As filed with the Securities and Exchange Commission on January 26, 2021.

Registration Statement No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM F-1

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

Calliditas Therapeutics AB

(Exact name of registrant as specified in its charter)

Sweden	**2834**	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Kungsbron 1, C8
SE-111 22
Stockholm, Sweden
Tel: +46 (0) 8 411 3005

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Calliditas Therapeutics Inc.
251 Little Falls Drive
Wilmington, Delaware 19808-1674
(302) 636-5400

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to public:
As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act. 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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[1][2]	Amount of registration fee[3]
Common shares, quota value SEK 0.04 per share[4]	$85,180,500	$9,294

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional common shares represented by American Depositary Shares, or ADSs, that the underwriters have the option to purchase.

(2) Includes common shares that are being offered in a private placement to qualified investors, as defined under the EU Prospectus Regulation 2017/1129, in Europe and other countries outside of the United States, but which may be resold from time to time in the United States in transactions requiring registration under the Securities Act, or an exemption therefrom. The total number of common shares (including shares in the form of ADSs) in the U.S. offering and the European private placement is subject to reallocation between them to the extent permitted under applicable laws and regulations.

(3) Calculated pursuant to Rule 457(o) under the Securities Act of 1933, as amended, based on an estimate of the proposed maximum aggregate offering price.

(4) All common shares in the U.S. offering are represented by ADSs, each of which represents two common shares of the registrant. ADSs issuable upon deposit of the common shares registered hereby are registered pursuant to a separate registration statement on Form F-6 (File No. 333-238726).

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), shall determine.

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

SUBJECT TO COMPLETION, DATED JANUARY 26, 2021

PRELIMINARY PROSPECTUS

4,500,000 Common Shares

(including Common Shares in the Form of American Depositary Shares)

calliditas THERAPEUTICS

$ per American Depositary Share
SEK per Common Share

We are offering 4,500,000 of our common shares, quota value SEK 0.04 per share, or common shares, in a global offering.

Of such common shares, we are offering common shares in the form of American Depositary Shares, or ADSs, representing ADSs, in the United States, referred to herein as the U.S. offering. Each ADS represents two common shares.

We are concurrently offering common shares in Europe and countries outside of the United States in a private placement to qualified investors, as defined under the EU Prospectus Regulation 2017/1129, referred to herein as the European private placement.

ADSs representing our common shares are listed on The Nasdaq Global Select Market under the symbol "CALT." On January 22, 2021, the last reported sale price of the ADSs on The Nasdaq Global Select Market was $32.92 per ADS. Such price is the assumed offering price per ADS in the U.S.offering.

Our common shares are traded on Nasdaq Stockholm under the symbol "CALTX." The closing price of our shares on Nasdaq Stockholm on January 22, 2021 was SEK 134.00 per share, which equals a price of $32.34 per ADS based on the SEK/U.S. dollar exchange rate of SEK 8.29 to $1.00 as of January 22, 2021 and an ADS-to-share ratio of 1:2.

The closings of the U.S. offering and the European private placement, which are together referred to as the global offering, will occur substantially simultaneously. The number of common shares (including common shares in the form of ADSs) in the U.S. offering and the European private placement is subject to reallocation between these offerings to the extent permitted under applicable laws and regulations.

We have granted the underwriters a 30-day option to purchase up to an additional 675,000 common shares (including common shares in the form of ADSs) at the public offering price less underwriting discounts and commissions.

Investing in the ADSs involves a high degree of risk. See the "Risk Factors" section beginning on page 16 of this prospectus.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, and have elected to comply with certain reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

None of the Securities and Exchange Commission, any state securities commission, the Swedish Financial Supervisory Authority or any other foreign securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Common Share	Per ADS	Total[1]
Public offering price	SEK	$	$
Underwriting discounts and commissions[2]	SEK	$	$
Proceeds to Calliditas Therapeutics AB (before expenses)	SEK	$	$

(1) Total gross proceeds from the global offering, including the European private placement, are $. Such proceeds less underwriting discounts and commissions are $.

(2) See "Underwriting" for additional information regarding underwriting compensation.

The underwriters expect to deliver the ADSs to purchasers in the U.S. offering against payment in New York, New York on or about , 2021 through the book-entry facilities of The Depository Trust Company. The underwriters expect to deliver the common shares to purchasers in the European private placement on or about , 2021 through the book-entry facilities of Euroclear Sweden AB.

Citigroup **Jefferies** **Stifel**

Kempen & Co **LifeSci Capital** **Carnegie**

, 2021

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We and the underwriters have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we may have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the underwriters are making an offer to sell the ADSs in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of the ADSs. Our business, financial condition, results of operations and any such prospects may have changed since the date on the front cover of this prospectus.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit the global offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the global offering of the ADSs and the common shares and the distribution of this prospectus outside of the United States.

We are incorporated under the laws of Sweden and a majority of our outstanding voting securities are owned by non-U.S. residents. Under the rules of the U.S. Securities and Exchange Commission, or the SEC, we are currently eligible for treatment as a “foreign private issuer.” As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended.

ABOUT THIS PROSPECTUS

Unless otherwise indicated or the context otherwise requires, all references in this prospectus 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 CALLIDITAS (registered in the European Union and filed a United States trademark application), CALLIDITAS THERAPEUTICS (filed a United States trademark application), PHARMALINK (registered in the United States and Sweden) and NEFECON (registered in the United States, Sweden and the European Union) and our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this prospectus are the property of their respective holders. Solely for convenience, the trademarks and trade names in this prospectus 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.

PRESENTATION OF FINANCIAL INFORMATION

We prepare our audited consolidated financial statements in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States. All references in this prospectus to "$" are to U.S. dollars and all references to "SEK" are to Swedish Kronor. Unless otherwise indicated, certain SEK amounts contained in this prospectus have been translated into U.S. dollars at the rate of SEK 8.29 to $1.00, which was the rate of Sveriges Riksbank on January 22, 2021. These translations should not be considered representations that any such amounts have been, could have been or could be converted into SEK at that or any other exchange rate as of that or any other date.

We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them. Our historical consolidated financial statements present the consolidated results of operations of Calliditas Therapeutics AB and its wholly owned subsidiaries.

PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our ADSs. You should carefully read the entire prospectus, and the registration statement of which this prospectus is a part, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes, in each case included in this prospectus, before making an investment decision.

Overview

We are a clinical-stage biopharmaceutical 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. Our lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. IgAN is a progressive, chronic disease that over time results in deterioration of kidney function in patients, many of whom end up at risk of developing end-stage renal disease, or ESRD, with the need for dialysis or kidney transplant. Nefecon is currently the only pharmaceutical candidate in development for IgAN that is intended to be disease-modifying. Nefecon targets the ileum, the distal region of the small intestine, which is the presumed origin of IgAN due to the ileum being the location of the highest concentration of the Peyer's patches, which are responsible for the production of secretory immunoglobulin A, or IgA, antibodies. Nefecon is the only compound in development for IgAN that has met the primary and key secondary endpoints in a randomized, double-blind, placebo-controlled Phase 3 clinical trial. Nefecon has been granted orphan drug designation for the treatment of IgAN in the United States and the European Union. We also recently acquired a controlling interest in Genkyotex S.A., or Genkyotex, providing us with access to 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 components, with a main focus on kidney and liver diseases.

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. See "Recent Developments" below. 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 16 mg arm versus baseline, with placebo showing a 5% mean reduction versus baseline, resulting in a 27% mean reduction at nine months of the 16 mg 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 9 months compared to a 0.17 ml/min/1.73m^2 decline in the treatment arm. In addition, the trial showed that Nefecon was generally well-tolerated. On the basis of the positive results of Part A of NefIgArd, we intend to submit a New Drug Application, or NDA, in the first quarter of 2021 for accelerated approval by the United States Food and Drug Administration, or FDA, followed by a Marketing Authorisation Application, or MAA, for conditional approval by the European Medicines Agency, or EMA, in the first half of 2021. In January 2021, we completed the enrollment of all 360 patients in NefIgArd, which includes 200 patients previously enrolled in Part A and another 160 patients enrolled in Part B. We intend to report data from Part B in early 2023, subject to any further impact from the COVID-19 pandemic to our business. We also previously conducted a Phase 2b trial with 150 patients, which met the identical primary and key secondary endpoint.

Although we observed a statistically significant and clinically meaningful reduction of proteinuria, the FDA and EMA have not provided a specific level of reduction of proteinuria that would be required to obtain marketing approvals. Accordingly, there can be no assurance that the level of reduction of proteinuria that we observed in our Phase 3 clinical trial will be sufficient to satisfy the FDA and EMA. The FDA accelerated approval pathway, and the conditional approval process of the EMA, 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 approved by the FDA, we expect that Nefecon will be the first treatment on the market indicated for IgAN. We believe that if Nefecon can successfully treat IgAN patients, their kidney

function will be preserved. We retain worldwide rights to Nefecon other than in Greater China and Singapore where we have established a strategic collaboration.

IgAN, sometimes referred to as Berger's disease, is a serious progressive autoimmune disease of the kidney in which up to 50% of patients end up 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 has been observed in Asia, including in Greater China, where IgAN has historically been a leading cause of ESRD. We estimate that IgAN affects approximately two million people in Greater China and approximately 180,000 people in Japan. We estimate the U.S. market opportunity for IgAN to be approximately $9.0 billion to $10.0 billion annually, based on our estimate of the prevalence of the disease in the United States and primary market research conducted by IQVIA that we commissioned to assess preliminary reimbursement levels perceived acceptable by U.S.-based payors. In this market, we intend to primarily focus on treating those IgAN patients that are at risk of progressing to ESRD.

Although IgAN manifests in the kidney, most scientific studies have found that the pathogenesis of IgAN begins in the ileum. Masses of lymphatic tissue, known as Peyer's patches, are predominantly found 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 and 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, leading 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 membranes of the glomeruli, the kidney's filtration apparatus. These trapped immune complexes initiate an inflammatory cascade that damages the membranes, 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, resulting in potentially life-threatening complications that in many patients will lead to the need for dialysis or kidney transplant.

Despite a need for new therapies, there have been few new drugs developed for chronic kidney diseases during the last decade and there is no approved therapy for IgAN. Patients with IgAN are typically initially given antihypertensive medications as recommended by the non-profit organization Kidney Disease: Improving Global Outcome consortium, or KDIGO. This treatment regimen initially attempts to manage the symptoms of IgAN by decreasing blood pressure and reducing proteinuria but does not address the underlying cause of IgAN. Over time, physicians attempt to control disease progression with a variety of off-label treatments, as a significant proportion of patients experience continued deterioration of kidney function, with no approved treatment options currently available. 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, this high dosing of systemic corticosteroids is also associated with a wide range of adverse events, including high blood pressure, weight gain, diabetes, serious infections and osteoporosis.

Nefecon is currently the only pharmaceutical candidate in development that is designed to target the ileum, with the goal of being a disease-modifying treatment. Nefecon is designed to release a high dose of a locally acting immunosuppressive agent in the ileum, where the highest concentration of Peyer's patches exists, to reduce the formation of secretory galactose-deficient IgA antibodies and their appearance in the blood.

Nefecon's active ingredient is budesonide, an established, highly potent locally acting corticosteroid. After the active ingredient has been released and has had its effect in the intestinal mucosa, it enters the liver, where 90% is cleared in first pass metabolism, resulting in the inactivation of a majority of the active

ingredient before the substance reaches the systemic circulation. This high metabolism may limit systemic immunosuppressive activity and decreases the significant side effects associated with systemic corticosteroids that are currently used off-label to treat IgAN, of which only 20% to 30% are cleared in first pass metabolism. Other locally delivered approved therapies where budesonide is the active ingredient include those for asthma, allergic rhinitis, Crohn's disease and ulcerative colitis. Based on the written minutes from our End-of-Phase 2 meeting, the FDA has indicated alignment on a pathway toward accelerated approval in the United States based on the evaluation of a surrogate endpoint rather than a clinical outcome endpoint. We have received similar feedback from the EMA on a conditional market access pathway in the European Union. Additionally, since Nefecon is a reformulation of the active ingredient in an existing approved drug, we are pursuing the Section 505(b)(2) pathway for regulatory approval by the FDA in the United States and the hybrid application pathway for conditional approval by the EMA in the European Union.

Nefecon Phase 3 Clinical Trial Results

Nefecon is the most advanced clinical-stage product candidate for the treatment of IgAN. In November 2020, we reported positive topline data from our global, pivotal Phase 3 clinical trial in IgAN, which we refer to as NefIgArd. NefIgArd is designed to evaluate reduction of the surrogate marker proteinuria as its primary endpoint, which is the same endpoint used in our previously completed NEFIGAN clinical trial. We randomized our first patient in NefIgArd in November 2018. NefIgArd is a double-blind, placebo-controlled, two-part Phase 3 clinical trial. The first part of NefIgArd, which we refer to as Part A, is a pivotal efficacy and safety trial. The primary endpoint of Part A is the decrease in proteinuria in the first 200 randomized and dosed patients. In addition, a secondary endpoint of Part A is the difference in kidney function between treated and placebo patients as measured by eGFR. We believe that the key secondary endpoint in Part A, which is a measure of eGFR over a nine-month period, is informative of the primary endpoint of Part B, as discussed below. On the basis of the positive Part A results, we intend to submit an NDA in the first quarter of 2021 for accelerated approval by the FDA followed by an MAA for conditional approval by the EMA in the first half of 2021.

