions, approvals, licenses or the like necessary or convenient to import, distribute, develop, and/or commercialize (as applicable and as permitted herein) the IMP and Licensed Product supplied from such added or changed Approved Supplier(s) in the Territory; and (ii) not supply IMP or Licensed Product to Licensee from any added or changed Approved Supplier(s) until Licensee obtains such permissions, approvals, licenses or the like and notifies Calliditas in writing that it may proceed with such supply.

10.3.2 Licensee will, upon receipt of such notification from Calliditas, promptly file applications with the relevant Government Authority(ies) to obtain such permissions, approvals, or the like.

10.4 Commencing [***], the Parties shall negotiate in good faith a supply agreement for the supply by Calliditas to Licensee of all of Licensee's requirements for IMP for use in Territory Development Activities (the "**IMP Supply Agreement**"). The Parties have agreed, that until the execution of the IMP Supply Agreement and supersession thereby, the following provisions shall be binding on both Parties:

10.4.1 Licensee may place an order for IMP with Calliditas in writing (including by email), specifying the quantity of IMP ordered and the desired delivery date. Such order will be deemed to be a binding firm order on both Parties, provided that Licensee has complied with the lead time set out in Section 10.4.2. Notwithstanding the foregoing, Calliditas shall in good faith fulfil and deliver Licensee's full order of IMP as soon as reasonably practicable.

10.4.2 The desired delivery date for IMP orders shall be consistent with the IMP lead time set forth in the applicable manufacturing services or other agreement between Calliditas and its Approved Suppliers. As of the Effective Date, the lead time for Licensee's IMP orders shall be equal to the IMP lead time set forth in such applicable manufacturing services or other agreement between Calliditas and its Approved Suppliers, but in no event longer than [***]. Should the lead time be changed, Calliditas will provide Licensee with prompt notice thereof.

10.4.3 Licensee shall make good faith efforts based on its good faith estimation of required IMP to place a single order for Licensee's full requirements of IMP, provided that Licensee shall have the right to place additional orders for IMP as and when required. The amount of IMP ordered shall be adjusted to multiples of Calliditas' then current batch size. Calliditas represents and warrants that as of the Effective Date, the batch size is approximately [***] capsules per batch of active IMP and up to [***] capsules per batch of placebo IMP.

10.4.4 Active IMP shall be manufactured by an Approved Supplier used by Calliditas to commercially manufacture Licensed Product sold in the United States, following the procedures and specifications used by Calliditas in such commercial manufacturing, and placebo IMP shall be manufactured following the procedures and specifications used by Calliditas for its clinical trials. Any deviations or additions to product specifications required by mandatory regulations in the Territory, including changes to manufacturing or testing procedures related to such Territory-specific product specifications, shall be initiated by Licensee and implemented in accordance with the change order procedures to be provided for in the quality agreement entered into under the IMP Supply Agreement, [***]; orders for IMP that are the subject of change orders may be placed only after such change order procedures are completed. Manufacturing of IMP shall be conducted in accordance with United States and Japan cGMP and any additional requirements implemented in accordance with the change order procedures

referred to above. Calliditas shall timely implement change orders with the Approved Supplier(s), keep Licensee reasonably apprised of the progress in implementing change orders, and promptly report the completion of each change order.

10.4.5 The price of IMP shall be Calliditas' direct, out-of-pocket costs to have IMP manufactured, which shall be the price charged by Calliditas' approved suppliers throughout the whole supply chain (including API and other components not procured by the Approved Supplier), increased by [***]. As of the Effective Date, the unit price to Licensee of active IMP is [***]. For the avoidance of doubt, the price of Licensed Product and the price of placebos of Licensed Product shall be determined separately and invoiced as separate line items. Calliditas shall deliver orders of IMP to Licensee EXW Approved Supplier's manufacturing facility within [***] after Licensee's desired delivery date, provided that such desired delivery date is consistent with the IMP lead time set forth in Section 10.4.2. IMP supplied hereunder shall (a) be delivered in bright stock bottles, (b) be compliant with all Applicable Laws for the United States, including cGMP and any additional requirements implemented in accordance with the change order procedures referred to in Section 10.4.4 above, and (c) except for placebos, meet all specifications for the Licensed Product as set forth in the United States NDA and any additional requirements implemented in accordance with the change order procedures referred to in Section 10.4.4 above. The shelf-life of IMP is [***], and IMP shall be delivered with a minimum [***] remaining shelf-life.

10.5 Commencing no later than promptly after the delivery to Calliditas of the initial version of the Commercialization Plan, the Parties shall negotiate in good faith a supply agreement for the supply by Calliditas to Licensee of all of Licensee's requirements for Licensed Product for commercialization in the Territory (the "**Commercial Supply Agreement**"), provided that Licensee shall provide forecasts prior to such date as may reasonably be requested by Calliditas to fulfill its forecasting obligations towards the Approved Suppliers.

10.5.1 Licensee may place an order for commercial supply of Licensed Product with Calliditas in writing (including by email), specifying the quantity of Licensed Product ordered and the desired delivery date. Such order will be deemed to be a mutually binding firm order, [***].

10.5.2 The desired delivery date for Licensed Product orders shall be consistent with the Licensed Product lead time set forth in the applicable manufacturing services or other agreement between Calliditas and its Approved Suppliers. As of the Effective Date, such Licensed Product lead time is [***] after the first day of the month after which the order was placed, provided the order is placed before the [***] day of the month. Should the lead time be changed, Calliditas will provide Licensee with prompt notice thereof. Licensee shall place its orders no later than the [***] day of the month in which the order is placed. Calliditas agrees, and shall procure, that no orders of Licensed Product will be delivered earlier than [***] prior to the delivery date in the binding firm order.

10.5.3 The price of Licensed Product supplied under the Commercial Supply Agreement shall be Calliditas' direct, out-of-pocket costs to have such Licensed Product manufactured, which shall be the price charged by Calliditas' approved suppliers throughout the whole supply chain (including API and other components not procured by the Approved Supplier), increased by [***], subject to any price adjustments by Calliditas' approved suppliers as provided in Calliditas' agreements with the same. Before application of the above-referenced [***] charge, the unit price of such Licensed Product (as normalized to a [***] Capsule) supplied by Calliditas to Licensee shall be no greater than [***]. As of the Effective Date, the unit price to Licensee of such Licensed Product is [***]. Calliditas represents and warrants to Licensee that its supply agreements with other licensees as of the Effective Date also provide for supply at cost plus [***] and covenants that it will adjust its pricing method with Licensee to align Licensee's pricing with any

more favorable pricing method agreed to with another Licensee, provided that Calliditas may, without changing its pricing method with Licensee, offer another licensee a manufacturing support percentage adjustment lower than [***] if such licensee orders more than [***] Capsules (normalized to a [***] capsule) per contract year.

10.6 Licensee shall be responsible for arranging [***] any required secondary packaging, labelling, and release testing for Licensed Product for the Territory. Licensed Product shall be manufactured by an Approved Supplier used by Calliditas to commercially manufacture Licensed Product sold in the United States, following the procedures and specifications used by Calliditas in such commercial manufacturing. Any deviations or additions to product specifications required by mandatory regulations in the Territory, including changes to manufacturing or testing procedures related to such Territory-specific product specifications, shall be initiated by Licensee and implemented in accordance with the change order procedures to be provided for in the quality agreement entered into under the Commercial Supply Agreement, [***]; orders for Licensed Product that are the subject of change orders may be placed only after such change order procedures are completed. Manufacturing of Licensed Product shall be conducted in accordance with United States and Japan cGMP and any additional requirements implemented in accordance with the change order procedures referred to in this Section 10.6. Calliditas shall timely implement change orders with the Approved Supplier(s), keep Licensee reasonably apprised of the progress in implementing change orders, and promptly report the completion of each change order.

10.7 In the event of a global supply shortage, [***].

10.8 In the event of a failure to deliver to Licensee (or Calliditas' notice to Licensee that it will be unable to timely fill) [***]of a binding firm order of Licensed Product ordered under Section 10.5.1, and/or [***] of IMP ordered under Section 10.4.1, as applicable, specified in the applicable purchase order of Licensee within [***] after the delivery date in the binding firm order provided by Licensee consistent with Section 10.4.2 or Section 10.5.2 (as applicable) with respect to such order; provided that such failure is not predominantly attributable to any act or omission of Licensee or its Affiliates or sublicensees (a "**Supply Failure**"), Calliditas shall reimburse Licensee, its Affiliates, and its and their permitted sublicensees within [***] of Calliditas' receipt of written notice of documented Losses incurred by or imposed upon such Licensee, Affiliate, or permitted sublicensee, as applicable, to the extent such documented Losses are caused by a Supply Failure, for so long as such Supply Failure continues; provided that with respect to a Supply Failure of Licensed Product: (i) prior to the delivery date in the binding firm order which gives rise to the Supply Failure, Licensee had ordered sufficient Licensed Products (normalized to a [***] Capsule) enabling Licensee to reasonably maintain an inventory (not including inventory supply levels customarily held by its third parties in its supply channels) equal to at least [***] of unit sales of Licensed Products (normalized to a [***] Capsule) in the Territory immediately prior to the delivery date in the binding firm order which gives rise to the Supply Failure; (ii) subject to Calliditas' delivery in full of such order(s) in (i) Licensee had up to the delivery date in the binding order which gives rise to the Supply Failure maintained such inventory; and (iii) [***].