The second part of NefIgArd, which we refer to as Part B, is a post-approval confirmatory trial designed to provide evidence of long term renal benefit. Following completion of enrollment in Part A in December 2019, we completed the enrollment in Part B of an additional 160 patients in January 2021, in order to power Part B to assess the difference in kidney function between treated and placebo patients as measured by eGFR over a two-year period from the start of dosing of each patient. Having successfully completed enrollment,we expect to report data from Part B in early 2023. Across both parts, NefIgArd will generate nine months of dosing data, as well as an aggregate of 15 months of follow-up data from Parts A and B. If approved by the FDA, we intend to market and commercialize Nefecon in the United States as a treatment specifically designed to have a disease-modifying effect for IgAN by preserving kidney function and thereby avoiding progression to ESRD.

Nefecon Phase 2 Clinical Trial Results

In our completed pan-European Phase 2b clinical trial, Nefecon was also observed to statistically significantly reduce proteinuria and to provide clinical benefit by preserving kidney function, as measured by estimated glomerular filtration rate, eGFR, which is considered a key metric for measuring kidney disease progression. This trial, known as NEFIGAN, was a double-blind, placebo-controlled trial in 150 patients randomized to receive either 8 mg or 16 mg per day of Nefecon or placebo, each on top of optimized renin-angiotensin, or RAS, blockade to lower blood pressure, the predominant current standard of care. NEFIGAN achieved its primary endpoint of reduction in proteinuria for the 16 mg dose cohort. As measured by the urine protein creatinine ratio, or UPCR, patients in the placebo cohort exhibited an increase in proteinuria of 2.7%, while patients in the 16 mg dose cohort also exhibited statistically significant and clinically meaningful reductions in proteinuria of 27.3%. Patients treated with Nefecon also exhibited stabilization of eGFR, reflecting preservation of kidney function, while patients administered with placebo continued to show deterioration.

In order to approve a drug, the FDA generally requires one or more clinical trials demonstrating that the product candidate meets an endpoint that represents a direct clinical outcome, such as survival, decreased pain or the absence of disease, which we refer to as a clinical endpoint. However, in certain circumstances, the FDA selectively allows the use of surrogate endpoints that are reasonably likely to predict clinical benefit

in clinical trials to permit a more rapid development and approval path of treatments for serious or life-threatening diseases. For treatments related to chronic kidney disease, clinical trials have generally relied on clinical endpoints such as time to dialysis or transplantation. Due to the significant expense associated with the large patient numbers and extended clinical trial duration required to adequately measure such clinical endpoints, few new therapeutic drug candidates have emerged over the past two decades to treat renal disease. In 2012, the FDA and the American Society of Nephrology, or ASN, founded the Kidney Health Initiative, or KHI, with the goal of supporting research and innovation for the development of safe and efficacious treatments for kidney disease. We funded a collaboration with Tufts University and the University of Utah to conduct a meta-analysis based on selected, well-defined clinical trials in IgAN patients in order to provide regulatory authorities with a data-driven basis to accept a novel surrogate marker for potentially accelerated approval of treatments for IgAN. The final analytical framework from this collaboration showed a robust statistical relationship between reduction in proteinuria and reduction of the risk of progression to ESRD. We believe that this framework, together with the research and analysis conducted by the KHI and spearheaded by ASN, the National Kidney Foundation and the FDA, led to the FDA's acceptance of an accelerated approval pathway at our End-of-Phase 2 meeting in January 2017. This change in regulatory approach was fundamental to our decision to commence our ongoing Phase 3 clinical trial for Nefecon in IgAN.

Clinical Development Plans for Nefecon and Setanaxib

Beyond IgAN, we are exploring applications of Nefecon or its active ingredient for other autoimmune diseases in which it may have therapeutic potential, such as primary biliary cholangitis, or PBC, and autoimmune hepatitis, or AIH. We are planning to evaluate setanaxib as our first candidate in PBC, but will also continue to evaluate Nefecon for the treatment of PBC, a progressive and chronic autoimmune disease of the liver, that causes damage to the small bile ducts that drain bile from the liver, which can result in cholestasis and ultimately destruction of the bile ducts, leading to liver cell damage and ultimately liver failure, resulting in the need for a liver transplant. There are currently no approved therapies that specifically address the autoimmune response that is believed to drive PBC or the inflammatory consequences of the autoimmune response. Nefecon is designed to deliver high peak concentrations of its active ingredient to the intestine, which is then transported directly to the liver in order to locally reduce the autoimmune processes that drive PBC. We have received orphan drug designation for the treatment of PBC by the FDA. In addition, through our recent acquisition of a controlling interest in Genkyotex, we have acquired access to a novel NOX inhibitor platform from which the lead compound, setanaxib, has completed a Phase 2 trial in PBC and recently received orphan drug designation for the treatment of PBC in the United states and Europe. Based on its Phase 2 results indicating clinically relevant anti-fibrotic activity despite not achieving its primary endpoint in a trial in PBC, Genkyotex had interactions with the FDA during 2020 regarding the clinical development pathway for setanaxib in PBC. In January 2021, Genkyotex reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to 1,600 mg/day. Based on this positive data, Genkyotex plans to initiate a Phase 2/3 trial in PBC in the second half of 2021, incorporating higher dosing than that used in the Phase 2 trial and using alkaline phosphatase, or ALP, as a primary endpoint. The final design and protocol are subject to further feedback and commentary by the FDA. In addition, Genkyotex plans to initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021, which will study administration of setanaxib in conjunction with immunotherapy targeting cancer associated fibroblasts, or CAFs. Genkyotex has received orphan drug designation by the FDA and orphan designation by the EMA for PBC.

We have also in-licensed Budenofalk 3 mg oral capsules from the German pharmaceutical company Dr. Falk Pharma GmbH, or Falk Pharma, in order to obtain regulatory approval and commercialize Budenofalk in the United States for the treatment of AIH, another rare immune inflammatory liver indication. 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. Budenofalk is a formulation of budesonide originally developed to treat Crohn's disease. We believe Budenofalk has the potential to complement our activities in the United States. We have received orphan drug designation for the treatment of AIH using budesonide by the FDA. We discussed our development plans with the FDA for AIH during 2020 and have received helpful feedback as to the potential regulatory pathway forward. However, we expect to have further interactions with FDA in 2021 before we are in a position to affirmatively decide on the design and timing of a clinical program.

If approved by the FDA, we intend to commercialize Nefecon independently in the United States by establishing a targeted commercial sales infrastructure with a primary focus on IgAN patients at risk of progressing to ESRD. We intend to launch Nefecon in the United States in the first half of 2022, if approved. We are currently focused on disease education, interaction with patient advocacy groups and market access, with the goal of educating physicians about the disease origin, understanding patient needs and preparing our market access strategy for Nefecon. We believe this market can be addressed by a small and dedicated number of marketing and medical sales specialists, initially approximately 40, to efficiently cover the approximately 3,700 nephrologists focused on our target patient population in the United States.

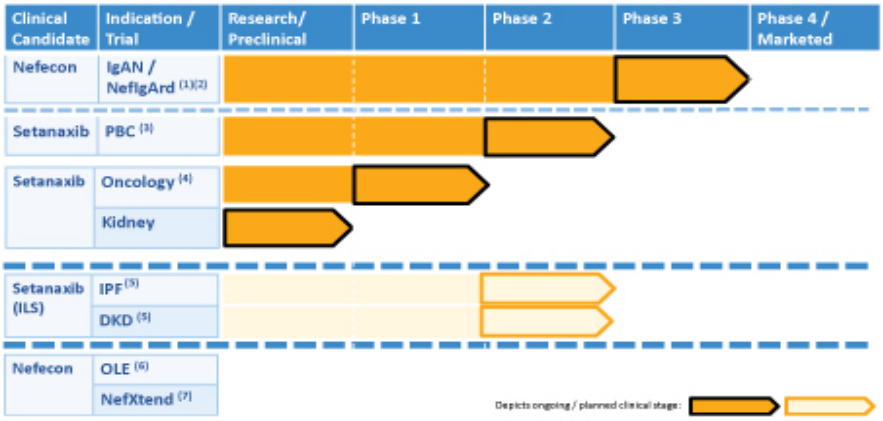
In 2019, we entered into an agreement with Everest Medicines, or Everest, pursuant to which we granted Everest an exclusive license to develop and commercialize Nefecon for IgAN in Greater China and Singapore. In other key territories such as Europe, we intend to commercialize Nefecon through either a broad regional partnership or on a country-by-country basis.

Genkyotex Acquisition

In 2020, we acquired a controlling interest in Genkyotex, which provides us with access to a novel platform of NOX inhibitors that we intend to develop for orphan diseases with fibrotic components, primarily focused on kidney and liver disease. Examples of fibrotic indications include PBC, primary sclerosing cholangitis, or PSC, and idiopathic pulmonary fibrosis, or IPF, and non-alcoholic steatohepatitis, or NASH. The lead compound, setanaxib, has shown clinically relevant activity across a variety of biomarkers related to fibrosis as well as Fibroscan in a recently completed Phase 2 trial in PBC, despite not achieving its primary endpoint. In addition, two investigator-led trials are underway, exploring setanaxib in IPF and diabetic kidney disease, or DKD. In January 2021, Genkyotex reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to1,600 mg/day. Based on this positive data, Genkyotex plans to initiate a Phase 2/3 trial in PBC in the second half of 2021. In addition, Genkyotex plans to initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021.

Our Pipeline

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



(1) Pursuing accelerated approval pathway in the United States, an expedited pathway, and conditional approval pathway in the European Union. We plan to submit an NDA in the first quarter of 2021 for accelerated approval by the FDA.

(2) Pursuing under the Section 505(b)(2) pathway in the United States and, as applicable, the hybrid application pathway in the European Union.

(3) Phase 2/3 trial planned in the second half of 2021.

(4) Phase 2 trial planned in head and neck cancer in 2021.

(5) Investigator-led trial. Not controlled or funded by Calliditas.

(6) Open label extension of the NefIgArd study.

(7) Open label extended dosing trial with Nefecon.

In addition, we have in-licensed Budenofalk 3 mg oral capsules and intend to develop Budenofalk in the United States for the treatment of AIH, subject to regulatory feedback. We have discussed the development plans with the FDA for AIH during 2020, but additional interaction is required before establishing any definitive clinical development plans.

Recent Developments

Nefecon Phase 3 Clinical Trial Results

In November 2020, we reported positive topline results from Part A of NefIgArd, which investigated the effect of Nefecon versus placebo in adult patients with primary IgAN. The trial met its primary objective of demonstrating a statistically significant reduction in the urine protein creatinine ratio, or UPCR, after nine months of treatment with 16 mg of Nefecon compared to placebo, with significant continued improvement at 12 months. The trial also met the key secondary endpoint showing a statistically significant difference in eGFR after nine months of treatment with Nefecon compared to placebo. Collectively, the efficacy data from nine months treatment with 16 mg of Nefecon indicated a significant and beneficial effect on key factors correlated to the progression to ESRD for IgAN patients.

Topline Results

The analysis included 199 patients diagnosed with primary 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—treatment or placebo—and treated orally for nine months daily.

24-hour UPCR (Proteinuria) Data

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). Based on the trends from the data observed from those patients who had reached 12 months at the time of the database lock, the company would expect the proteinuria reduction versus baseline to end up between 42% and 48% at 12 months for the 16 mg treatment cohort.

eGFR Data

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 represented an absolute decline of 4.04 ml/min/1.73 m^2 in the placebo arm over nine months compared to a 0.17 ml/min/1.73 m^2 decline in the treatment group.

Safety Profile

The results indicate that Nefecon was generally well-tolerated, with adverse events similar to those observed in the Phase 2b trial, including no clinically relevant changes in weight, blood pressure or HbA1c in the treatment arm. There were also no severe infections, and overall, it was consistent with the known safety profile of Nefecon's active ingredient, budesonide. The withdrawal rate in this trial was significantly less than that observed in the Phase 2b NEFIGAN trial.

On the basis of these Part A results, we intend to submit an NDA, in the first quarter of 2021 for accelerated approval by the FDA followed by an MAA for conditional approval by the EMA in the first half of 2021.

The NefIgArd trial is continuing on a blinded basis with patients continuing in the observational Part B of the trial for a 12 month period following the completion of Part A. In January 2021, we completed the enrollment of all 360 patients in NefIgArd, which includes 200 patients previously enrolled in Part A and another 160 patients enrolled in Part B. Having successfully completed enrollment, we intend to report data from Part B in early 2023, subject to any further impact from the COVID-19 pandemic to our business.