10.9 In the event of a failure to deliver to Licensee (or Calliditas' notice to Licensee that it will be unable to timely fill) [***]of a binding firm order of Licensed Product ordered under Section 10.5.1, and/or [***] of IMP ordered under Section 10.4.1, as applicable, specified in the applicable purchase order of Licensee within [***] after the delivery date in the binding firm order consistent with Section 10.4.2 or Section 10.5.2 (as applicable), provided that such failure is not predominantly attributable to any act or omission of Licensee or its Affiliates or sublicensees (a "**Qualifying Supply Failure**"), (1) Calliditas shall, subject to the conditions and limitations set forth in Section 22.10.4, reimburse Licensee, its Affiliates, and its and their respective permitted sublicensees, [***]; (2) Calliditas shall use commercially reasonable

efforts to restore supply to Licensee as quickly as possibly utilizing any and all Approved Suppliers to manufacture Licensed Product for Licensee; and (3) [***].

10.10 Concomitantly with the negotiation of each of the Supply Agreements, the Parties shall negotiate in good faith a quality agreement defining the roles and responsibilities of each Party and the Approved Supplier(s) with respect to quality assurance. The quality agreements shall conform to Applicable Laws governing each Party's respective activities and shall be negotiated in good faith to conform to the extent possible with each Party's generally applicable policies and procedures.

11. REMUNERATION

11.1 Upfront Payment. Licensee shall pay to Calliditas the [***] amount of twenty (20) million USD within [***] after the Effective Date, on the basis of an invoice to be issued by Calliditas to Licensee promptly after the Effective Date (the "**Upfront Payment**").

11.2 Milestone Payments

11.2.1 Upon first achievement of each of the milestone events set out in the following table ("**Milestone Event**") for Licensed Product by Licensee, its Affiliate or its sublicensees, Licensee shall pay to Calliditas the non-refundable, non-creditable amounts ("**Milestone Payment**") set out next to such Milestone Event in the table below:

Milestone Event	**Milestone Payment**
[***]	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Total	**Eighty (80) million USD**

11.2.2 For the avoidance of doubt, in the event Licensee elects to terminate this Agreement pursuant to Section 26.3(c), the Milestone Payment in the amount of [***] USD in connection with [***] (the "**First Milestone Payment**") shall not be due and payable. The Milestone Payments are

only payable on the initial achievement of the relevant Milestone Event and no additional payment shall be due hereunder for subsequent or repeated achievements of such Milestone Event regardless of how many times such Milestone Event has occurred for one or more Licensed Product. If a Milestone Event for Licensed Product is not achieved because development or commercialization activities occurred such that achievement of such earlier Milestone Event was unnecessary or did not otherwise occur, then upon achievement of the next Milestone Event, such earlier skipped Milestone Event shall be deemed to have been achieved and the Milestone Payment applicable to such earlier skipped Milestone Event will also become due with respect to Licensed Product.

11.2.3 Licensee shall notify Calliditas within [***] after the first achievement of any development Milestone Event set forth in this Section 11.2 by or on behalf of Licensee or its Affiliates or its or their sublicensees, and with respect to the commercial Milestone Events, within [***] after the [***] in which such commercial Milestone Events are achieved. Calliditas shall invoice Licensee for corresponding Milestone Payment promptly after receipt of such notice. The Milestone Payment shall be paid within [***] after the achievement of a development Milestone Event (with respect to the commercial Milestone Payments, within [***] in which such commercial Milestone Events are achieved).

11.3 Royalties

11.3.1 Licensee shall pay to Calliditas a royalty in the amount of [***] of Net Sales of Licensed Product in the Territory, regardless of whether such Net Sales is made by Licensee, its Affiliates and/or its or their permitted sublicensees.

11.3.2 The initial royalty term ("**Initial Royalty Term**") shall start on the Effective Date and end on [***].

11.3.3 Beginning with [***], Licensee shall send Calliditas a report of Net Sales within [***]until it ceases all sales of Licensed Products, and within [***] such cessation of sales, in respect of Net Sales made, as the case may be, during such [***] or the unreported period prior to the date of the cessation of sales. Such report of Net Sales shall be in such form as Licensee and Calliditas may agree from time to time. Calliditas shall, promptly after the receipt of each such report of Net Sales for [***] each year, submit to Licensee via email an invoice for Royalties due under this Agreement for the preceding [***]. Such invoice shall be paid by Licensee within thirty (30) days of receipt.

11.4 Expiration of Exclusivity. After the Initial Royalty Term has expired, the royalty rate for the remainder of the Term shall be [***].

11.5 Royalty Stacking. If for the commercial exploitation of the Licensed Technology in the Field and the Territory there is no commercially reasonable alternative to obtaining a license from any third-party ("**Third-Party License**") in order to avoid infringing such third-party's patent(s) in the course of the development or commercialization of Licensed Product, the royalties payable under this Agreement shall be reduced by [***] of the royalty amount paid under the Third-Party License, provided that the amount of royalty payable by Licensee to Calliditas totally or in any given calendar year, shall not be reduced by more than [***] of the amount that would have been payable in the absence of this Section 11.5. Licensee shall notify Calliditas of any obligation to obtain a Third-Party License and provide sufficient documentation to show the existence of such obligations or commercial necessity and its relation to the Licensed Patents. The deductions referred to in this Section 11.5 shall only be made where the infringement of the third-party patent arises from the use of the inventions claimed in the Licensed Patents in accordance with the provisions of this Agreement, and not from the use of any other intellectual property that Licensee chooses to use in the development or commercialization of Licensed Product.

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 "[***]".

11.6 Limitation. In no event shall royalty reductions pursuant to Sections 11.4 and 11.5 above result in that the royalties payable by Licensee to Calliditas totally or in any calendar year, are reduced by more than [***] of the amount that would have been payable in the absence of such reductions.

12. REPORTS; RECORDS; AUDIT

12.1 In connection with payment of royalties on Net Sales, Licensee shall provide Calliditas with a written report concerning the calculation of the royalty payable by Licensee to Calliditas hereunder. Each such report shall contain total number of units of Licensed Product sold or transferred by Licensee or its Affiliates or sublicensees during the most recent [***], together with any exchange rates used for conversion, and total royalties due. Promptly after receipt of such report, Calliditas shall invoice Licensee for the royalty payment due.

12.2 Receipt or acceptance by Calliditas of any of the reports furnished pursuant to Section

12.3 above or of any sums paid hereunder shall not preclude Calliditas from questioning the correctness thereof based on the audit conducted in accordance with Section 12.3, and in the event any inconsistencies or mistakes are discovered in such reports or payments, they shall be promptly rectified and appropriate payment, if necessary, shall be made by Licensee of any amounts.

12.4 Licensee shall maintain, and cause to be maintained, for a period of [***] following the end of the calendar year to which they pertain, complete and true books of accounts and other records in sufficient detail so that the royalties and other payments payable to Calliditas hereunder can be properly ascertained. These records shall be ready for inspection and examination during normal business hours upon no less than [***] written notice, by an independent auditor, reasonably acceptable to Licensee and bound by a confidentiality agreement or professional secrecy, for the purpose of verifying correct royalty payments. Records may be audited no more than once per calendar year, and records audited may not be reviewed again in subsequent audits, except for cause. Such independent auditor shall disclose simultaneously to each Party only whether such royalties and other payments are correct or incorrect and the specific details concerning any discrepancies. Licensee shall co-operate at such audit and shall give any explanations that may reasonably be requested. The cost and expense for such audit shall be borne by Calliditas, provided that, without prejudice to any other remedy or action available due to breach of this Agreement, if the audit should determine a discrepancy between royalty reported and the royalty actually due resulting in underpayment of royalties of more than [***], then the cost and expense of the audit shall be borne by Licensee. Licensee shall promptly pay to Calliditas all amounts determined by any such audit to be due to Calliditas, with interest in accordance with Section 13.2 below from the date the same should have been paid. Calliditas shall promptly refund to Licensee any overpayment determined by any audit.

12.5 Licensee shall impose obligations substantially equivalent to those of this Section 12 on its Affiliates and sublicensees and procure corresponding audit rights for Calliditas in relation to Licensee's sublicensees for the same purpose.

13. PAYMENT TERMS

13.1 All payments under this Agreement shall be made in USD. For the purpose of computing payments made in a currency other than USD, such currency shall be converted into USD at the conversion rates used by Licensee in the rest of its business to consolidate foreign currencies, provided only that such rates are obtained from a credible source and are applied in a manner consistent with generally accepted accounting principles.

13.2 If Licensee at any time should fail to pay in full on its due date the undisputed amount of any payment due under this Agreement (including any amount determined to be due after an audit of any payments), Calliditas may claim interest on the unpaid amount from the date when first due until the date payment is made, based on the then-current reference interest rate of the [***].

13.3 All sums payable under this Agreement are exclusive of any value added tax or any other sales tax or duties, which where applicable, shall be payable by the payer in addition to any sum in respect of which they are calculated.

13.4 Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising from the activities performed by such Party in accordance with this Agreement.

13.5 If Licensee is required to deduct or withhold any withholding taxes, charges or other duties on the royalties or other amount payable to Calliditas hereunder, it will (a) promptly notify Calliditas of such requirement, (b) pay to the relevant Governmental Authorities the full amount to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against Calliditas, and (c) promptly forward to Calliditas an official receipt (or certified copy), or other documentation reasonably acceptable to Calliditas and obtainable by Licensee, evidencing such payments to such Governmental Authorities. The Parties agree to co-operate in all respects necessary to take advantage of available double taxation agreements, including not withholding taxes from payments if the Party receiving such payment has timely provided sufficient evidence of its then-current eligibility for exemption from withholding of taxes otherwise applicable to such payment.

14. OWNERSHIP OF INTELLECTUAL PROPERTY

14.1 Any intellectual property which is (a) created, conceived, reduced to practice or invented by or on behalf of Licensee during the Term, (b) Controlled by Licensee, and (c) that claims the composition of matter or formulation of, or method of making or using, Licensed Product shall be deemed "**Arising Product IP**" which shall be solely owned by Licensee or such licensor in Control of such intellectual property.

14.2 For clarity, Calliditas shall be the sole owner of any Improvements and other intellectual property which are created, conceived, reduced to practice or invented by or on behalf of Calliditas or its Affiliates.

14.3 Licensee agrees to grant, hereby grants, and shall cause to be granted to, Calliditas an exclusive (also towards Licensee and its Affiliates), [***] license ([***] the right to grant sublicenses) under the Arising Product IP to use the Arising Product IP in connection with the use or sale of Licensed Product outside the Territory and the worldwide manufacture of Licensed Product solely for sale outside the Territory. Notwithstanding the foregoing, Licensee retains the right to use and grant sublicenses (subject to Section 3.5) under the Arising Product IP for the purposes set forth in Sections 3.1 and 3.4.

14.4 Any Improvements which are Controlled by Calliditas or its Affiliates during the Term and which are used by Calliditas or its Affiliates or licensees in connection with the development (including obtaining Approvals) or commercialization of the Licensed Product in the Field shall be automatically included under the license granted to Licensee by Calliditas pursuant to Section 3.1 with no additional charge to Licensee, and become part of the Licensed Technology. The Parties shall update the Appendix 1 (Licensed Patents) accordingly.

14.5 The Parties agree that U.S. patent law on inventorship shall determine the inventorship of any invention for the purpose of interpreting and applying this Section 14.

14.6 Licensee warrants that it will procure ownership of and perfect the rights in and to the Arising Product IP from its employees by obligating such personnel in writing to assign such Arising Product IP to Licensee. Calliditas warrants that it will procure ownership of and perfect the rights in and to Improvements from its employees and consultants by obligating such personnel in writing to assign such Improvements to Calliditas.

15. NEW DATA AND TERRITORY DOSSIER

15.1 New Data shall be jointly owned by the Parties in equal parts, unless Applicable Laws prevent such joint ownership of New Data, in which case, Licensee shall grant to Calliditas an exclusive (also in relation to Licensee and its Affiliates), [***] license ([***] the right to grant sublicenses) to use New Data in connection with the use or sale of Licensed Product outside the Territory and the worldwide manufacture of Licensed Product solely for sale outside the Territory. The Territory Dossier shall be solely owned by Licensee.

15.2 To the degree and in a manner acceptable under Applicable Laws, and at times (not less than [***]) to be determined by the JSC, Licensee shall make available to Calliditas all New Data as well as other information and documentation regarding Licensee's development and regulatory activities that is necessary or useful for the development and regulatory activities with respect to Licensed Product outside the Territory. Such information and documentation may be provided initially in summary form, with more detailed information and documentation provided in a manner compliant with Applicable Laws governing data privacy, data security, and the exportation of data. Calliditas' use of the New Data is subject to the exclusive license granted to Licensee hereunder pursuant to Section 3.1.

15.3 Licensee hereby grants Calliditas an exclusive (also in relation to Licensee and its Affiliates), [***] license ([***] the right to grant sublicenses) under Licensee's share in the New Data to use New Data in connection with the use or sale of Licensed Product outside the Territory and the worldwide manufacture of Licensed Product solely for sale outside the Territory. Without limiting the generality of the foregoing, Licensee hereby grants to Calliditas an exclusive (also in relation to Licensee and its Affiliates), [***] right ([***] the right to grant sublicenses) to reference and use the Territory Dossier in development and regulatory activities with respect to Licensed Product outside the Territory. Upon Licensee's request, Calliditas will (a) take all steps necessary to ensure that the Parties' sharing of New Data and Calliditas' possession and use of New Data are compliant with then-current Applicable Laws and industry standards and (b) comply with Licensee's reasonable requests to certify or provide evidence of such compliance.

15.4 In the event that New Data includes any information that under Applicable Laws in the Territory, including data privacy and data security regulations, require specific contractual arrangements prior to disclosure to Calliditas, the Parties agree to enter into a data transfer agreement allowing the fullest disclosure and use permitted under Applicable Laws. Any New Data that can under no circumstances be disclosed to Calliditas under Applicable Laws in the Territory, or which disclosure would be inconsistent with the customary informed consent practices in the Territory, shall be excluded from the definition of New Data.

16. MAINTENANCE AND PROSECUTION OF PATENTS

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 "[***]".

16.1 Calliditas shall have the first right (but not the obligation), at its discretion, to control the preparation, filing, prosecution and maintenance ("**Prosecution**") of the Licensed Patents. Calliditas shall provide Licensee with a timely opportunity to comment on decisions related to the Prosecution of the Licensed Patents in the Territory and, absent reasonable cause not to do so, shall conduct such Prosecution in accordance with Licensee's comments. Calliditas shall bear all costs and expenses for the Prosecution of the Licensed Patents but Licensee shall provide such assistance, including signing such documents and taking such legally permitted actions, as requested by Calliditas to evidence and perfect Calliditas' rights in and ownership of the Licensed Patents. Should Calliditas decide that it is no longer interested in the Prosecution of a Licensed Patent in the Territory, it will promptly so notify the Licensee, and Licensee shall have the right (but not the obligation), by a notice sent to Calliditas not later than [***] after the receipt of Calliditas notice, to assume such Prosecution in the Territory at its sole cost and expense.

16.2 Licensee shall have the first right (but not the obligation), at its discretion, to control the Prosecution of patents and patent applications covering Arising Product IP. Licensee shall provide Calliditas with an opportunity to comment on decisions related to the Prosecution of the patents and patent applications covering Arising Product IP in the Territory and shall take into reasonable consideration Calliditas' comments. Licensee shall bear all costs and expenses for the Prosecution of the patents and patent applications covering Arising Product IP but Calliditas shall provide such assistance, including signing such documents and taking such legally permitted actions, as requested by Licensee to evidence and perfect Licensee's rights in and ownership of patents and patent applications covering Arising Product IP. Should Licensee decide that it is no longer interested in the Prosecution of any patent or patent application covering Arising Product IP in the Territory, it will promptly notify Calliditas, and Calliditas shall have the right (but not the obligation), by a notice sent to Licensee not later than [***] after the receipt of Licensee's notice, to assume such Prosecution in the Territory at its sole cost and expense.

17. THIRD-PARTY INFRINGEMENT

17.1 Each Party shall inform the other Party promptly if it becomes aware of any infringement or potential infringement of any of the Licensed Technology or any patents covering Arising Product IP, and the Parties shall consult with each other to decide the best way to respond to such infringement.

17.2 Licensee shall have the first right (but not an obligation), under its own control and [***], to take action with respect to any third-party infringements in the Territory of any of the Licensed Technology and any patents covering Arising Product IP, in which case Licensee will retain any and all proceeds obtained from such proceedings, provided that [***]. Licensee shall keep Calliditas reasonably informed of claims relating to the Licensed Technology or any patents covering Arising Product IP within the Field and the Territory and seek the assistance and input from Calliditas on matters that may be reasonably expected to affect the validity or enforceability of the Licensed Technology outside the Territory. Calliditas agrees to reasonably assist Licensee in any proceedings referred to in this Section 17.2, [***]. Licensee shall not, without the prior written consent of Calliditas, enter into any compromise or settlement relating to such proceedings that (a) admits the invalidity or unenforceability of any Licensed Technology or any patents covering Arising Product IP, or (b) admits any wrongdoing by, or result in injunctive or other relief being imposed against Calliditas.

17.3 If Licensee decides not to act against a third-party infringement in the Territory of the Licensed Technology or any patents covering Arising Product IP, Licensee shall notify Calliditas and Calliditas may, within [***] of receipt of such notice (or such shorter period as may be necessary to preserve any rights of action) elect by notice to Licensee to take such actions [***], in which case any and all proceeds obtained from such proceedings, [***]. Licensee agrees to reasonably assist Calliditas in any proceedings referred to in this Section 17.3 [***]. Calliditas shall not, without the prior written consent of

Licensee (not to be unreasonably conditioned, delayed, or denied), enter into any compromise or settlement relating to such proceedings that (a) admits the invalidity or unenforceability of any Licensed Technology or any patents covering Arising Product IP, or (b) admits any wrongdoing by, or result in injunctive or other relief being imposed against Licensee.