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 a controlling interest in Genkyotex adds a late-stage orphan pipeline asset and platform in inflammation and fibrosis to our product portfolio in orphan diseases. Genkyotex's lead product candidate, setanaxib, or GKT831, targets inhibition of NOX 1 and NOX 4, which are major drivers of fibrogenesis in multiple organs. They produce reactive oxygen species, or ROS, and modulate signaling by oxidizing signaling proteins, which drive multiple inflammatory and fibrogenic pathways. Setanaxib has shown clinically relevant anti-fibrotic activity in a Phase 2 clinical trial in PBC, a fibrotic orphan disease, despite not achieving its primary endpoint. Based on its Phase 2 results, Genkyotex had interactions with the FDA during 2020 regarding the clinical development pathway for setanaxib in PBC. In January 2021, Genkyotex reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to 1,600 mg/day. Based on this positive data, Genkyotex plans to initiate a Phase 2/3 trial in PBC in the second half of 2021. In addition, Genkyotex plans to initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021.

In November 2020, we acquired 7,236,515 ordinary shares from Genkyotex's largest shareholders and management team, or the Block Sellers, representing 62.7% of the share capital and voting rights for EUR 19.7 million in cash at EUR 2.73 per share. On November 26, 2020, we submitted a simplified public mandatory cash offer, or the Tender Offer, to the remaining shareholders in Genkyotex. The Tender Offer closed on December 11, 2020. As a result of the Tender Offer, we increased our ownership percentage to 86.2% of the share capital of Genkyotex. Collectively, the transactions above are referred to as the "Acquisition."

The Acquisition cost, excluding transaction costs, amounted EUR 27.8 million. In addition, we may owe shareholders of Genkyotex consideration of up to EUR 55 million, based on all shares of Genkyotex outstanding, contingent upon the achievement of certain milestones related to regulatory approvals of setanaxib in the U.S. and Europe. See "Description of Transaction" in Note 1 to the unaudited pro forma condensed combined financial information for more information.

Initial Public Offering

In June 2020, we completed an initial public offering, or the U.S. IPO, 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 U.S. 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.

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:

- Rapidly and efficiently advance Nefecon through Phase 3 clinical development and regulatory approval in order to establish a new standard of care for IgAN.
- Maximize the potential of Nefecon, if approved, through commercialization independently and through opportunistic collaborations with third parties.
- Leverage our existing pipeline, proprietary formulations and significant experience with drug release technology to explore treatments in select orphan hepatic diseases.
- Leverage and enhance our product pipeline complemented by selective acquisitions or in-licensing of product candidates focused on nephrology or orphan diseases.

Our Company and Management Team

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.

Corporate Information

We were founded as a public limited 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.

Our registered office is located at Kungsbron 1, C8, SE-111 22, Stockholm, Sweden, and our telephone number is +46 (0) 8 411 3005. Our website address is www.calliditas.com. We have included our website address in this prospectus solely as an inactive textual reference. The information contained on or accessible through our website is not incorporated by reference into this prospectus.

COVID-19 Pandemic

As of the date of this prospectus, the impact of the COVID-19 pandemic to our business has been limited. To date, we do not anticipate that the COVID-19 pandemic will significantly impact the ongoing clinical activities related to NefIgArd, our Phase 3 pivotal trial in IgAN. We reported topline results from Part A of NefIgArd in the fourth quarter of 2020. We fully recruited Part A in December 2019, and because 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, the impact of the COVID-19 pandemic to Part A of 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 believe we have been 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, trial nurses and our contract research organization. We experienced a reduced enrollment rate over the past several months due to the impact of the COVID-19 pandemic, and we did not complete full enrollment until January of 2021. Having completed enrollment, we expect to report data from Part B in early 2023, subject to any further impact from the COVID-19 pandemic to our business. There are, however, still uncertainties with regard to the continued development of COVID-19 and its implications, such as the potential inability of regulatory authorities to conduct pre-approval inspections of our manufacturing facilities, if required, and we will continue to assess the situation and seek to put in place relevant mitigating measures where necessary.

Although we believe we have implemented strategies to potentially minimize the impact of the COVID-19 pandemic to our business, we expect that we may experience delays with respect to the initiation of certain additional trials, including our extended dosing trial for Nefecon. The extent to which the COVID-19 pandemic impacts the timing of these additional trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, any restrictions on the ability of hospitals and trial sites to conduct trials that are not designed to address the COVID-19 pandemic and the perceived effectiveness of actions taken in the United States and other countries to contain and treat the disease. We will continue to evaluate the impact of the COVID-19 pandemic to our business.

Risks Associated With Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth in the section titled “Risk Factors” before deciding whether to invest in our ADSs. Among these important risks are, but not limited to, the following:

- The outbreak of the novel strain of coronavirus disease, COVID-19, could adversely impact our business, including our clinical trials, and the supply of our product candidates.
- We are substantially dependent on the success of our lead product candidate Nefecon. If we are unable to successfully complete clinical development of, obtain regulatory approval for and commercialize Nefecon or experience significant delays in doing so, our business will be materially harmed.
- The regulatory approval processes of the FDA, the EMA 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 Nefecon or future product candidates, our business will be substantially harmed.
- The use of proteinuria as a surrogate endpoint with an accelerated approval pathway to enable the advancement 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.
- We are pursuing the Section 505(b)(2) and hybrid application pathways for the regulatory approval of Nefecon and our other product candidates. If the FDA or EMA do not conclude that our other product candidates meet the requirements of Section 505(b)(2) or hybrid application, as applicable, or determine that Nefecon no longer qualifies for the Section 505(b)(2) regulatory pathway or hybrid application, as applicable, approval of such product candidates may be delayed, limited or denied, any of which would adversely affect our ability to generate operating revenues.
- 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 never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable partners.
- We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.
- We may fail to realize the anticipated benefits of our acquisition of Genkyotex, or those benefits may take longer to realize than expected.
- The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.
- If we were to be classified as a passive foreign investment company, there could be adverse U.S. tax consequences to certain U.S. holders.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies in the United States. These provisions include:

- the ability to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- exemption from the non-binding advisory votes on executive compensation, including golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal controls over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act.

Generally, we may take advantage of these exemptions for up to five years from the initial public offering of our ADSs or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.07 billion in annual revenue, we have more than $700.0 million in market value of our common shares (including in the form of ADSs) held by non-affiliates or we issue more than $1.0 billion of non-convertible debt over a three-year period.

We have taken advantage of certain reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities registered under the Exchange Act.

Implications of Being a Foreign Private Issuer

Our status as a foreign private issuer also exempts us from compliance with certain laws and regulations of the SEC and certain regulations of The Nasdaq Stock Market. Consequently, we are not subject to all of the disclosure requirements applicable to U.S. public companies. For example, we are exempt from certain rules under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our executive officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

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 U.S. 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.

We may take advantage of these exemptions until such time as we no longer qualify as a foreign private issuer. In order to maintain our current status as a foreign private issuer as of each June 30, either a majority of our outstanding voting securities must be directly or indirectly held of record by non-residents of the United States, or, if a majority of our outstanding voting securities are directly or indirectly held of record by residents of the United States, a majority of our executive officers or directors may not be United States citizens or residents, more than 50% of our assets cannot be located in the United States and our business must be administered principally outside the United States.

We have taken advantage of certain of these reduced reporting and other requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold equity securities.

THE GLOBAL OFFERING

Global Offering	4,500,000 common shares offered by us, consisting of common shares in the form of ADSs offered in the U.S. offering and common shares offered in the European private placement. The closings of the U.S. offering and the European private placement will occur substantially simultaneously. The total number of common shares (including common shares in the form of ADSs) in the U.S. offering and the European private placement is subject to reallocation between these offerings to the extent permitted under applicable laws and regulations.
ADSs offered by us in the U.S. Offering	ADSs, each representing common shares.
Common shares offered by us in the European Private Placement	common shares.
Option to purchase additional common shares (including common shares in the form of ADSs) in the Global Offering	The underwriters have an option for a period of 30 days from the date of this prospectus to purchase up to 675,000 additional common shares (including in the form of ADSs).
Common shares (including in the form of ADSs) to be outstanding immediately after the Global Offering	54,441,584 common shares (or 55,116,584 common shares if the underwriters exercise in full their option to purchase an additional 675,000 common shares (including in the form of ADSs)).
American Depositary Shares	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. To better understand the terms of our ADSs, see “Description of American Depositary Shares.” We also encourage you to read the deposit agreement, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.
Depositary	Citibank, N.A.
Use of Proceeds	We estimate that the net proceeds to us from the global offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, to be approximately $68.5 million (SEK 567.7 million), or $78.9 million (SEK 654.3 million) if the underwriters exercise their option to purchase additional ADSs from us in full. We intend to use the net proceeds from the global offering, together with our existing cash (i) to fund our ongoing Phase 3 clinical trial and related trials of Nefecon and to file for regulatory approval in the United States and the European Union; (ii) to fund the development of additional product candidates in indications for which Nefecon or its active ingredient and/or setanaxib may have therapeutic potential, including PBC and AIH, or for any

	product candidates that we in-license or acquire; and (iii) the remainder to fund pre-commercial and, if approved, commercial activities for Nefecon for the treatment of IgAN, or for any product candidates that we in-license or acquire, and for working capital and other general corporate purposes. See "Use of Proceeds" for a more complete description of the intended use of proceeds from the global offering.
Risk Factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our ADSs.
Nasdaq Global Select Market trading symbol for the ADSs	"CALT"
Nasdaq Stockholm trading symbol	"CALTX"

The number of common shares (including in the form of ADSs) to be outstanding after the global offering is based on 49,941,584 common shares outstanding as of September 30, 2020, and excludes:

- 1,279,086 common shares issuable upon the exercise of warrants to purchase common shares outstanding as of September 30, 2020 issued under our two warrant programs, with a weighted-average exercise price of SEK 74.37 per share, of which warrants to purchase 856,586 common shares may be exercised between January 1, 2022 and March 31, 2022, at an exercise price of SEK 74.30 per share; and warrants to purchase 422,500 common shares may be exercised between October 1, 2022 and December 31, 2022, at an exercise price of SEK 74.50 per share;
- 51,399 common shares issuable upon the exercise of options to purchase common shares outstanding as of September 30, 2020 under our Long-Term Board Incentive Plan 2019, or the LTIP 2019;
- 31,371 common shares issuable upon the exercise of options to purchase common shares outstanding as of September 30, 2020 under our Long-Term Board Incentive Plan 2020, or the LTIP 2020; and
- an additional 1,089,000 common shares that have been issued and 411,000 common shares that are reserved for future issuance under our long-term incentive plan, or the ESOP 2020.

Unless otherwise indicated, all information contained in this prospectus also reflects and assumes:

- no issuance or exercise of outstanding warrants or options after September 30, 2020;
- no exercise by the underwriters of their option to purchase additional shares (including in the form of ADSs) in the global offering; and
- excludes the effects of the Acquisition; for more information, see "Unaudited Pro Forma Condensed Combined Financial Information."

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables present the summary consolidated financial data as of the dates and for the periods indicated for our business. We have derived actual historical amounts included in the following summary of consolidated financial data as of and for the years ended December 31, 2019 and 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. The consolidated statements of income for the nine months ended September 30, 2020 and 2019 and the consolidated statement of financial position data as of September 30, 2020 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited consolidated financial statements. Historical results are not necessarily indicative of the results that may be expected in the future and the results for the nine months ended September 30, 2020 or any other interim period are not necessarily indicative of results to be expected for the full year ending December 31, 2020 or any other period. The summary consolidated financial data set forth below should be read together with our audited consolidated financial statements for the years ended December 31, 2019 and 2018 and the related notes to those statements, and our unaudited condensed consolidated financial statements for the nine months ended September 30, 2020 and 2019 and the related notes to those statements, as well as the sections of this prospectus captioned "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." We prepare our financial statements in accordance with IFRS as issued by the IASB.

	Years Ended December 31,		Nine Months Ended September 30,	
	2019	2018	2020	2019
	(SEK in thousands, except per share amounts)			
Consolidated Statement of Income Data:				
Net sales	184,829	—	474	138,243
Operating expenses				
Research and development	(149,826)	(99,260)	(167,379)	(108,117)
Administrative and selling	(62,882)	(31,132)	(77,843)	(39,092)
Other operating income	4,385	—	969	3,515
Other operating expenses	(4,525)	(2,090)	—	(4,525)
Operating loss	(28,019)	(132,482)	(243,779)	(9,976)
Financial income	926	441	504	2,158
Financial expenses	(5,408)	(8)	(19,603)	(1,710)
Loss before income tax	(32,501)	(132,049)	(262,878)	(9,528)
Income tax expense	(77)	—	(185)	—
Loss for the period attributable to shareholders	(32,578)	(132,049)	(263,063)	(9,528)
Loss per share before and after dilution	(0.88)	(5.09)	(6.09)	(0.26)

	As of December 31,		As of September 30, 2020	As of September 30, 2020
	2019	2018	Actual	As Adjusted[2]
			(SEK in thousands)	
Consolidated Statement of Financial Position Data:				
Cash	753,540	646,175	1,396,869	1,964,604
Working capital[1]	767,762	617,727	1,357,343	1,925,078
Total assets	845,200	648,417	1,440,183	2,007,918
Total liabilities	57,129	30,242	63,395	63,395
Total equity	788,071	618,175	1,376,788	1,944,523

(1) Each $1.00 (SEK 8.29) increase or decrease in the assumed offering price of $32.92 per ADS in the U.S. offering (SEK 136.42 per common share in the European private placement), would increase (decrease) the amount of cash, total equity and total capitalization after the global offering by $2.1 million (SEK 17.5 million), assuming the number of common shares (including common shares in the form of ADSs) offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 common shares (including common shares in the form of ADSs) offered by us would increase (decrease) the amount of cash, total equity and total capitalization after the global offering by $15.5 million (SEK 128.2 million), assuming no change in the assumed offering price per ADS or common share. The as adjusted information is illustrative only, and we will adjust this information based on the actual offering price and other terms of the global offering determined at pricing.