18. INFRINGEMENT CLAIMS

18.1 Calliditas and Licensee shall promptly notify each other of any written notice to it of alleged infringement or misappropriation, based upon its performance of its obligations hereunder, of a third-party's intellectual property rights of which it shall become aware ("**Infringement Claim**"), and the Parties shall discuss the best way to respond to the Infringement Claim; provided that this shall not preclude the recipient of the Infringement Claim from taking necessary actions to protect its interests under its own control and at its own expense. This notwithstanding, neither Party shall acknowledge to a third-party the validity of any such Infringement Claim without the prior written consent of the other Party.

18.2 If Licensee is the recipient of the Infringement Claim, Licensee shall keep Calliditas reasonably informed of all material developments in connection with such Infringement Claim. Licensee shall provide Calliditas with copies of all pleadings filed in such action and to allow Calliditas reasonable opportunity to participate in the defense of the claims. Calliditas shall assist Licensee in connection with such Infringement Claim as reasonably requested by Licensee, provided that Licensee shall reimburse Calliditas for any out-of-pocket costs or expenses incurred by Calliditas in connection with assistance rendered at Licensee's request, and that Calliditas shall have the right to be separately represented by its own counsel at its own expense.

18.3 If Calliditas is the recipient of the Infringement Claim and provided that the Infringement Claim has relevance for Licensee's development and commercialization of Licensed Product in the Field in the Territory, Calliditas shall keep Licensee reasonably informed of all material developments in connection with such Infringement Claim. Further, Calliditas agrees to provide Licensee with copies of all pleadings filed in such action and to allow Licensee reasonable opportunity to participate in the defense of the claims. Licensee shall assist Calliditas in connection with such Infringement Claim as reasonably requested by Calliditas, provided that Calliditas shall reimburse Licensee for any out-of-pocket costs or expenses incurred by Licensee in connection with the Infringement Claim, and that Licensee shall have the right to be separately represented by its own counsel at its own expense.

18.4 In no event may either Party settle any Infringement Claim in a manner that would limit the rights of the other Party or impose any obligation on the other Party, without such other Party's prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned.

19. PATENT EXTENSIONS

19.1 With respect to any election for patent term extensions, supplemental protection certificates or any of their equivalents with respect to the Licensed Patents, Calliditas shall have the sole and exclusive right (but not the obligation) to seek such extensions in the Territory at Calliditas' sole cost and expense. Upon the written request by Calliditas, Licensee will reasonably cooperate with the implementation of such decisions. Calliditas shall consider reasonably and in good faith requests from Licensee with respect to such extensions in the Territory. If Calliditas confirms in writing to Licensee that it does not intend to seek any such extensions in the Territory, Licensee may seek such extensions in the Territory at Licensee's sole cost and expense, in Calliditas' name.

20. TRADEMARKS

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 "[***]".

20.1 Calliditas grants Licensee during the Term, an [***] license to the NEFECON mark for use in commercializing the Licensed Product in the Field in the Territory. The Parties will, within [***], execute a trademark license agreement on terms customary in the Territory. The trademark license agreement will provide that if Licensee uses the NEFECON mark to commercialize the Licensed Product in the Field in the Territory, all costs and expenses related to registering, maintaining, defending or enforcing the NEFECON mark in the Field in the Territory shall be borne by [***].

20.2 For the avoidance of doubt, nothing in this Agreement shall require Licensee to use the NEFECON mark. Licensee shall have the right to commercialize Licensed Product in the Field and the Territory in its own name and under its own trademark(s), in which case Licensee shall use a product name and distinctive artwork and logos (the "**Trademark(s)**") not confusingly similar with those used by Calliditas or its other licensees. Licensee shall own and be solely responsible for the Trademark(s) in the Territory and may, in its sole discretion, apply for registration or other protection of such Trademark(s) in the Territory, [***].

21. LIMITED WARRANTIES; DISCLAIMER

21.1 Mutual Representations and Warranties of Calliditas and Licensee. Each of Licensee, on behalf of itself and its Affiliates, and Calliditas, represents and warrants to the other Party as of the Effective Date, that:

(a) It is duly organized and validly existing under the laws of the jurisdiction of its incorporation or formation, as applicable;

(b) It has the requisite corporate power and authority to conduct its business as presently being conducted and as proposed to be conducted by it;

(c) All corporate actions on its part, necessary for (i) the authorization, execution, delivery and performance by it of this Agreement, and (ii) the consummation of the transactions contemplated hereby, have been duly taken and it has the requisite corporate power and authority to enter into this Agreement and to perform its obligations contemplated hereunder;

(d) This Agreement constitutes a valid and binding obligation, enforceable against it in accordance with its terms (except in all cases as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting the enforcement of creditors' rights generally and except that the availability of the equitable remedy of specific performance or injunctive relief is subject to the discretion of the court or other tribunal before which any proceeding may be brought);

(e) The execution, delivery and performance of this Agreement, and compliance with the provisions of this Agreement, by such Party do not and will not: (i) violate any provision of any Applicable Laws, (ii) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which such Party or any of its assets are bound, or (iii) violate or conflict with any of the provisions of such Party's organizational documents;

(f) Apart from expiration or termination of any applicable waiting periods (including any extensions thereof) required by any Applicable Laws or governmental entity for antitrust purposes in the Territory, there are no filings, consents, approvals, authorizations or other orders of, or notice to, any

Governmental Authority or other third parties that are necessary to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement; and

(g) To such Party's knowledge, as concerns any activities required for the performance of its obligations under this Agreement, neither it nor its officers, employees, agents, consultants or any other person used by such Party in the performance of the respective activities under this Agreement is: (i) debarred or disqualified from providing services to a pharmaceutical company; (ii) listed by any government or regulatory agencies as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs or excluded, debarred, suspended or otherwise made ineligible to participate in any such program; (iii) convicted of a criminal offense related to the provision of healthcare products or services, or (iv) is subject to any such pending action or proceeding with respect to such a measure.

21.2 Additional Representations, Warranties, and Covenants of Calliditas. Calliditas further represents and warrants to Licensee, as of the Effective Date, that:

(a) it has the authority to grant to Licensee the rights specified in this Agreement;

(b) it is the sole owner of or has necessary license rights to the Licensed Technology, free and clear of all liens, and has not granted (and will not grant during the Term of this Agreement) any license or other rights under the Licensed Technology that is inconsistent with the rights granted to Licensee hereunder;

(c) it and its licensees have no knowledge of and have not received any notice (written or otherwise) of any assertion, challenge, litigation, proceedings, investigations or claims of any nature, pending or threatened, which relate to the Licensed Technology or Licensed Product, including with respect to infringement or potential infringement of any third party intellectual property rights regarding the use, formulation, active moiety, or other aspect of the Licensed Product, and there is no judgement or settlement against it relating to the Licensed Technology or Licensed Product (including the use, formulation, active moiety, or other aspect thereof) which affects the Licensee's rights under this Agreement;

(d) it has no actual knowledge of any infringement or misappropriation of any Licensed Technology by any third-party in the Field and the Territory; and

(e) it has no actual knowledge of any third-party patent or other intellectual property right that would be infringed by the use of the Licensed Product as contemplated by this Agreement, it being understood and agreed that Calliditas did not conduct a freedom to operate analysis for the Territory and had no obligation, express or implied, to conduct such an analysis.

21.3 Additional Representations, Warranties and Covenants of Licensee. Licensee, on behalf of itself and its Affiliates, further represents and warrants to Calliditas, as of the Effective Date, that:

(a) there are no pending, or to the knowledge of Licensee, threatened, claims or disputes by any person or entity against it that would materially impair (i) Licensee's ability to perform its obligations under this Agreement or (ii) Calliditas right to exploit the licenses and other rights granted by Licensee to Calliditas under this Agreement;

(b) Licensee's routine accounting practices are consistent with generally accepted accounting principles applicable to Licensee and Licensee covenants that it will maintain at all times during

the Term routine accounting practices that are consistent with generally accepted accounting principles applicable to Licensee; and

(c) it is solvent and has the ability to pay and perform all of its obligations as and when such obligations become due, including payment obligations and other obligations under this Agreement.

21.4 Mutual Covenants

(a) No Debarment. In the course of the exploitation of Licensed Product hereunder, neither Party nor its Affiliates shall use any person or entity who has been debarred by any Competent Authority, or, to such Party's or its Affiliates' knowledge, is the subject of debarment proceedings by a Competent Authority, in each case in relation to the performance by such Party of its obligations hereunder. Each Party shall notify the other Party promptly upon becoming aware that any such person or entity has been so debarred or is the subject of such debarment proceedings by any Competent Authority.

(b) Compliance. Each Party and its Affiliates shall comply in all material respects with all Applicable Laws (including all anti-corruption and anti-bribery laws) in the performance of its obligations and exercise of its rights under this Agreement.