(2) We define working capital as current assets less current liabilities.

RISK FACTORS

Investing in our common shares and ADSs involves a high degree of risk. Before you decide to invest in our common shares and ADSs, you should consider carefully the risks described below, together with the other information contained in this prospectus, including our consolidated financial statements and the related notes appearing at the end of this prospectus. We believe the risks described below are the risks that are material to us as of the date of this prospectus. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common shares the ADSs could decline, and you may lose all or part of your investment. Please also see "Special Note Regarding Forward-Looking Statements."

Risks Related to the Development and Commercialization of Our Product Candidates

We are substantially dependent on the success of our lead product candidate, Nefecon and our recently acquired product candidate, setanaxib. If we are unable to successfully complete clinical development of, obtain regulatory approval for and commercialize Nefecon and setanaxib or experience significant delays in doing so, our business will be materially harmed.

We currently have no product candidates approved for commercial sale. We have not completed the clinical development of any product candidates and we cannot guarantee that we will ever have marketable drug products. To date, we have invested substantially all of our efforts and financial resources in the research and development of Nefecon, which is currently in an ongoing Phase 3 clinical trial. We reported positive topline results from Part A of NefIgArd in the fourth quarter of 2020, where the trial met the primary and key secondary endpoint. Additionally, as a result of our acquisition of Genkyotex, we are developing Genkyotex's lead product candidate, setanaxib, or GKT831. Setanaxib has shown clinically relevant anti-fibrotic activity in a Phase 2 clinical trial in PBC, a fibrotic orphan disease, despite not achieving its primary endpoint. Based on its Phase 2 results, Genkyotex had interactions with the FDA during 2020 regarding the clinical development pathway for setanaxib in PBC. In January 2021, Genkyotex reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to 1,600 mg/day. Based on this data, Genkyotex plans to launch a pivotal and potentially registrational Phase 2/3 trial in setanaxib in PBC in the first half of 2021. In addition, Genkyotex plans to initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021. Our near-term prospects, including our ability to finance our operations and generate revenue, will depend substantially on the successful development and commercialization of Nefecon and, to a lesser degree, setanaxib. The clinical and commercial success of our product candidates will depend on a number of factors, including:

- the timely completion of our planned and ongoing clinical trials;
- our ability to implement strategies to minimize the impact of the COVID-19 pandemic to our business, including with respect to initiating, enrolling, conducting or completing our planned and ongoing clinical trials and addressing any potential disruption or delays to the supply of our product candidates;
- our ability to demonstrate our product candidates' safety and efficacy to the satisfaction of the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, 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, EMA or comparable foreign regulatory authorities to conduct additional clinical trials in connection with approval to market our product candidates, including any additional testing following any accelerated or conditional approval by such regulatory authorities;
- our ability to obtain marketing approvals in the United States under the FDA's Accelerated Approval Program and in Europe under the EMA's conditional approval program;
- the FDA's continued position that the 505(b)(2) regulatory pathway is available for Nefecon;
- our ability to confirm long-term renal benefit in Part B of NefIgArd, and anti-fibrotic activity in our pivotal and potentially registrational Phase 2/3 trial in setanaxib in PBC;

- our ability to maintain any regulatory approvals to market our product candidates that we may receive;
- the prevalence and severity of adverse side effects of our product candidates;
- our ability to successfully commercialize our product candidates, if approved for marketing and sale by the FDA, EMA or comparable foreign regulatory authorities, whether alone or in collaboration with others;
- the ability of our third-party manufacturers to manufacture quantities of our product candidates using commercially sufficient processes and at a scale sufficient to meet anticipated demand and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our success in educating physicians and patients about the benefits, risks, administration and use of our product candidates;
- achieving and maintaining compliance with all regulatory requirements applicable to our product candidates;
- acceptance of our 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 our product candidates by third-party payors and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- our ability to obtain and sustain an adequate level of reimbursement for our product candidates by third-party payors;
- 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 our 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 our product candidates following approval; and
- if approved, our ability to raise sufficient capital resources to fund the commercialization of our product candidates.

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 our 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. Any of the foregoing scenarios could materially harm the commercial prospects for Nefecon and setanaxib. If we are not successful in commercializing Nefecon and setanaxib, or are significantly delayed in doing so, our business will be materially harmed.

The regulatory approval processes of the FDA, the EMA 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 Nefecon or future product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the EMA 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. We have not obtained regulatory approval for any product candidate and it is possible that Nefecon or any product candidates we may seek to develop in the future will never obtain regulatory approval.

Any of our product candidates, including Nefecon or setanaxib, 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 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 by the EMA;
- the data collected from clinical trials of our 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 European Union or elsewhere;
- the scientific advice and regulatory feedback provided by the FDA and EMA, as applicable, during the drug development phase is not legally binding, and the FDA or 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 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 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 or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials;
- the FDA, the EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes 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 EMA 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, the EMA 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 EMA or other comparable foreign regulatory authorities.

Additionally, disruptions at the FDA and other 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 U.S. 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. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials which the FDA continues to update. As of June 23, 2020, the FDA noted it was conducting mission critical domestic

and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. On July 10, 2020, the FDA announced its goal of restarting domestic on-site inspections during the week of July 20, 2020, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a Complete Response Letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed.

Accelerated approval by the FDA, and conditional approval by EMA, even if pursued for Nefecon or any other 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 Nefecon and such other product candidates could be delayed, abandoned or become significantly more costly.

Based on feedback from the FDA and EMA, we plan to seek approval of Nefecon, and, if considered appropriate by the regulatory authorities, may seek approval of future product candidates using the FDA's accelerated approval and the EMA's conditional approval pathways. For Nefecon, our strategy is to use the accelerated approval pathway that would allow our Phase 3 clinical endpoint for FDA approval to be based on biomarker data from the 200 patients in Part A of the NefIgArd trial. For chronic kidney disease, clinical trials have generally relied on clinical endpoints based on outcomes, which have led to few new therapeutic drug candidates. In certain circumstances, the FDA selectively allows the use of surrogate endpoints to permit a faster development and an accelerated approval path. At our End-of-Phase 2 meeting with the FDA, the agency indicated its acceptance of proteinuria as a surrogate marker in IgAN. Although this trial is designed to support accelerated approval if the data are positive, Nefecon may not have faster development or regulatory review timelines.

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 NefIgArd is intended to serve as such a post-approval confirmatory trial to measure long term renal benefit and to verify the clinical benefit of Nefecon. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. If the FDA or the EMA do not approve Nefecon on the basis of data presented after Part A of NefIgArd, but instead require the completion of the full Phase 3 clinical trial prior to the filing of marketing applications, the development and commercialization timeline of Nefecon will be delayed. Even if we do receive accelerated approval or conditional approval, we may not ultimately receive full approval from the regulatory agencies. The additional data generated through post-marketing clinical trials may not confirm that the benefit-risk balance of Nefecon or any other future product candidate is positive or the burden to further complete the obligations may become too high.

In the European Union, the conditional marketing authorization is subject to an annual renewal procedure that assesses the marketing authorization holder's compliance with the specific obligations of the authorization. If conditions are not being complied with, the EMA may decide to extend the timeline for the existing obligations, change the scope of such obligations or add new obligations, which may require additional financial resources and time. We may not be able to comply with such changed or additional obligations and may need to withdraw the marketing authorization. The EMA may also decide not to renew the conditional marketing authorization, although such measure is rarely applied in practice. An analysis of reimbursement decisions for conditionally authorized medicines in the European Union has shown some delays in the timeline for reaching a positive health technology recommendation. If this happens for Nefecon or any other future product candidate, it may delay the timing and success of the commercialization of such product.

The use of proteinuria as a surrogate endpoint with an accelerated approval pathway to enable the advancement of Nefecon is a novel approach in nephrology.

Part A of our Phase 3 clinical trial of Nefecon is designed with reduction of proteinuria, a surrogate biomarker, rather than an outcomes-based clinical endpoint, as the primary endpoint of the trial intended

to support marketing applications with the FDA, EMA and comparable foreign regulatory authorities. The reduction in proteinuria is a novel surrogate biomarker that is designed to facilitate the advancements of new IgAN drugs such as Nefecon through the clinical trial process towards potential regulatory approval. However, we may not succeed in demonstrating the efficacy of Nefecon using this novel biomarker to the satisfaction of the regulatory agencies, notwithstanding the positive results we reported from Part A of the NefIgArd trial and the positive results in earlier trials. In addition, the FDA, EMA or comparable regulatory authorities have not determined the required level of reduction of proteinuria that we would need to demonstrate in NefIgArd to obtain marketing approvals for Nefecon based on this surrogate biomarker.

Additionally, although we believe we have properly worked with FDA and EMA to facilitate the advancement of proteinuria as a surrogate endpoint, there can be no assurances that FDA and EMA adhere to this advice and ultimately approve Nefecon. The FDA and/or EMA 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 or EMA may also withdraw any approval granted based on a surrogate endpoint of Nefecon if Part B, the post-approval confirmatory phase of NefIgArd, does not validate the clinical benefit of Nefecon.

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 product candidates, we must demonstrate through extensive clinical trials that our product candidates are safe and effective in humans. 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 completing clinical trials and initiating or completing additional 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 ethics committee approval 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;
- 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.

Disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or ethics committees, 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, the EMA 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. For example, while the FDA accepted a protocol design modification for NefIgArd that reduced the total trial size from 450 to 360 patients and shortened the follow-up period, there can be no assurance that NefIgArd will proceed in an expedient or capital-efficient manner.

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. In addition, 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.

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 Nefecon, setanaxib or any other product candidates we may develop, we must demonstrate through lengthy, complex and expensive clinical trials that our 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 product candidates. In some instances, there can be significant variability

in safety or efficacy results between different clinical trials of the same 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 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 marketing approval, if at all.

Even if the trials are successfully completed, clinical data such as the positive data we reported from Part A of NefIgArd in November 2020 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 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. For example, even if reductions in proteinuria are observed in Part A of NefIgArd, regulatory authorities may determine that such levels of reduction are not sufficient to warrant accelerated or conditional approval. To the extent that the results of the trials are not satisfactory to the FDA, the EMA 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.

Additionally, some of the clinical trials of Nefecon performed to date, including our Phase 2a clinical trial, were from open-label trials. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.

Some of our clinical trials for our product candidates have been, 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 U.S. population and U.S. 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. For example, while our ongoing NefIgArd trial of Nefecon has a similar trial design as the Phase 2b clinical trial in terms of the endpoints evaluated, and we reported positive data from Part A of the NefIgArd trial, the results from the earlier trial and Part A of the NefIgArd trial may not necessarily be predictive of results that we may observe in Part B of the NefIgArd trial or other trials we may be required to conduct. Furthermore, 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 change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. For example, in November 2020, we announced positive topline results from Part A of NefIgArd, which investigated the effect of Nefecon versus placebo in adult patients with IgAN. Preliminary and interim data from our clinical trials may change as more patient data become available. 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 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 data being materially different from the preliminary data we previously published. As a result, preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

We are pursuing the Section 505(b)(2) and hybrid application pathways for the regulatory approval of Nefecon and our other product candidates. If the FDA or EMA do not conclude that our other product candidates meet the requirements of Section 505(b)(2) or hybrid application, as applicable, or determine that Nefecon no longer qualifies for the Section 505(b)(2) regulatory pathway or hybrid application, as applicable, approval of such product candidates may be delayed, limited or denied, any of which would adversely affect our ability to generate operating revenues.

We are pursuing a regulatory pathway pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, and the hybrid application of the EU Centralized Procedure pursuant to article 10(3) of Directive 2001/83/EC for the approval of Nefecon. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval.

If the FDA determines that our other product candidates do not meet the requirements of Section 505(b)(2), we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If our product candidates do not meet the requirements of Section 505(b)(2) of the FDCA or are otherwise ineligible for approval via the Section 505(b)(2) regulatory pathway, the time and financial resources required to obtain FDA approval for

these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, a 505(b)(2) application will not be approved until any non-patent exclusivity listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, or for any other drug with the same protected conditions of approval as our product, has expired. An inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Some pharmaceutical companies and other actors have objected to the FDA's interpretation of Section 505(b)(2) of the FDCA to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA has adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if it does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's interpretation, the approval of one or more of our product candidates may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with our product candidates, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Moreover, even if these product candidates are approved under the Section 505(b)(2) regulatory pathway the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Our product candidates 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 our product candidate 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 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, the EMA or other comparable foreign regulatory authorities. Budesonide 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.

The results of our Phase 3 clinical trial for Nefecon or 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 EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates 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 or any of our future product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by Nefecon or such other 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 may find it difficult to enroll 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, EMA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. In particular, because our ongoing Phase 3 clinical trial of Nefecon is evaluating IgAN, an orphan indication with relatively small patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. 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;
- continued enrollment of prospective patients by clinical trial sites; and
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites or enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented and other factors.

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.

As an organization, we have never completed pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, EMA or comparable foreign regulatory authority to market Nefecon or any future product candidate. Carrying out later-stage clinical trials is a complicated process. As an organization, we have not previously completed any later stage or pivotal clinical trials. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. See "—Risks Related to our Dependence on Third Parties." Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to filings for market approval for Nefecon or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

Changes in methods of product candidate manufacturing or formulation 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 manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. 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, EMA 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.

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 European Commission granted Nefecon orphan designation for the treatment of primary IgAN. We have also received Orphan Drug

Designation for PBC and AIH. In addition, we acquired a controlling interest in Genkyotex, which owns setanaxib and has received Orphan Drug Designation from the FDA and orphan designation from the European Commission for 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 European Union, 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 European Union, the European Commission grants orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Orphan designation is intended to promote the development of drugs that (i) are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in the European Union or that (ii) are intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union. Orphan designation will only be granted to the aforementioned categories of drugs if no satisfactory method of diagnosis, prevention, or treatment has been authorized, or where such method exists, the product would be of significant benefit to those affected. In the European Union, orphan designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally in the United States and the European Union, 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 EMA, as applicable, from approving another marketing application for the same drug and indication in the United States or a similar drug for the same indication in the European Union for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the European Union. The European Union exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan designation *inter alia* if the drug is sufficiently profitable such that market exclusivity is no longer justified. Where the European Union application for an orphan drug includes the results of all studies conducted in compliance with an agreed pediatric investigation plan, the ten-year market exclusivity period is extended to twelve years. We obtained a positive opinion from the EMA Pediatrics Committee on our Pediatric Investigation Plan for Nefecon for the treatment of IgAN in December 2019. The European Commission is evaluating the experience gathered with the orphan regulation and may propose changes to the market exclusivity incentive as it exists today.

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 can subsequently approve the same drug for the same condition if the FDA 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 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 our estimates of the number of treatable patients 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 these diseases in a position to receive Nefecon, if approved, 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 our product candidates, if approved, 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 the Acquisition (as defined below). 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 "Business—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.

If we fail to develop and commercialize other product candidates in addition to Nefecon, including 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 the treatment of IgAN is our primary focus, as part of our longer-term growth strategy we plan to evaluate Nefecon or its active ingredient budesonide in other indications, including PBC and AIH, and setanaxib for the treatment of PBC and head and neck cancer. We also intend to evaluate additional potential indications for budesonide and may choose to in-license or acquire other product candidates as well as commercial products to treat patients suffering from other orphan diseases with significant unmet medical needs and limited treatment options. These other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including clinical trials and approval by the FDA, EMA and/or applicable comparable foreign regulatory authorities. All future potential 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 you 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 that 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 the development of Nefecon and setanaxib, and we may forego or delay pursuit of opportunities with other product candidates or for other indications for Nefecon 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 Nefecon, setanaxib 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.

To date, we have no products authorized for marketing, and even if Nefecon, setanaxib or one or more of our future product candidates are approved for commercialization, they 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 will be successful in marketing Nefecon, if approved. In addition, efforts to educate the medical community and third-party payors on the benefits of Nefecon or our other product candidates may require significant resources and may never be successful which would prevent us from generating significant revenues or becoming profitable. While we believe that the U.S. IgAN market could be adequately covered by a specialized salesforce of approximately 40 representatives, we may underestimate the number of representatives that we will actually require. In addition, we are currently focused on developing drug products that can be approved under abbreviated regulatory pathways in the United States, such as the 505(b)(2) regulatory pathway, and in the European Union such as article 10 (3) Directive 2001/83/EC legal basis, which allows us to rely on existing knowledge of the safety and efficacy of the relevant reference listed drugs to support our applications for

approval in the United States and in the European Union. While we believe physicians, patients and other members of the medical community may more readily accept and use our product candidates, if approved, as compared to entirely new chemical entities, 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 EMA or comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, the EMA 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 product candidates 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 Nefecon or any future product candidates we develop 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, 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 United States, the European Union 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. It is possible that a third-party payor may consider our product candidate 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 product candidate, pricing of existing drugs may limit the amount we will be able to charge for our product candidate. 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 candidates, 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 United States, 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 of 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, 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 United States. 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 United States, 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, Canada and other countries has 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 United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, 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 European Union member states, or 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 ever-increasing European Union 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 European Union, the United States 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 expect to 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 United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition in the United States for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, 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 U.S. 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 HHS made such certification to Congress, and on October 1, 2020, FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, 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 market implications of the final rule and guidance are unknown at this time. Proponents of drug reimportation may attempt to

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

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable partners.

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of biopharmaceutical products. To achieve commercial success for any approved product, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into partnerships.

There are risks involved in both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. If approved by the FDA, we intend to commercialize Nefecon for IgAN in the United States independently. In other key territories such as Europe, we intend to commercialize Nefecon through either a broad regional partnership or on a country-by-country basis. Even if we establish sales and marketing capabilities, we may fail to launch or market our products effectively because we have no experience in the sales and marketing of biopharmaceutical products. In addition, recruiting and training a sales force is expensive and time consuming and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. 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;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- costs of marketing and promotion above those anticipated by us.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell any products that we develop ourselves. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements 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 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.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our products, 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 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 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 U.S. 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.

There remain executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, effective as of January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and eliminating the implementation of certain ACA-mandated fees. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. It is also unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Since January 2017, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA.

Moreover, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase the point-of-sale discount (from 50% under the ACA to 70%) that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closed the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Since then, the ACA risk adjustment program payment parameters have been updated annually. In addition, CMS published a final rule that gave states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, the 2020 federal spending package permanently eliminated effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax.

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, including the BBA, will remain in effect through 2030 unless additional

Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020. 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 U.S. 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. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Although a number of these and other measures may require additional authorization to become effective, and it is unclear whether President Joseph Biden will work to reverse these measures or pursue similar policy initiatives, 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 European Union, the policy debate is focused on the impact of intellectual property protection and regulatory incentives on innovation and patient access. Specifically, the European Commission has gathered information on the experience with the orphan drug regulation and paediatric regulation and may consider changes to incentives such as market exclusivity for orphan drugs, small scale pharmacy compounding and compulsory licensing of patented drugs.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction, particularly in light of the recent presidential election. In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic. 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.

Even if we, or any future collaborators, obtain regulatory approvals for Nefecon or any other future product candidate, the terms of approvals 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 therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain regulatory approval. 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 any 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 EMA 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, EMA 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 FDA or other 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 FDA, EMA and other 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.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction, particularly in light of the recent presidential election. In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic.

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 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. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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

Obtaining and maintaining marketing approval of our current and future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of Nefecon or any other future product candidate, the EMA and comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those jurisdictions. Approval procedures vary among jurisdictions and can involve requirements and administrative

review periods different from, and greater than, those in the United States, 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 United States, 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 biopharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of our existing or future product candidates by us and our collaborators in clinical trials, and the potential 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, pharmaceutical companies, 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 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 intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will 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 are developing Nefecon initially for the treatment of IgAN. If Nefecon is approved by the FDA, EMA or comparable foreign regulatory authorities, we may only promote or market it for its specifically approved indications. We will train our marketing and sales force against promoting Nefecon or any future product candidates 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, EMA 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 of Nefecon or future product candidates 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.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European Union member states.

We intend to seek approval to market our product candidates in the United States, the European Union and selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our 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 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.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including the European Economic Area, or EEA, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced Member States, can further reduce prices. 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. In some countries, we may be required to conduct a clinical trial or other trials that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our inception, we have incurred significant operating losses. We incurred total comprehensive losses of SEK 32.6 million and SEK 263.1 million for the year ended December 31, 2019 and the nine months ended September 30, 2020, respectively. As of December 31, 2019 and September 30, 2020, we had an accumulated loss of SEK 488.1 million and SEK 751.2 million, respectively. Our losses resulted principally from costs incurred in clinical development of Nefecon and from administrative costs associated with our operations. We expect to continue to incur significant and increasing operating losses for the foreseeable future, and we do not know whether or when we will become profitable. Our losses, among other things, will continue to cause our working capital and shareholders' equity to decrease. We anticipate that our expenses will increase substantially if and as we:

- continue to develop and advance Nefecon through NefIgArd, for the treatment of IgAN;
- initiate and continue clinical development for Nefecon or its active ingredient budesonide in other potential indications, such as primary biliary cholangitis, or PBC, and autoimmune hepatitis, or AIH;
- seek regulatory approval for Nefecon and/or any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure and scale-up external manufacturing to commercialize Nefecon, if approved;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts;
- expand our operations in the United States and Europe;
- incur additional legal, accounting and other expenses associated with operating as a public company in the United States; 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 delays or other business interruptions due to the COVID-19 pandemic.

To date, we have funded our operations through public and private placements of equity securities, upfront payments, and interest income from the investment of our cash and financial assets.

We do not currently have any approved products and have never generated any revenue from product sales. To become and remain profitable, we must succeed in developing and eventually commercializing Nefecon and/or other approved products that generate significant revenue. This will require us to be successful in a range of challenging activities, including successfully completing our ongoing Phase 3 clinical trial of Nefecon, in-licensing and developing additional product candidates or indications for Nefecon or its active ingredient budesonide and/or setanaxib, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. 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. Even if Nefecon or another product candidate that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. 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. Even if we are able to generate revenue from the sale of any 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.

Even if the global offering is successful, we will 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. We expect to require substantial additional funding in the future to sufficiently finance our operations and advance the clinical development, seek regulatory approval and potentially commercialize Nefecon or any other product candidates we may develop.

As of September 30, 2020, we had SEK 1,396.9 million in cash. Based on our current operating plan, we expect that our existing cash, together with the anticipated net proceeds from the global offering, will enable us to fund our operating expenses and capital expenditure requirements until we are cash flow positive, which is expected in the first half of 2023, subject to Nefecon being approved by regulatory authorities for marketing and sale and successfully commercialized. 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. Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of clinical trials for Nefecon or clinical trials for any future product candidates;
- the number of potential new product candidates we identify and decide to develop, if any;
- the time and costs involved in obtaining regulatory approval for Nefecon and other product candidates we may choose to develop, 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 potential commercialization of Nefecon or future product candidates;
- the costs and timing of preparing, filling and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending against any intellectual property claims or infringements raised by third parties;
- the costs related to our obligations under our existing collaboration agreements and the entry into new collaboration agreements;
- the cost and timing of future pre-commercialization activities and, with respect to any product candidates that receive regulatory approval, post-commercialization activities, and costs involved in the creation of an effective sales and marketing organization;
- the revenue, if any, we may receive either directly from commercial sales or in the form of royalty payments from future sales of Nefecon or future product candidates, if approved;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the effect 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 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 or purchasers of our common shares or purchasers of ADSs in the global offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. 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 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 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 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.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Since we began operations in 2004, we have invested most of our resources in developing our lead product candidate Nefecon, our technology, building our intellectual property portfolio, conducting business operations, raising capital and providing administrative support for these operations. Consequently, we have limited operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug 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.

Nefecon is being investigated in an ongoing Phase 3 clinical trial for the treatment of IgAN. We have not yet demonstrated an ability to successfully conduct any Phase 3 clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or conduct sales and marketing activities necessary for successful product commercialization or obtain reimbursement in the countries of sale. In addition, given our limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other

known and unknown factors in achieving our business objectives. Additionally, we expect our financial condition and operating results to 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.

In addition, we will need to transition at some point from a company with a development focus to a company capable of supporting commercial activities, and we may not be successful in such a transition.

Risks Related to Our Acquisition of Genkyotex

We may fail to realize the anticipated benefits of our acquisition of Genkyotex, or those benefits may take longer to realize than expected.

In November 2020, we acquired a controlling interest in Genkyotex. Our ability to realize the anticipated benefits of such acquisition will depend, to a large extent, on our ability to integrate Genkyotex and its NOX inhibitor platform into our business and business strategy and realize anticipated growth opportunities and synergies. The integration process has been, and we expect will continue to be, complex and time-consuming. The expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of the acquisition could cause an interruption of, or a loss of momentum in, our development, and could adversely affect our business, financial condition and results of operations.

In addition, in November 2020, we submitted a simplified public mandatory cash offer, or the Tender Offer, to the remaining shareholders in Genkyotex. The Tender Offer closed on December 11, 2020. As a result of the Tender Offer, we increased our ownership percentage to 86.2% of the share capital of Genkyotex. Collectively, the transactions above are referred to as the "Acquisition."