21.5 Other than expressly set forth above, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, ARE MADE OR GIVEN BY OR ON BEHALF OF ANY PARTY, AND ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

22. INDEMNIFICATION; LIABILITY

22.1 By Licensee

Licensee shall be solely responsible for its use of the Licensed Technology and its promotion, sale, lease or other disposition of Licensed Product. Licensee agrees to indemnify and hold harmless or, at Calliditas' option, defend Calliditas and its Affiliates, officers, directors, employees, customers, consultants, (sub)licensees and agents and their respective successors, heirs and assigns ("**Indemnitees**"), from and against any and all third-party damages, liabilities, actions, causes of action, suit, claims, demands, losses, costs and expenses (including reasonable attorney's fees, expense of litigation and costs and expenses for enforcing this indemnity) ("**Losses**"), incurred by or imposed upon Calliditas or the Indemnitees or any one of them in connection with (i) the breach or non-performance of the Agreement by Licensee or its Affiliates, agents and/or sublicensees; (ii) the negligence or willful misconduct of Licensee or its Affiliates, agents and/or sublicensees; and/or (iii) any third-party claims, suits, actions, demands or judgments to the extent arising from or attributable to the promotion, sale, lease or other disposition of Licensed Product or other use of the Licensed Technology by Licensee or its Affiliates, agents and/or sublicensees (including claims based on product liability laws); except, in the case of sub-clauses (i) through (iii) above for those Losses for which Calliditas, in whole or in part, is liable to indemnify Licensee pursuant to Section 22.2 below, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

22.2 By Calliditas

Calliditas agrees to indemnify and hold harmless or, at Licensee's option, defend Licensee and its Indemnities from and against any Losses incurred by or imposed upon Licensee or the Indemnitees or any one of them due to (i) the breach or non-performance of this Agreement by Calliditas or its Affiliates or

agents; (ii) the negligence or willful misconduct of Calliditas or its Affiliates or agents and/or (iii) Calliditas' development, manufacture and/or commercialization of Licensed Product; except, in the case of sub-clauses (i) through (iii) above for those Losses for which Licensee, in whole or in part, is liable to indemnify Calliditas pursuant to Section 22.1 above, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

22.3 Notice of Claim

All indemnification claims in respect of a Party and Indemnitees shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice of any Losses or the discovery of a fact upon which such Indemnified Party intends to base a request for indemnification under this Section 22 but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice.

22.4 Control of Defense

22.4.1 At its option, the indemnifying Party may assume the defense of any third-party claim by giving written notice to the Indemnified Party within [***] after the indemnifying Party's receipt of the above notice. The assumption of the defense of a claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of such claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification.

22.4.2 Upon assuming the defense of a claim, the indemnifying Party may appoint as lead counsel in the defense of the third-party claim any legal counsel selected by the indemnifying Party and reasonably acceptable to the Indemnified Party. Should the indemnifying Party assume the defense of a claim, except as provided in Section 22.5, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the third-party claim unless specifically requested in writing by the indemnifying Party. If it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the claim, the Indemnified Party shall reimburse the indemnifying Party for any and all Losses incurred by the indemnifying Party in its defense of the claim.

22.5 Right to Participate in Defense

Without limiting Section 22.4, the Indemnified Party shall be entitled to participate in, but not control, the defense of such claim and to employ counsel of its choice for such purpose; provided that such employment shall be at the Indemnified Party's own expense unless (a) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing or (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 22.4 (in which case the Indemnified Party shall control the defense). If the interests of the Indemnified Party and the indemnifying Party with respect to such claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Laws, ethical rules or equitable principles, each Party shall retain its own counsel, at its own cost and expense.

22.6 Settlement

22.6.1 With respect to any third-party claim the defense of which has been assumed by the indemnifying Party, the indemnifying Party shall have the sole right to consent to the entry of any

judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate, provided that (a) such judgment, settlement and other disposition, as applicable, shall provide solely for the payment of money damages, shall not result in the Indemnified Party's becoming subject to injunctive or other relief, shall not require the Indemnified Party to admit any fault or culpability, and shall fully and finally release such Indemnified Party from all liability in respect of such claim, and (b) the indemnifying Party shall have provided the Indemnified Party with a written acknowledgment of the indemnifying Party's obligation to indemnify the Indemnified Party hereunder.

22.6.2 With respect to all other Losses, where the indemnifying Party has assumed the defense of the claim in accordance with Section 22.4, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party, which shall not be unreasonably conditioned, delayed, or denied.

22.6.3 If the indemnifying Party does not assume and conduct the defense of a claim as provided above, the Indemnified Party may defend against and settle such claim, provided that any such settlement shall not modify any other rights or obligations of the Parties with respect to such claim.

22.7 Cooperation

Regardless of whether the indemnifying Party chooses to defend or prosecute any claim, the Indemnified Party shall, and shall cause each Indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

22.8 Expenses

Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a [***] basis in arrears by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund if the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

22.9 Deductions for [***]

22.9.1 Payments by any indemnifying Party pursuant to Section 22.1 or Section 22.2 in respect of any Losses shall be limited to [***].

22.10 Limitation of Liability

22.10.1 Except for damages caused by gross negligence or intentional misconduct or breach of a Party's confidentiality obligations under Section 24, a breach of a Party's obligations under Section 4.3, a breach of exclusivity of the license granted under Section 3.1, or as provided in Section

22.10.4, and except and to the extent any such damages are required to be paid to a third-party as part of a claim for which a Party provides indemnification under Section 22, neither Party nor any of its Affiliates shall be liable for any indirect, incidental, special or consequential damages, including without limitation damages for loss of profit or revenue, loss of goodwill, loss of business opportunity, loss of production, or loss of data or use, incurred by the other Party, whether an action in contract or tort, even if a Party has been advised of the possibility of such damages.

22.10.2 The aggregate and cumulative liability of Calliditas under this Agreement shall not exceed (i) prior to [***]; (ii) commencing [***], provided that, in each case, such liability cap shall not apply in the event of (a) fraud, intentional misconduct or intentional breach of representations or warranties by Calliditas, (b) breach by Calliditas of confidentiality obligations under Section 24, (c) a breach of Calliditas' obligations under Section 4.3, (d) a breach by Calliditas of exclusivity of the license granted under Section 3.1, (e) damages required to be paid to a third-party by Calliditas as part of a claim for which a Party provides indemnification under Section 22, and/or (f) to expense reimbursement by Calliditas under Section 22.8.

22.10.3 The aggregate and cumulative liability of Licensee under this Agreement shall not exceed (i) prior to [***]; (ii) commencing on [***], provided that, in each case, such liability cap shall not apply in the event of (a) fraud, intentional misconduct or intentional breach of representations or warranties by Licensee, (b) breach by Licensee of confidentiality obligations under Section 24, (c) breach of Licensee's non-competition obligations under Section 6, (d) damages required to be paid to a third-party by Licensee as part of a claim for which a Party provides indemnification under Section 22, (e) expense reimbursement by Licensee pursuant to Section 22.8, and/or (f) Licensee's obligations to make payments under Section 11 or under any of Sections 5.3, 8.1, 8.8 or 12.3.

22.10.4 Notwithstanding the provisions of Sections 22.10.1 and 22.10.2, Calliditas shall reimburse Licensee, its Affiliates, and its and their permitted sublicensees, for documented Losses and documented lost profits incurred by or imposed upon such Licensee, Affiliate, or permitted sublicensee, as applicable, up to [***], to the extent such Losses and lost profits are caused by [***].

22.11 Supply Agreements

The indemnification and liability provisions in this Section 22 shall be independent of and in addition to any indemnification or liability terms included in any Supply Agreements between the Parties. Remedies arising from or related to the supply of Licensed Product in accordance with Article 10 shall be governed solely by Section 22.10.4 and the Supply Agreements.

23. INSURANCE

Each Party agrees to maintain at its own cost and expense, while this Agreement is in effect, including any surviving obligations, a general liability insurance coverage that is reasonably adequate and customary in the insurance market in relevant locations and jurisdictions. Licensee further agrees to maintain at its own cost and expense product liability insurance in an amount and with coverage customary for pharmaceutical companies in the Territory and to name Calliditas as an additional insured and loss payee under such policy. Written proof of the existence of such insurance shall be provided to the other Party upon the other Party's request.

24. CONFIDENTIALITY

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 "[***]".

24.1 Unless explicitly provided for herein, the Parties each agree that the Confidential Information (as hereinafter defined) of the Party disclosing such information (the "**Disclosing Party**") will be used by the Party receiving such information (the "**Recipient**") solely for the purpose of the performance of this Agreement and the Recipient hereby undertakes to keep Confidential Information in strict confidence and not disclose such information to any third-party unless having obtained written approval from the Disclosing Party. Confidential Information shall be disclosed solely to Recipient's Affiliates and the officers, employees, agents, consultants, and authorized subcontractors of the Recipient and/or the Recipient's Affiliates on a "need to know" basis and shall be kept confidential under procedures no less stringent than those used by the Recipient for its own Confidential Information.