Our ability to realize the anticipated benefits of the Acquisition is expected to entail numerous additional material potential difficulties, including, among others:

- any delay or failure in progressing setanaxib in clinical development and manufacturing, or any delay or failure to ultimately obtain marketing approval for commercialization of setanaxib in the United States and Europe thereafter;
- changes in laws or regulations that adversely impact the anticipated benefits of the Acquisition;
- increased complexity of compliance and cost of operations due to any delay in reaching 90% ownership of Genkyotex or failure to delist Genkyotex from Euronext;
- challenges related to the perception by patients, the medical community and third-party payors of setanaxib for the treatment of primary biliary cholangitis, or PBC, idiopathic pulmonary fibrosis, or IPF, nonalcoholic steatohepatitis, or NASH, and other fibrotic indications;
- disruptions to our manufacturing arrangements with third-party manufacturers, including our manufacturing and supply arrangements with respect to setanaxib and disruptions to our third-party distribution channel;
- difficulties in achieving the anticipated business opportunities and growth prospects from the Acquisition;
- the size of the treatable patient population for setanaxib may be smaller than we believe it is; and
- potential unknown liabilities, adverse consequences, unforeseen increased expenses or other unanticipated problems associated with the Acquisition.

We do not own or control all of the outstanding shares of Genkyotex, which may limit our ability to take certain actions, other than on an arms length basis in the ordinary course of business. As a French listed company, Genkyotex is subject to conflict of interest rules arising from French corporate law and codified in the French Commercial Code has adopted the corporate governance code recommended by MiddleNext, a French association of mid-cap listed companies, and follows recommendations adopted by the French Financial Markets Authority. If, under these provisions, directors of Genkyotex who are directors, officers or employees of Calliditas cannot vote on certain matters (such as those where there is a disqualifying conflict of interest), we may not be able to obtain required board approval of decisions that we favor.

Similarly, if there are transactions requiring the approval of Genkyotex shareholders and as to which Calliditas has a disqualifying conflict of interest, such transactions would require the approval of Genkyotex' minority shareholders, who may not approve a transaction that we favor.

Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially adversely impact our business, financial condition and results of operations.

The Acquisition cost, excluding transaction costs, amounted to EUR 27.8 million. In addition, we may owe shareholders of Genkyotex consideration of up to EUR 55 million, based on all shares of Genkyotex outstanding, contingent upon the achievement of certain milestones related to regulatory approvals of setanaxib in the U.S. and Europe. We also expect to incur expenses related to the continued development, regulatory approval process and commercialization with respect to setanaxib. Because we have limited financial resources, by investing in the Acquisition, we may forgo or delay pursuit of other opportunities that may have proven to have greater commercial potential.

All of these factors could decrease or delay the expected accretive effect of the Acquisition and negatively impact our stock price. As a result, it cannot be assured that the Acquisition will result in the full realization of the benefits anticipated from the Acquisition or in the anticipated time frames or at all.

The work required to integrate Genkyotex may divert management resources from operational matters and other strategic opportunities.

We expect that the successful integration of Genkyotex's operations, pipeline of product candidates and personnel will require management time and attention. The amount of time that our management will be required to devote to the integration may divert their attention from the day to day operation of the business or other strategic opportunities. In addition, uncertainty regarding the Acquisition and its impact on our results of operations, employees, regulatory compliance may create additional demands on management's time and resources. The trading price for our ADSs and common shares is predicated in part by investor expectations for our future growth, including organic growth and other potential opportunities for growth through strategic acquisitions. If diversion of management's impairs our results of operations, our share price could be negatively impacted.

The Acquisition will result in the combined company operating in additional jurisdictions, increasing our exposure to international business risks.

We have focused our operations primarily in Sweden, with some operations in the United States. Genkyotex primarily operates in France and Switzerland. The Acquisition will result in our operations in a number of additional jurisdictions worldwide exposing our business to additional risks related to:

- challenges caused by distance as well as language and cultural differences;
- general economic conditions in each country or region;
- political unrest, terrorism and the potential for other hostilities;
- complexities in compliance overlapping or changes in tax regimes;
- difficulties in transferring funds from certain countries;
- increased exposure to currency fluctuations; and
- increased compliance costs associated with local regulatory compliance.

If we are unable to adequately manage our operations in these new jurisdictions, we could experience decreased revenues or increased operating expenses, any of which could adversely affect our business, financial condition, and results of operations.

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 GCP requirements, which are regulations and guidelines enforced by the FDA, the EMA 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, 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.

The COVID-19 pandemic and government measures taken in response may also have an impact on our CRO, including due to travel or quarantine policies or prioritization of resources toward the pandemic, and any disruption in their performance would affect our ability to complete our 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 COVID-19 pandemic 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 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. 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 we expect to continue to rely on third parties for the clinical and commercial supply of Nefecon and other future product candidates. The development of Nefecon or such other product candidates, and the commercialization of any approved products, could be stopped, delayed 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 or any other 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. For example, the COVID-19 pandemic may impact our ability to procure sufficient future supplies for Nefecon and our other product candidates, and the extent of any impacts will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects; however, we do not currently anticipate any interruptions in our supply of Nefecon for our ongoing and planned clinical trials. 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.

In complying with the manufacturing regulations of the FDA, the EMA 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 EMA 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 product candidates could suffer significant interruptions. 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 are dependent on a single supplier for the manufacture of the active pharmaceutical ingredient in Nefecon.

We currently depend on a single supplier for the active ingredient in Nefecon. We cannot ensure that this supplier will remain in business or have sufficient capacity or supply to meet our needs, or that it will

not be purchased by one of our competitors or another company that is not interested in continuing to work with us. While we believe we can identify and transition to alternate suppliers for the active ingredient if necessary, our use of a single supplier exposes us to several risks, including disruptions in supply, price increases or late deliveries, including any disruptions resulting from factors related to the COVID-19 pandemic. We do not currently anticipate any interruptions in our supply of the active ingredient for our ongoing and planned clinical trials. Our current vendor may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Finding a suitable replacement supplier, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption or delay in supply could compromise our ability to pursue development and eventual commercialization of our product candidates.

We have not yet manufactured on a commercial scale and expect to rely on third parties to produce and process commercial quantities of Nefecon or future product candidates, if approved.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for Nefecon or future product candidates. We have not yet entered into any arrangement with a third party for the supply of commercial quantities of Nefecon. To the extent that we enter into future manufacturing arrangements with third parties for commercial supply of Nefecon or future product candidates, if approved, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA, EMA or comparable foreign regulatory authorities following inspections that will be conducted after we submit an application to such regulatory authorities. We do not directly control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We may collaborate with third parties for the commercialization of Nefecon or future product candidates, if approved, in select jurisdictions. If we are unable to establish such collaborations, we may not be successful in our commercialization efforts.

In order to market and successfully commercialize any product candidate we develop, if approved, we must build our sales and marketing capabilities or enter into collaborations with third parties for these services. We currently have no sales, marketing or distribution capabilities and as a company have no experience in marketing products. If approved by the FDA, we intend to commercialize Nefecon for IgAN in the United States independently. In other key territories, including Europe, we may commercialize Nefecon through a broad regional partnership. For example, in 2019 we entered into an agreement with Everest Medicines, or Everest, pursuant to which we granted Everest an exclusive license to develop and commercialize Nefecon for the treatment of IgAN in Greater China and Singapore.

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.

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.

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 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 and our other 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 enforceable. The patent position of biopharmaceutical 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.

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 from challenges by others from time to time. It is possible that one or more of our U.S. patents may be challenged by parties who file a request for post-grant review or *inter partes* review or *ex parte* reexamination. Post-grant proceedings are increasingly common in the United States and are costly to defend. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome 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 or our 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 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, however, 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 to enforce 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 or future product candidates without infringing 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 U.S. and non-U.S. 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 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 EPO or USPTO and opposition or other proceedings before 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 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 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 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 you 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 shares of our common stock. 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 United States, 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 may become dependent on intellectual property licensed from third parties for certain of our product candidates, and termination of any of these licenses could result in the loss of significant rights, which would substantially harm our business.

If we in-license additional product candidates in the future, we might become dependent on proprietary rights from third parties with respect to those 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 candidates 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 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 candidate or program and our business and financial condition could suffer.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world. Furthermore, our proprietary name of Nefecon is subject to review by regulatory authorities for commercial use. FDA has indicated that we will not be able to use the name Nefecon for our product candidate, and we will be required to propose an alternative name for review. This proposed proprietary name is still subject to review by EMA and other foreign regulatory authorities, and if we are forced to use an alternative proprietary name, as we will be in the United States, any goodwill and recognition that we have built for the name Nefecon would be lost.

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 United Kingdom or Sweden). International applications under the Patent Cooperation Treaty, or PCT, are filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our product candidates may be marketed. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. 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 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 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 the same as or similar to our product candidates but that are not covered by 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 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 biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical 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 U.S. 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 U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. 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 U.S. 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 U.S. 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

The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our clinical trials.

In December 2019, a novel strain of the coronavirus disease, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and has spread to a number of countries, including the United States, and the World Health Organization declared the COVID-19 virus a global pandemic. The outbreak and government measures taken in response to contain the spread of the virus have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. Governments have instituted travel and other restrictions in order to reduce the spread of

the disease that, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings and events and order cessation of non-essential travel. In response to the spread of COVID-19, we have instituted a work-from-home policy for most of our administrative employees.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity, disrupt our ongoing research and development activities and impact our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

As a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures deemed non-essential, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, including the potential inability of FDA or other regulatory authorities to conduct pre-approval inspections of our manufacturing facilities, which may impact review and approval timelines as well as delay our ability to continue development of our programs in PBC or AIH;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

In addition, federal, local and other governmental authorities, such as those in the United States, have imposed orders restricting travel and gathering of individuals that have the impact of impairing normal business operations. Such orders may also impact personnel at third-party manufacturing facilities, or the availability or cost of materials, which would disrupt our supply chain; however, we do not currently anticipate any interruptions in our supply of Nefecon for our ongoing and planned clinical trials.

To date, we do not anticipate that the COVID-19 pandemic will significantly impact the ongoing clinical activities related to NefIgArd, our Phase 3 pivotal trial in IgAN. We reported positive topline results from Part A of NefIgArd in the fourth quarter of 2020. We fully recruited Part A in December 2019, and because Nefecon is orally-administered by patients at home at home and the trial is conducted globally and designed to require only limited interaction among patients and the healthcare system, the impact of the COVID-19 pandemic to Part A of the trial was limited. We experienced a reduced enrollment rate over the past several months due to the impact of the COVID-19 pandemic, and we did not complete full enrollment until January of 2021. Having successfully completed enrollment, we expect to report data from Part B in early 2023. There are, however, still uncertainties with regard to the continued development of COVID-19 and its implications, such as the potential inability of regulatory authorities to conduct pre-approval inspections of our manufacturing facilities, if required, and we will continue to assess the situation and seek to put in place relevant mitigating measures where necessary.

The spread of COVID-19, which has caused a broad impact globally, may materially affect our financial position. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common shares and ADSs.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, any restrictions on the ability of hospitals and trial sites to conduct trials that are not designed to address the COVID-19 pandemic and the perceived effectiveness of actions taken in the United States and other countries to contain and treat the disease.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

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, including Renée Aguiar-Lucander, Fredrik Johansson, Richard Philipson and Andrew Udell, 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 United States 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-U.S. economies and markets;

- 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-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the Swedish Krona, U.S. dollar and Euro and currency controls;
- changes in a specific country's or region's political or economic environment, including the implications of the United Kingdom's withdrawal from the European Union;
- 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 United Kingdom's withdrawal from the European Union 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 United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, which ended on December 31, 2020, the United Kingdom will no longer be covered by the centralized procedures for obtaining European Union-wide marketing and manufacturing authorizations from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products will be required in the United Kingdom, the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom or the European Union 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 European Union, or we may incur expenses in establishing a manufacturing facility in the European Union in order

to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the European Union 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 United Kingdom. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the European Union.

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 U.S. dollar 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.

Additionally, although we are based primarily in Sweden, we may receive payments from our business partners in U.S. dollars and Euros, and we regularly acquire services, consumables and materials in U.S. 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.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with the COVID-19 pandemic. While we have not to our knowledge experienced any such material system failure or security breach to date, if such an event were to occur and 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 computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach 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.

Failure to comply with health and data protection laws and regulations 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.

We and any potential collaborators may be subject to U.S. federal and state and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state 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, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, 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.

Further, California recently passed the California Consumer Protection Act, or CCPA, which went into effect January 2020 and provides broad rights to CCPA California consumers with respect to the collection and use of their information by businesses. In March 2020, the California State Attorney General proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in adopting regulations, the California State Attorney General will commence enforcement actions against violators beginning July 1, 2020. The CCPA further expands the privacy and process enhancements and commitment of resources in support of compliance with California's regulatory requirements and may lead to similar laws in other U.S. states or at a national level.

Compliance with U.S. and international data protection laws and regulations 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. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. 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 protection 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.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

Because we are conducting clinical trials in the European Union, we are subject to additional privacy restrictions. The collection and use of personal health data in the European Economic Area, or EEA (being the European Union plus Norway, Iceland and Liechtenstein) is governed by the General Data Protection Regulation 2016/679, or GDPR, which became effective May 25, 2018. The GDPR applies to the processing of personal data by any company established in the EEA and to companies established outside the EEA to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for data controllers of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, like the United States (which, while deemed a third country, has the benefit of the Privacy Shield regime for transatlantic data transfers). Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States and Norway, Iceland and Liechtenstein may result in fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. Given the breadth and depth of changes in data protection obligations, maintaining compliance with the GDPR will require significant time, resources and expense, and we may be required to put in place additional controls and processes ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition and results of operations. There has been limited enforcement of the GDPR to date, particularly in biopharmaceutical 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. Further, the United Kingdom's decision to leave the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the European Union.

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 biopharmaceutical 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 U.S. federal and state 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.

Although we do not currently have any products on the market, 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 U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. 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 U.S. 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 U.S. 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 U.S. 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;

- 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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 their 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 U.S. 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 and teaching hospitals, as well as ownership and investment interests held by physicians (as defined by such law) and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value in the previous year made to certain non-physician providers,

including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives;

- 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 U.S. 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.

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, 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, EMA 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 U.S. 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 U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The 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 to government officials or other persons to induce them to improperly perform a relevant function or activity (or reward them for such behavior).

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 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 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 FCPA and these other 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 foreign officials.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of Sweden, Norway and the United States, and authorities in the European Union, 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.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the 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 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 Global Offering and 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 clinical-stage biopharmaceutical companies has been highly volatile and is likely to remain highly volatile in the future. Since the ADSs were sold at our initial U.S. public offering in June 2020 at a price of $19.50 per ADS, the price per ADS has ranged as low as $19.00 and as high as $38.00 through December 28, 2020. During this same period, common share prices have ranged from as low as SEK 40.70 to as high as SEK 144.60. 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, including our ongoing Phase 3 trial of Nefecon;
- positive or negative results from, or delays in, testing and clinical trials by us, strategic partners or competitors;
- 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 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 biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

COVID-19 has spread rapidly around the world since December 2019 and has negatively affected the stock market and investor sentiment. The stock market in general, and The Nasdaq Global Select Market and biotechnology companies 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.

If you purchase ADSs in the U.S. offering, you will suffer immediate dilution of your investment.

You will suffer immediate and substantial dilution in the net tangible book value of the ADSs if you purchase ADSs in the U.S. offering. Based on an assumed offering price of $32.92 per ADS in the U.S. offering, the closing price of our ADSs on the Nasdaq Global Market on January 22, 2021 (equivalent to SEK 136.42 per common share in the European private placement), after giving effect to the U.S. offering, purchasers of ADSs in the U.S. offering will experience immediate dilution in net tangible book value of $24.37 per ADS. In addition, after giving effect to the U.S. offering, investors purchasing ADSs in the global offering will contribute 21.1% of the total amount invested by shareholders since inception but will only own 8.3% of the common shares outstanding. See "Dilution" for a more detailed description of the dilution to new investors in the U.S. offering.

We have broad discretion in the use of the net proceeds from the global offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from the global offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of the ADSs. The failure by our management to apply these funds effectively could result in financial

losses that could have a material adverse effect on our business, cause the price of the ADSs to decline and delay the development of Nefecon and our other product candidates. Pending their use, we may invest the net proceeds from the global offering in a manner that does not produce income or that loses value, including due to negative interest rates in Sweden. These investments may not yield a favorable return to our investors.

We will continue to incur increased costs as a result of operating as a U.S.-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 public company, and particularly after we no longer qualify as an emerging growth 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-U.S. 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 beginning with our second annual report on Form 20-F. However, while we remain an emerging growth company, we will not be 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 a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations.

In connection with our preparation and the audits of our financial statements as of and for the years ended December 31, 2019 and 2018, our independent registered public accounting firm identified a material

weakness 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. The material weakness 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 weakness identified relates 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.

We intend to implement measures designed to remediate this material weakness, including hiring or engaging additional accounting personnel with knowledge and experience in SEC reporting requirements in order to timely and reliably report our financial results in accordance with the requirements of the SEC. However, the implementation of these measures may not fully address these material weaknesses in our internal control over financial reporting in which case we would not be able to conclude that they have been fully remedied. Our failure to correct this material weakness 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.

Neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provision of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified.

We are subject to reporting obligations under U.S. 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 our annual report on Form 20-F beginning with our annual report for the fiscal year ending December 31, 2021. If we fail to remediate the material weakness identified above, our management may conclude that our internal control over financial reporting is not effective. 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. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an emerging growth company.

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, including as a result of remote working policies due to the COVID-19 pandemic, 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 weakness identified relates 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.

We will be required to disclose changes made in our internal controls and procedures on a bi-annual basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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 40.17% of our outstanding common shares (including common shares in the form of ADSs). 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, because many of these shareholders purchased their common shares at prices substantially below the price at which ADSs and common shares are being sold in the global offering 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.

Future sales, or the possibility of future sales, of a substantial number of our securities could adversely affect the price of the common shares or ADSs and dilute shareholders.

If our existing shareholders sell, or indicate intent to sell, substantial amounts of our securities in the public market, the trading price of common shares or ADSs could decline significantly and could decline below the public offering price in the global offering. Upon completion of the global offering, we will have outstanding 54,441,584 common shares (including common shares represented by the ADSs) based on the number of common shares outstanding as of September 30, 2020, 487,000 of which are subject to a 90-day contractual lock-up. The representatives of the underwriters may permit us and the holders of the lock-up shares to sell common shares or ADSs prior to the expiration of the lock-up agreements. See "Underwriting." After the lock-up agreements pertaining to the global offering expire, and based on the number of common shares (including common shares represented by ADSs) outstanding upon completion of the global offering, additional common shares (including common shares represented by the ADSs) will be eligible for sale in the public market, all of which shares are held by directors and certain members of our executive management and certain principal stockholders and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, for sales in the United

States. In addition, common shares subject to outstanding options under our equity incentive plans and the common shares reserved for future issuance under our equity incentive plan will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, we intend to register all common shares that we may issue under our equity compensation plans. Once we register these common shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Shares and ADSs Eligible for Future Sale." We may also issue substantial amount of additional securities in the future, especially pursuant to the share issue authorization granted to our board of directors at our 2020 annual general meeting, under which the board could issue up to 20% new shares with deviation from the shareholders' preferential rights without the involvement or approval of the shareholders.

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, U.S. dollar 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 U.S. dollars and Euro. 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 will trade on The Nasdaq Global Select Market in U.S. dollars, fluctuations in the exchange rate between the U.S. 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.

By participating in the U.S. offering, you will become a holder of ADSs with underlying common shares in a company incorporated under Swedish law. 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 "Description of 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 "Description of 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 prospectus and the deposit agreement, which is filed as an exhibit to the registration statement of which this prospectus forms a part, 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 U.S. 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 United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

The United States 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 U.S. 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 United States or any state in the United States. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. 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 U.S. 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 U.S. 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, U.S. investors may not be able to enforce against us or certain of our directors any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

We qualify as a foreign private issuer and, as a result, we are not subject to U.S. 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 U.S. domestic public company.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. 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 U.S. 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 U.S. 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 will rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are entitled to 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 U.S. companies listed on Nasdaq. For example, we are exempt from Nasdaq regulations that require a listed U.S. company and intend to 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 U.S. 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 U.S. 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 U.S. 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 U.S. domestic issuers. In order to maintain our current status as a foreign private issuer as of each June 30, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50 percent of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we lose foreign private issuer status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. 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 U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. 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 U.S. 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.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make the ADSs less attractive to investors.

We are an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an "emerging growth company," we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to five years following completion of our initial public offering, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common shares held by non-affiliates exceeds $700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our fiscal year-end). We cannot predict if investors will find the ADSs less attractive because we may rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the price of the ADSs may be more volatile.

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 U.S. 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 U.S. 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 United States 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 U.S. federal securities laws and the rules and regulations promulgated thereunder.

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

Under the Internal Revenue Code of 1986, as amended, we will be a "passive foreign investment company" for U.S. federal income tax purposes, or a PFIC, for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly 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 U.S. Holder (as defined below in "Material Income Tax Considerations—Material U.S. federal income tax considerations for U.S. holders") holds our common shares, or ADSs, the U.S. 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.

A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. Our status as a PFIC depends on the value of our assets and the composition of our income and assets. The total value of our assets for purposes of the asset test generally will be calculated using the market price of the common shares or ADSs, which may fluctuate considerably. Fluctuations in the market price of the common shares or ADSs may result in our being a PFIC for any taxable year. In addition, the composition of our assets will also be affected by how, and how quickly, we spend the cash we raise in any offering, including the global offering. Our income for a taxable year will be affected by whether we receive certain milestone payments in such year, and whether certain gains from foreign currency exchanges are treated as qualifying income for purposes of the PFIC income test. Based upon the value of our assets and the composition of our income and assets, we do not believe we were a PFIC for the 2019 taxable year. It is uncertain whether we will be a PFIC for the 2020 taxable year, 2021 taxable year or any subsequent taxable years. Because of the uncertainties involved in determining our PFIC status, we cannot provide any assurances regarding our PFIC status.

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 Organisation for Economic Co-Operation and Development's, Base Erosion and Profit Shifting, Project, the European Commission'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. 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 U.S. 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 U.S. 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 U.S. 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 "Material Swedish Income Tax Consequences" 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 U.S. 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 U.S. 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 U.S. company under applicable U.S. laws. For additional information on these and other aspects of Swedish corporate law and our articles of association, see "Description of Share Capital." As a result of these differences between Swedish corporate law and our articles of association, on the one hand, and U.S. 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 U.S. 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. At the extraordinary general meeting held on March 3, 2020, our shareholders agreed to waive their pre-emptive subscription rights with respect to the proposed authorization to our board of directors to effect the capital increase necessary to effectuate the global offering. Such shares may be issued at or above market value or below market value in the case of rights issues or pursuant to a resolution of the shareholders. The absence 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 U.S. 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 U.S. 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. See "Description of Share Capital—Differences Between Delaware Law and Swedish Corporate Law."

Our articles of association designate specific courts in the United States as the exclusive forum for certain U.S. 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 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. 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 U.S. 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 United States 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 U.S.-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 (U.S. 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 United States 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 United States.

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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains express or implied forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue," "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. 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 prospectus are based upon information available to our management as of the date of this prospectus 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 prospectus include, but are not limited to, statements about:

- the timing, progress and results of our ongoing Phase 3 clinical trial for Nefecon and development plans for sentanaxib or any other future product candidates;
- the potential attributes and benefits of Nefecon, sentanaxib and other product candidates and their competitive position with respect to alternative treatments;
- the timing, scope or likelihood of domestic and foreign regulatory filings and approvals;
- the potential benefit of orphan drug designation, the FDA's accelerated approval pathway, the EMA's conditional approval pathway, the FDA's Section 505(b)(2) pathway and the EMA's hybrid application pathway for Nefecon or any other future product candidates;
- our ability and plans to use proteinuria as the primary endpoint for our Phase 3 clinical trial for Nefecon to support approval by the FDA, EMA or comparable foreign regulatory authorities;
- our ability to successfully identify and develop other potential product candidates;
- the impact of the COVID-19 pandemic to our business and clinical trials as well as supply of our product candidates;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our manufacturing, commercialization and marketing capabilities and strategy;
- the rate and degree of market acceptance and clinical utility of Nefecon, sentanaxib and any future product candidates;
- the timing of our submission of marketing applications to the FDA and EMA for Nefecon;
- the anticipated benefits of our acquisition of Genkyotex S.A., or Genkyotex;
- our ability to integrate Genkyotex's operations, pipeline of product candidates and personnel with our business;
- 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 if Nefecon or other future product candidates are approved;
- 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, including estimates of the size and growth potential of the markets for our product candidates;

- our plans to enter into collaborations for commercialization of Nefecon, sentanaxib 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;
- our exposure to additional scrutiny as a U.S. public company;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our use of proceeds from the global offering; and
- the impact of laws and regulations.

You should refer to the section titled "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 prospectus 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 prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part 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.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we believe our internal company research as to such matters is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Special Note Regarding Forward-Looking Statements."

USE OF PROCEEDS

We estimate that the net proceeds to us in the global offering will be $68.5 million (SEK 567.7 million), based on an assumed offering price of $32.92 per ADS in the U.S. offering, the closing price of our ADSs on the Nasdaq Global Select Market on January 22, 2021 (equivalent to SEK 136.42 per common share in the European private placement), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase 675,000 additional ADSs from us in full, we estimate that the net proceeds to us from the global offering will be $78.9 million (SEK 654.3 million), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 (SEK 8.29) increase (decrease) in the assumed offering price of $32.92 per ADS in the U.S. offering (SEK 136.42 per common share in the European private placement) would increase (decrease) our net proceeds from the offering by $2.1 million (SEK 17.5 million), assuming the number of common shares (including common shares in the form of ADSs), as set forth on the cover page of this prospectus, remains the same and after deducting underwriting commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 common shares (including common shares in the form of ADSs) offered by us would increase (decrease) the net proceeds to us by approximately $15.5 million (SEK 128.2 million), assuming that the assumed offering price per ADS and common share remains the same and after deducting underwriting commissions and estimated offering expenses payable by us. The actual net proceeds payable to us will adjust based on the actual number of common shares (including common shares in the form of ADSs) offered by us, the actual offering price and other terms of the offering determined at pricing.