24.2 The term "**Confidential Information**" shall mean all information and data of a confidential, non-public, or proprietary nature relating to the Disclosing Party's technology and business that the Recipient gets access to under or in connection with this Agreement, including without limitation the Licensed Technology, trade secrets, research, technical, development, marketing, sales, business, and process information. The term shall include all analyses, compilations and other documents prepared by either of the Parties that contain or otherwise reflect or are generated from such information. All information disclosed under the Confidentiality Agreement between the Parties dated October 15, 2021 shall be deemed Confidential Information for purposes of this Agreement.

24.3 Confidential Information shall not include information that:

(a) is, or becomes through no breach of the Recipient's obligations stated in this Agreement, public knowledge, provided, however, that Confidential Information shall not be deemed to be in the public domain merely because any part of said information is embodied in general disclosures or because individual features, components, or combinations thereof are now, or become, known to the public;

(b) which was in the possession of the Recipient at the time of disclosure, as evidenced by written records;

(c) is independently developed by the Recipient without reference to or use of the materials comprising Confidential Information under this Agreement after the Effective Date (as evidenced by written records); or

(d) is acquired from a third-party who has the lawful right to make such disclosure.

24.4 The confidentiality obligations in this Section 24 shall not prevent either Party from disclosing Confidential Information in connection with:

(a) filing or prosecuting patent applications in accordance with this Agreement;

(b) regulatory filings or as otherwise required by Competent Authorities; or

(c) prosecuting or defending litigation;

(d) complying with law or stock exchange regulations or the order or request of a governmental body in accordance with Applicable Laws; provided that the Recipient shall promptly notify the Disclosing Party of such legally required disclosure and to the extent practical and permitted under Applicable Laws, seek a protective order or confidential treatment for such information at the cost and expense of the Disclosing Party, which shall promptly pay such amounts upon receipt of an invoice therefor; or

(e) reasonably necessary disclosure to (i) such Party's directors, attorneys, independent accountants or financial advisors for the sole purpose of enabling such directors, attorneys, independent accountants or financial advisors to provide advice to such Party; or (ii) to any actual or potential acquirer, merger partner, underwriter, investor, lender or other provider of financing, in each case in respect of the Recipient, and the employees, directors, agents, consultants and advisors of any such third-party, provided that they have entered into legally binding written obligations relating to confidentiality at least as restrictive of those contained herein (but of duration customary in confidentiality agreements entered into for a similar purpose).

24.5 The Parties agree that the terms of this Agreement will be considered Confidential Information of both Parties. Subject to Section 24.4 and except as set forth below, no Party shall, without the prior written consent of the other Party, disclose in any manner to any third-party the terms of this Agreement, except for terms or subject matter which has been the subject of prior public disclosure or has been mutually approved by the Parties in writing for such disclosure. Each Party acknowledges that the other Party may be legally required to file this Agreement as an exhibit to its filings with an applicable securities regulator (for example, as may pertain to the United States Securities and Exchange Commission), subject to customary and legally permitted redaction of Confidential Information of the other Party. In addition: (a) either Party may disclose such terms as are required to be disclosed in its publicly-filed financial statements or other public statements, pursuant to Applicable Laws and stock exchange rules (e.g., the rules of the United States Securities and Exchange Commission, or any other stock exchange on which securities issued by either Party may be listed); provided that, such Party shall, to the extent permitted and if feasible in light of applicable time constraints, provide the other Party with a copy of the proposed text of such statements or disclosure (including any exhibits containing this Agreement) sufficiently in advance (to the extent possible) of the scheduled release or publication thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text (including redacted versions of this Agreement), (b) either Party shall have the further right to disclose the terms of this Agreement under a confidentiality obligation no less protective than those set forth in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose), to any actual or potential sublicensee, strategic partner, collaborator, acquirer, merger partner, underwriter, investor, lender or other provider of financing, and the employees, directors, agents, consultants and advisors of any such third-party, and (c) each Party shall have the right to disclose information regarding the development or commercialization status of Licensed Product in their respective territory to the extent such disclosure is required by Applicable Laws.

24.6 The Receiving Party shall procure that all of its employees, contractors, and sublicensees pursuant to this Agreement (if any) who have access to any of the Disclosing Party's information to which Section 24.1 applies shall be made aware of and subject to these obligations and shall have obligations of confidentiality running to Receiving Party or its Affiliates at least as restrictive as this Section 24 which apply to the Disclosing Party's Confidential Information.

24.7 This Section 24 shall be valid [***], except with respect to any information that constitutes a trade secret (as defined under Applicable Laws), in which case the Receiving Party will continue to be bound by its obligation of confidentiality and non-use under this Section 24 for so long as such information continues to constitute a trade secret, but in no event for a period of less than the [***] specified immediately above.

25. PUBLIC ANNOUNCEMENTS; USE OF NAMES; PUBLICATION

25.1 Calliditas may issue a public announcement regarding the execution of this Agreement, substantially in the form of the press release attached hereto as Appendix 3, and neither Party shall make

any other statement to the public regarding the execution or any other aspect of the subject matter of this Agreement, except to the extent expressly permitted under this Agreement, including without limitation, pursuant to Section 24.5.

25.2 Neither Party shall make use of the name of the other Party or any of its Affiliates in any advertising or promotional material, or otherwise, without the prior written consent of such other Party (which shall not be unreasonably conditioned, delayed, or denied), except as permitted pursuant to Section 24.5 or Section 25.1. For the avoidance of doubt, either Party may use the name of the other Party or its Affiliates in public filings in accordance with applicable securities law, or as required by any Governmental Authority or Competent Authority.

25.3 Either Party may use the text of a statement previously approved by the other Party in subsequent public announcements. Each Party shall use Commercially Reasonable Efforts to provide to the other Party drafts of publications regarding Licensed Product that include statements not previously approved sufficiently in advance of their submission to provide a reasonable opportunity for comment and discussion between the Parties, and for the removal of any Confidential Information of such other Party, and such Party shall consider in good faith any such comments; provided, however, that, except as otherwise provided in this Agreement, such Party shall not be obligated to incorporate any such comments into such publications. If the non-publishing Party wishes to request a reasonable delay in publication in order to protect patentable information, the publishing Party shall delay the publication for a period of no more than [***] to enable patent applications to be filed in accordance with Section 16. Licensee shall include a customary acknowledgment of Calliditas as the licensor of Licensed Product in any publications by or on behalf of Licensee. Nothing in this Section 25.3 grants to either Party any right to publish the Confidential Information of the other Party (even if the other Party has had the opportunity to review the proposed publication) and the provisions of this Section 25.3 are without prejudice to the provisions of Section 24.

26. TERM AND TERMINATION

26.1 Unless previously terminated in accordance with other provisions of this Agreement, this Agreement shall be in effect throughout the Term. As used herein, "**Term**" means the term of this Agreement, which shall commence on the Effective Date and continue until the expiration of Licensee's obligations to make payments to Calliditas under Section 11 (Remuneration), unless terminated earlier in accordance with this Section 26. Upon the expiration of this Agreement by reason of the expiration of Licensee's obligations to make payments to Calliditas under Section 11, the license and rights granted to Licensee hereunder shall become non-exclusive, fully-paid, royalty-free, perpetual and irrevocable.

26.2 A Party shall have the right to immediately terminate this Agreement by written notice to the other Party on occurrence of any of the following:

26.2.1 If the other Party commits or permits any material or persistent breach of any of the terms of this Agreement which, (a) if curable, is not cured within [***] after written notice thereof is delivered to the breaching Party or [***] in the case of a failure to pay an amount due hereunder, or (b) in the case of a breach that cannot be cured within [***], within a reasonable period not exceeding [***] after written notice thereof is delivered to the breaching Party, so long as the breaching party is making a good faith effort to cure such breach; or

26.2.2 If the other Party suspends payments (other than for disputed amounts), is placed in bankruptcy, enters into liquidation or corporate reorganization, commences composition negotiations with its creditors, or may otherwise be deemed to be insolvent.

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 "[***]".

26.3 Licensee may terminate this Agreement for convenience by written notice to Calliditas (a) at any time, with a notice period of at least [***], (b) with a notice period of [***], given within [***], or (c) with a notice period of [***], given within [***]. In connection with subparagraph (b) above, Calliditas shall provide to Licensee [***] promptly after their receipt by Calliditas. If Licensee does not intend to exercise its termination rights under subsection (c) above, it shall confirm to Calliditas by notice within such [***] that it will continue its clinical development program as soon as practicable.

26.4 [***].

26.5 A Party's right of termination under this Agreement, and the exercise of any such right, shall be without prejudice to any other right or remedy (including any right to claim damages) that such Party may have in the event of a breach of contract or other default by the other Party.

26.6 Upon termination of this Agreement for any reason otherwise than expiry in accordance with Section 26.1, the Parties shall meet to discuss arrangements for an orderly transition (including a disposition of remaining inventories of Licensed Product) and, except as may otherwise be agreed by the Parties:

26.6.1 Upon termination of this Agreement, other than a termination by Licensee under Section 26.2 (breach or insolvency of Calliditas):

26.6.1.1 Licensee shall be entitled, for a period of [***] after the effective date of such termination and on its customary terms and conditions of sale, to sell, use, or otherwise dispose of (subject to payment of all amounts due under Section 11) any unsold or unused stocks of Licensed Product, provided that Licensee complies with all terms and conditions of this Agreement (and for that purpose the Agreement will remain in effect on a non-exclusive basis). This paragraph shall, however, not apply if Calliditas has terminated this Agreement pursuant to Section 26.2 or 26.4;

26.6.1.2 Either upon the effective date of the termination in the event of a termination by Calliditas pursuant to Section 26.2 (breach or insolvency of Licensee) or Section 26.4 (patent challenge), or otherwise at the end of the [***] referred to above, Calliditas shall at its sole option and at Calliditas' sole cost either (i) purchase from Licensee and make arrangements for the return, freight prepaid, of any remaining unsold or unused stocks of Licensed Product with any remaining shelf life at the cost paid by Licensee for such Licensed Product (such sales to Calliditas not included in Net Sales and not subject to payment under Section 11); or (ii) require Licensee to destroy any unused stocks of Licensed Product.

26.6.1.3 Subject to Section 26.6.1.1 above, Licensee shall no longer be licensed to use or otherwise exploit in any way, either directly or indirectly, the Licensed Technology, without limitation on Licensee's use of Licensed Patents that no longer remain in force;

26.6.1.4 Subject to Section 26.6.1.1 above, Licensee shall cancel, remove, or withdraw any registrations of the license granted to it and hereby grants Calliditas an irrevocable power of attorney to do so;

26.6.1.5 Any sublicenses granted by Licensee shall terminate automatically unless otherwise agreed by Calliditas and the sublicensee;

26.6.1.6 Each Party shall return to the other or, at the other Party's request, destroy any documents or other materials that are in its possession or under its control and that contain the other Party's Confidential Information; provided, however, that nothing in the foregoing shall require

Licensee to return or destroy: (i) Arising Product IP; (ii) New Data; (iii) the Approvals; (iv) the Territory Dossier; (v) Regulatory Documentation; or (vi) such documents or other materials included in any of (i)-(v). For the avoidance of doubt, each of (i)-(vi) remains Licensee's sole property except for (ii) (New Data) which is jointly owned. Each Party may retain one copy to the extent required by Applicable Laws, provided that the obligations of confidentiality in Section 24 above shall continue to apply for such retained copies;

26.6.1.7 At Calliditas' option, Licensee shall transfer to Calliditas [***], should Calliditas so request not later than the effective date of the termination, [***]. To the extent such transfer is not permitted under Applicable Laws, Licensee shall grant and cause to be granted, and hereby grants, to Calliditas an [***] right and license to access, use, and cross-reference the same for any purpose including [***]. Should Calliditas exercise its option to obtain a license to Licensee's rights, title, and interest in and to Arising Product IP and New Data, Calliditas shall pay to Licensee a [***] royalty for the rights granted in this Section 26.6.1.7 with respect to Arising Product IP or New Data, such royalty to be determined by agreement of the Parties no later than [***] after the effective date of the termination or, in the absence of such an agreement, by an expert appointed for this purpose by the International Chamber of Commerce, at the request of either Party;

26.6.1.8 At Calliditas' option, Licensee will cooperate with Calliditas to transfer any ongoing clinical trials or post-approval studies for which it has responsibility hereunder in which patient dosing has commenced or, if such transfer is not reasonably practicable, Licensee shall use reasonable efforts to complete such trials (and then assign all related Regulatory Documentation and investigator and other agreements relating to such trials) on behalf of Calliditas; and

26.6.1.9 Calliditas shall have an option to acquire the Trademark(s) (including any and all goodwill, acquired distinctiveness and/or use based rights that may arise in connection with Licensee's use) against reasonable compensation mutually agreed between the Parties no later than [***] after the effective date of the termination or, in the absence of such an agreement, by an expert appointed for this purpose by the International Chamber of Commerce, at the request of either Party.

26.6.2 Upon termination of this Agreement by Licensee under Section 26.2.1 (breach of Calliditas):

26.6.2.1 Licensee shall be entitled, for a period of [***] days after the effective date of such termination and on its customary terms and conditions of sale, to sell, use, or otherwise dispose of (subject to payment of all amounts due under Section 11) any unsold or unused stocks of Licensed Product, provided that Licensee complies with all terms and conditions of this Agreement (and for that purpose the Agreement will remain in effect on a non-exclusive basis);

26.6.2.2 Subject to Section 26.6.2.1 above, Licensee shall no longer be licensed to use or otherwise exploit in any way, either directly or indirectly, the Licensed Technology, without limitation on Licensee's use of Licensed Patents that no longer remain in force;

26.6.2.3 Subject to Section 26.6.2.1 above, each Party shall cancel, remove, or withdraw any registrations of the license granted to it by the other and hereby grants the other Party an irrevocable power of attorney to do so;

26.6.2.4 Without limitation on Section 26.6.2.6, any sublicenses granted by Licensee or by Calliditas hereunder shall terminate automatically unless otherwise agreed by Calliditas and the sublicensee;

26.6.2.5 Each Party shall return to the other or, at the other Party's request, destroy any documents or other materials that are in its possession or under its control and that contain the other Party's Confidential Information; provided, however, that nothing in the foregoing shall require Licensee to return or destroy: (i) Arising Product IP; (ii) New Data; (iii) the Approvals; (iv) the Territory Dossier; (v) Regulatory Documentation; or (vi) such documents or other materials included in any of (i)-(v). For the avoidance of doubt, each of (i)-(vi) remains Licensee's sole property except for (ii) (New Data) which is jointly owned. Each Party may retain one copy to the extent required by Applicable Laws, provided that the obligations of confidentiality in Section 24 above shall continue to apply for such retained copies;

26.6.2.6 Calliditas' rights under Section 14.3 (license to Arising Product IP), Section 15.1 (New Data), and Section 15.3 (New Data and Territory Dossier) shall terminate as to any such items developed or arising after the date on which a notice of termination is received by Calliditas, without limitation on the continued exercise by Calliditas and any permitted sublicensees of any rights that vested in Calliditas prior to such date.

26.6.2.7 Expiration or termination of this Agreement for any reason shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein. Except as otherwise expressly set forth herein, termination of this Agreement in accordance with and fulfillment of all obligations set forth in this Section 26 shall not affect any other rights or remedies that may be available to a Party in law or equity, all remedies being cumulative and not exclusive.

26.6.3 Upon termination of this Agreement by Licensee under Section 26.2.2 (insolvency of Calliditas), or if this Agreement is terminated by a third party (such as termination or rejection by a receiver or trustee, or by operation of law or judicial or administrative action or order):

26.6.3.1 Calliditas agrees that Licensee, as exclusive licensee of certain rights and licenses under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any non-U.S. equivalent thereof. Calliditas further agrees that, in the event of the commencement of a bankruptcy proceeding by or against Calliditas under the U.S. Bankruptcy Code or other Applicable Laws governing Calliditas, Licensee shall have the right to retain any and all rights and licenses granted to it hereunder, to the maximum extent permitted by Applicable Laws (such as under Sections 365(n)(1) and 365(n)(2) of the U.S. Bankruptcy Code or any non-U.S. equivalent thereof) and be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Licensee's possession, shall be promptly delivered to it upon any such commencement of a bankruptcy proceeding, unless Calliditas (or its bankruptcy trustee) elects to assume this Agreement and continue to perform all of its obligations under this Agreement; and

26.6.3.2 Calliditas shall grant and hereby grants Licensee a [***] license to use or otherwise exploit in the Field in the Territory in any way, either directly or indirectly, the Licensed Technology and Calliditas' right, title, and interest in New Data, without limitation on Licensee's use of Licensed Patents that no longer remain in force.

26.7 In addition to the termination consequences set forth in Section 26.6, the following provisions will survive expiration or termination of this Agreement for any reason, unless explicitly provided otherwise: Article 2 (Definitions), Article 11 (Remuneration), Article 12 (Reports; Records; Audit), Article 13 (Payment Terms), Sections 14.1, 14.2, 14.3, 14.5, 14.6, 15.1, 15.3, 15.4, 17.2, 17.3, Article 22 (Indemnification; Liability), Article 23 (Insurance) (until the expiration of the last-to-expire lot of Licensed Product placed in market in the Territory by Licensee), Article 24 (Confidentiality), Article 25

(Public Announcements; Use Of Names; Publication), Sections 26.6, 26.7, Article 28 (Miscellaneous), and Article 29 (Governing Law And Dispute Resolution) and any other obligations and rights which are intended to survive this Agreement (whether expressly or due to their context and content).

26.8 If after the Effective Date Calliditas licenses technology from third parties that is included in the Licensed Technology, Calliditas will advise its licensor(s) of the existence of this Agreement and request that such licensor(s) (a) agree to copy Licensee on notices regarding any alleged breach of the license by Calliditas, and (b) grant to Licensee (i) the right for Licensee to cure any breach by Calliditas of the underlying license, should Calliditas fail timely to do so, or (ii) a direct license from such third-party licensor on commercially reasonable terms. Should Licensee elect to cure such breach, such cure shall be at Licensee's cost.

27. FORCE MAJEURE

Neither Party shall have any liability or be deemed to be in breach of this Agreement for any delays or failures in performance of this Agreement that result from circumstances beyond the reasonable control of that Party, including but not limited to strikes, lock outs or labor disputes of any kind (whether relating to its own employees or others), fire, flood, explosion, natural catastrophe, pandemic or epidemic, military operations, blockade, sabotage, revolution, riot, civil commotion, war or civil war, acts of terror, plant breakdown, computer or other equipment failure and inability to obtain equipment, legislative measures or regulations promulgated by Governmental Authorities, delay in transportation or defects or delays in deliveries by sub-suppliers or similar event affecting the performance of a Party or its subcontractor. The Party affected by such circumstances shall promptly notify the other Party when such circumstances cause a delay or failure in performance and when they cease to do so, and shall take all commercially reasonable actions necessary to mitigate the effects of such circumstances. Nothing in this Section 27, however, shall excuse any late payment by Licensee of any amount(s) due under this Agreement.

28. MISCELLANEOUS

28.1 Assignment.

28.1.1 Neither Party may assign or otherwise transfer its rights or obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, except that either Party may assign this Agreement to (a) [***], or (b) a third party on Change of Control of such Party. [***], provided that (x) any such assignment, sale, or pledge shall be made subject to and without limitation on the obligations of Calliditas to Licensee hereunder and (y) Calliditas shall remain liable with any permitted Affiliate assignee for such assignee's timely and complete performance of Calliditas' obligations hereunder, subject to Section 28.1.3.

28.1.2 For the avoidance of doubt, if Calliditas assigns this Agreement, it shall at the same time assign to the same assignee the Supply Agreements, if they have been entered into. In particular, in the event of a Qualifying Supply Failure, the assignee shall be subject to all of the terms and conditions of this Agreement relating thereto.

28.1.3 Any assignee of Calliditas must undertake in writing towards Licensee to be bound by and perform the obligations of Calliditas under this Agreement. In addition, Calliditas shall remain liable for the timely and complete performance of any Affiliate assignee for performance by such Affiliate assignee hereunder until the first receipt of Approval of Licensed Product in the Field in the Territory.

28.1.4 Any assignment of the rights or obligations under this Agreement in violation of this Section 28.1 shall be null and void. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns. In the event of an assignment to an Affiliate, the assigning Party shall remain liable for the timely and complete performance of this Agreement by the Affiliate assignee.

28.2 No waiver. No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.

28.3 Invalidity. If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the invalid part or provision but otherwise retain the provision and the other provisions of this Agreement to the maximum extent permissible under Applicable Laws.

28.4 Independent Contractors. Each Party is an independent contractor and neither Party has, nor shall have, any power, right or authorization to bind the other or to assume or create any obligations or responsibilities, express or implied, on behalf of the other or in the other's name.

28.5 Further Assurance. Each Party agrees to execute, acknowledge, and deliver such further certificates, documents, and instruments, and do all further similar acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

28.6 Entire Agreement. This Agreement, the Supply Agreements, and the Pharmacovigilance Agreement represent the entire understanding between the Parties, and supersedes all other agreements, express or implied, between the Parties concerning the subject matter hereof, including the Confidentiality Agreement between the Parties dated October 15, 2021, and shall not be subject to any change or modification except by the execution of a written instrument duly signed by the Parties thereto.

28.7 Counterparts. This Agreement may be executed simultaneously via facsimile or electronically via "**PDF-file**" and in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. A Party may evidence execution of the Agreement by any such means.

28.8 Notices. Any notice to be given under this Agreement shall be in writing and shall be sent to the address of the relevant Party set out at the head of this Agreement or to such other address as that Party may from time to time notify to the other Party in accordance with this Section 28.8. A copy of any notice to Calliditas shall be sent by email to contract.notification@calliditas.com.

29. GOVERNING LAW AND DISPUTE RESOLUTION

29.1 The validity, construction, and performance of this Agreement shall be governed by the laws of the State of New York, without regard to its choice of law principles.

29.2 All disputes arising out of or in connection with the present contract or its negotiation or performance shall be referred to the respective Senior Executive of the Parties or their designees, for good faith negotiations attempting to resolve the dispute.

29.3 Should the Senior Executives or their designees be unable to resolve such dispute within [***] after such dispute has first been referred to them, either Party may pursue any remedy available to

such party at law or in equity, subject to the terms and conditions of this Agreement. Each Party hereby irrevocably: (a) consents to submit itself in any suit, action or proceeding arising out of or related to this Agreement to the exclusive personal jurisdiction of the courts of the State of New York sitting in New York County, New York; (b) agrees that it will not attempt to defeat or deny such personal jurisdiction by motion or other request for leave from such court; and (c) agrees that it will not bring any action arising out of or related to this Agreement or any of the transactions contemplated hereby in any court other than any such court. Notwithstanding the foregoing, any disputes related to the validity, scope or enforceability of any patents or patent applications or trademarks shall be submitted to the forum, including governmental agencies, with jurisdiction over the relevant intellectual property rights involved in the dispute.

29.4 EACH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF EITHER PARTY IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT HEREOF.

29.5 Nothing in this Section 29 precludes either Party's right to seek interim relief or similar provisional measures in a court of competent jurisdiction, such as a temporary restraining order, preliminary injunction or other interim measure, if necessary to protect the interests of such Party.

Signature page follows.

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 "[***]".

This Agreement has been executed in two (2) originals, of which the Parties have received one (1) each.

CALLIDITAS THERAPEUTICS AB (PUBL)

_____

Name: Renee Aguiar-Lucander

Title: CEO

VIATRIS PHARMACEUTICALS JAPAN INC.

_____

Name:

Title: CEO

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 "[***]".

APPENDIX 1

LICENSED PATENTS

Territory	**Application No.**	**Application Date**	**Grant No.**	**Grant Date**
[***]	[***]	[***]	[***]	[***]

APPENDIX 2

LICENSED PRODUCT

The formulation, which is a [***] capsule containing the active ingredient budesonide comprises two components:

- enteric-coated capsules to deliver the active ingredient to the ileum (delayed release);
- triple coated sustained-release beads containing the active ingredient, which are filled into the capsules.

[***].

APPENDIX 3

PRESS RELEASE

Press release begins on next page.

PRESS RELEASE

Stockholm, Sweden [***]

Calliditas Therapeutics Announces License Agreement with Viatris to register and commercialize specialty therapy for IgA Nephropathy in Japan

Calliditas announces that it has entered into an agreement with Viatris to bring Nefecon®, a specialty therapy focused on downregulating IgA1, to Japanese patients. The agreement, worth up to $100M in upfront and milestone payments, combines Calliditas' specifically formulated drug candidate with Viatris' development, marketing and sales expertise.

Stockholm, Sweden; [-] TBD 2022 – Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") announced tomo that they have entered into an exclusive license agreement with Viatris Pharmaceuticals Japan Inc., a subsidiary of Viatris Inc. (Nasdaq: VTRS) ("Viatris"), to register and commercialize Nefecon, a specialty drug recently approved in Europe and the US for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in Japan.

Under the terms of the agreement, Calliditas is entitled receive an initial upfront payment of US$20M upon signing and up to an additional US$80M in pre-defined development and commercialization milestones. Viatris will also pay mid-teens percentage royalties on net sales.

IgAN, also known as Berger´s disease, is a rare and serious progressive autoimmune disease in which up to 50% of patients end up at risk of developing end stage renal disease and thus requiring dialysis or a kidney transplant.

"We are excited to be entering into this license agreement with Viatris, through its Global Healthcare Gateway®, to bring this IgAN therapy to patients in Japan, where there is a significant unmet medical need. We look forward to working in close collaboration to pursue a Japanese marketing authorization with the goal of bringing the first ever medication designed specifically to target the origin of the disease to Japanese IgAN patients as soon as possible," said Renée Aguiar-Lucander, CEO of Calliditas.

Locust Walk acted as transaction advisor to Calliditas.

For further information, please contact:

Marie Galay, IR Manager, Calliditas
Tel.: +44 79 55 12 98 45, email: marie.galay@calliditas.com

The information in the press release is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the Calliditas contact person set out above, on October [-], 2022 at [-] a.m. CET.

About Calliditas

Calliditas Therapeutics is a commercial stage biopharma company based in Stockholm, Sweden 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. Calliditas' lead product, Nefecon, has been granted accelerated approval by the FDA under the trade name TARPEYO® and conditional marketing authorization by the European Commission under the trade name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, setanaxib. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans, regulatory submissions and focus, as well as Calliditas' license agreement with Viatris, the parties' plans with respect to registration and commercialization of the specialty therapy, the terms of the collaboration and the intended benefits therefrom, the regulatory pathway and interactions for Nefecon, including the pursuit of Japanese marketing authorization and timing thereof. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, the conduct of Calliditas' license agreement with Viatris, the potential for regulatory acceptance and the success and timeline of its regulatory marketing application in Japan, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other pharmaceutical companies, and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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 26, 2023

/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 26, 2023

/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, 2022, 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 26, 2023

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 26th day of April 2023.

/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, 2022, 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 26, 2023

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 26th day of April, 2023.

/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, and

(2) Registration Statement Form F-3 (333-265881) of Calliditas Therapeutics AB;

of our reports dated April 26, 2023, 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) for the year ended December 31, 2022.

/s/ Ernst & Young AB

Stockholm, Sweden
April 26, 2023