As of September 30, 2020, we had cash of $168.5 million (SEK 1,396.9 million). We currently expect to use the net proceeds from the global offering, together with our existing cash, as follows:

- $45 to $50 million to fund our ongoing Phase 3 clinical trial and related trials of Nefecon and to file for regulatory approval in the United States and the European Union;
- $55 to $60 million to fund the development of additional product candidates in indications for which Nefecon or its active ingredient and/or setanaxib and may have therapeutic potential, including PBC and AIH, or for any product candidates that we in-license or acquire; and
- the remainder to fund pre-commercial and, if approved, commercial activities for Nefecon for the treatment of IgAN, or for any product candidates that we in-license or acquire, and for working capital and other general corporate purposes.

This expected use of net proceeds from the global offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the consummation of the global offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates and commercialize approved products can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, our plans to develop our in-house product manufacturing capabilities, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from the global offering. See “Risk Factors—Risks Related to the Global Offering and Ownership of our Securities—We have broad discretion over the use of the net proceeds from the global offering and may not use them effectively.”

Based on our planned use of the net proceeds from the global offering and our existing cash, we estimate that such funds will be sufficient to fund our operations and capital expenditure requirements until we are cash flow positive, which is expected in the first half of 2023, subject to Nefecon being approved by regulatory authorities for marketing and sale and successfully commercialized. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. There can be no assurance that Nefecon will be approved by regulatory authorities, or that we will be successful in marketing Nefecon, if approved. See “Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—Even if the global offering is successful, we will 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."

Pending our use of proceeds from the global offering, we plan to invest these net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations and investment-grade instruments.

CAPITALIZATION

The following table sets forth our cash and capitalization as of September 30, 2020 on:

- an actual basis; and
- an as adjusted basis to give effect to the issuance of common shares (including common shares in the form of ADSs), in the global offering at an assumed offering price of $32.92 per ADS in the U.S. offering, (SEK 136.42 per common share in the European private placement), after deducting underwriting commissions and discounts and estimated offering expenses payable by us.

You should read this information together with our audited consolidated financial statements as of and for the year ended December 31, 2019 and related notes and our unaudited condensed consolidated financial statements for the nine months ended September 30, 2020 and related notes appearing elsewhere in this prospectus and the information set forth under the sections titled "Selected Consolidated Financial Data," "Use of Proceeds" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of September 30, 2020			
	Actual		As Adjusted	
	$	SEK	$	SEK[1]
	(in thousands)			
Cash	168,545	1,396,869	237,048	1,964,604
Shareholders' equity				
Share capital	241	1,998	263	2,178
Additional paid-in capital	256,524	2,126,016	325,004	2,693,571
Reserves	—	—	—	—
Retained earnings including net loss for the year	(90,642)	(751,159)	(90,642)	(751,226)
Total equity attributable to shareholders	166,122	1,376,788	234,625	1,944,523
Total capitalization	166,480	1,379,753	234,983	1,947,488

(1) Each $1.00 (SEK 8.29) increase or decrease in the assumed offering price of $32.92 per ADS in the U.S. offering (SEK 136.42 per common share in the European private placement), would increase (decrease) the amount of cash, total equity and total capitalization after the global offering by $2.1 million (SEK 17.5 million), assuming the number of common shares (including common shares in the form of ADSs) offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting commissions and estimated offering expenses payable by us. Each increase (decrease) of 1,000,000 common shares (including common shares in the form of ADSs) offered by us would increase (decrease) the amount of cash, total equity and total capitalization after the global offering by $15.5 million (SEK 128.2 million), assuming no change in the assumed offering price per ADS or common share. The as adjusted information is illustrative only, and we will adjust this information based on the actual offering price and other terms of the global offering determined at pricing.

The foregoing tables and calculations are based on the number of common shares outstanding as of September 30, 2020, and exclude:

- 1,279,086 common shares issuable upon the exercise of warrants to purchase common shares outstanding as of September 30, 2020 issued under our two warrants programs, with a weighted-average exercise price of SEK 74.37 per share;
- 51,399 common shares issuable upon the exercise of options to purchase common shares outstanding as of September 30, 2020 under the LTIP 2019;
- 31,371 common shares issuable upon the exercise of options to purchase common shares outstanding as of September 30, 2020 under the LTIP 2020; and
- an additional 1,089,000 common shares that have been issued and 411,000 common shares that are reserved for future issuance, under the ESOP 2020.

DILUTION

If you invest in the common shares or ADSs in the global offering, your interest will be immediately diluted to the extent of the difference between the offering price per common share or ADS paid by you and the as adjusted net tangible book value per common share after the global offering. Dilution results from the fact that the offering price per common shares is substantially in excess of the net tangible book value per common share. As of September 30, 2020, we had a historical net tangible book value per common share of $3.29, or SEK 27.25 per common share (equivalent to $6.58 per ADS). Our net tangible book value per share represents total consolidated tangible assets less total consolidated liabilities, all divided by the number of shares outstanding as of September 30, 2020.

After giving effect to the sale of 4,500,000 shares (including common shares in the form of ADSs) in the global offering at an assumed offering price of $32.92 per ADS in the U.S. offering, and (equivalent to SEK 136.42 per common share in the European private placement), and after deducting estimated underwriting commissions and discounts and estimated offering expenses payable by us, our pro forma net tangible book value at September 30, 2020 would have been $4.27 per common share (equivalent to $8.55 per ADS). This represents an immediate increase in pro forma net tangible book value of $0.99 per common share ($1.97 per ADS) to existing shareholders and an immediate dilution of SEK 100.99 per common share ($24.37 per ADS) to new investors. The following table illustrates this dilution per common share:

Public offering price per ADS	$32.92
Historical net tangible book value per ADS as of September 30, 2020	$ 6.58
Increase in pro forma net tangible book value per ADS attributable to new investors	$ 1.97
Pro forma net tangible book value per ADS after the global offering	$ 8.55
Dilution per ADS to new investors participating in the global offering	$24.37

Each $1.00 (SEK 8.29) increase or decrease in the assumed offering price of $32.92 per ADS in the U.S. offering (SEK 136.42 per common share in the European private placement), would increase (decrease) our pro forma net tangible book value after the global offering by SEK 0.32 per common share, or $0.08 per ADS, and would increase (decrease) dilution to investors in the global offering by SEK 0.32 per common share or $0.08 per ADS assuming that the number of common shares (including common shares in the form of ADSs) offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting commissions and discounts and estimated offering expenses payable by us.

We may also increase or decrease the number of common shares (including common shares in the form of ADSs) we are offering. An increase of 1,000,000 in the number of common shares (including common shares in the form of ADSs) we are offering would increase our pro forma net tangible book value after the global offering by SEK 1.67 per common share or $0.40 per ADS, and would decrease dilution to investors in the global offering by SEK 1.67 per common share or $0.40 per ADS, assuming the assumed offering price per common share remains the same, after deducting estimated underwriting commissions and discounts and estimated offering expenses payable by us. A decrease of 1,000,000 in the number of common shares (including common shares in the form of ADSs) we are offering would decrease our pro forma net tangible book value after the global offering by SEK 1.74 per common share or $0.42 per ADS, and would increase dilution to investors in the global offering by approximately SEK 1.74 per common share or $0.42 per ADS, assuming the assumed offering price per ADS or common share remains the same, after deducting estimated underwriting commissions and discounts and estimated offering expenses payable by us.

The pro forma information is illustrative only, and we will adjust this information based on the actual offering price and other terms of the global offering determined at pricing. If the underwriters fully exercise their option to purchase additional common shares (including common shares in the form of ADSs from us), pro forma net tangible book value after the global offering would increase to SEK 36.56 per common share or $8.82 per ADS, and there would be an immediate dilution of SEK 99.86 per common share or $24.10 per ADS to new investors.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise

additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our equity holders. The following table shows, as of September 30, 2020 on a pro forma basis, the number of common shares purchased from us, the total consideration paid to us and the average price paid per share by existing shareholders and by new investors purchasing common shares (including common shares in the form of ADSs) in the global offering at an assumed offering price of $32.92 per ADS in the U.S. offering, and SEK 136.42 per common share in the European private placement, before deducting estimated underwriting commissions and discounts and estimated offering expenses payable by us (in thousands, except share and per share amounts and percentages):

	Shares or ADSs[1] Purchased		Total Consideration (in thousands)		Average Price per Share	Average Price per ADS
	Number	Percent	Amount	Percent		
Existing shareholders	49,941,584	91.7%	$276,418,470	78.9%	$ 5.53	$11.07
New investors	4,500,000	8.3%	$ 74,070,000	21.1%	$16.46	$32.92
Total	54,441,584	100%	$350,488,470	100%	$ 6.44	$12.88

(1) Includes shares in the form of ADSs. Each ADS represents two common shares.

If the underwriters exercise their option to purchase additional common shares (which may be in the form of ADSs) in full, the number of common shares held by the existing shareholders after the global offering would be reduced to 90.6% of the total number of common shares (including common shares in the form of ADSs) outstanding after the global offering, and the number of common shares (including common shares in the form of ADSs) held by new investors participating in the global offering would increase to 9.4% of the total number of common shares (including common shares in the form of ADSs) outstanding after the global offering.

The foregoing tables and calculations are based on the number of common shares outstanding as of September 30, 2020, and exclude:

- 1,279,086 common shares issuable upon the exercise of warrants to purchase common shares outstanding as of September 30, 2020 issued under our two warrants programs, with a weighted-average exercise price of SEK 74.37 per share;
- 51,399 common shares issuable upon the exercise of options to purchase common shares outstanding as of September 30, 2020 under the LTIP 2019;
- 31,371 common shares issuable upon the exercise of options to purchase common shares outstanding as of September 30, 2020 under the LTIP 2020; and
- an additional 1,089,000 common shares that have been issued and 411,000 common shares that are reserved for future issuance, under the ESOP 2020

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables present the selected consolidated financial data as of the dates and for the periods indicated for our business. We have derived the following selected consolidated statement of income for the years ended December 31, 2019 and 2018 and the consolidated statement of financial position as of December 31, 2019 and 2018 from our audited consolidated financial statements for the years ended December 31, 2019 and 2018 appearing elsewhere in this prospectus. The consolidated statements of income data for the nine months ended September 30, 2020 and 2019 and the consolidated statement of financial position data as of September 30, 2020 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited consolidated financial statements. Historical results are not necessarily indicative of the results that should be expected for any future period and the results for the nine months ended September 30, 2020 or any other interim period are not necessarily indicative of results to be expected for the full year ending December 31, 2020 or any other period. The selected consolidated financial data set forth below should be read together with our audited consolidated financial statements for the years ended December 31, 2019 and 2018 and the related notes to those statements, our unaudited interim condensed consolidated financial statements for the nine months ended September 30, 2020 and 2019 and the related notes to those statements as well as the section of this prospectus captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations." We prepare our financial statements in accordance with IFRS as issued by the IASB.

	Years Ended December 31,		Nine Months Ended September 30,	
	2019	2018	2020	2019
	(SEK in thousands, except per share amounts)			
Consolidated Statement of Income Data:				
Net sales	184,829	—	474	138,243
Operating expenses				
Research and development	(149,826)	(99,260)	(167,379)	(108,117)
Administrative and selling	(62,882)	(31,132)	(77,843)	(39,092)
Other operating income	4,385	—	969	3,515
Other operating expenses	(4,525)	(2,090)	—	(4,525)
Operating loss	(28,019)	(132,482)	(243,779)	(9,976)
Financial income	926	441	504	2,158
Financial expenses	(5,408)	(8)	(19,603)	(1,710)
Loss before income tax	(32,501)	(132,049)	(262,878)	(9,528)
Income tax expense	(77)	—	(185)	—
Loss for the period attributable to shareholders	(32,578)	(132,049)	(263,063)	(9,528)
Loss per share before and after dilution	(0.88)	(5.09)	(6.09)	(0.26)

	As of December 31,		As of September 30,
	2019	2018	2020
	(SEK in thousands)		
Consolidated Statement of Financial Position Data:			
Cash	753,540	646,175	1,396,869
Working capital[(1)]	767,762	617,727	1,357,343
Total assets	845,200	648,417	1,440,183
Total liabilities	57,129	30,242	63,395
Total equity	788,071	618,175	1,376,788

(1) We define working capital as current assets less current liabilities.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On November 3, 2020, Calliditas Therapeutics AB ("we", "us", or "our") acquired 62.7% of the share capital in Genkyotex S.A., or Genkyotex, a biopharmaceutical company specializing in nicotinamide adenine dinucleotide phosphate oxidase, or NOX, therapies with offices in France and Switzerland, or the Initial Acquisition. On November 26, 2020, we submitted a simplified public mandatory cash offer, or the Tender Offer, to the remaining shareholders in Genkyotex. The Tender Offer closed on December 11, 2020. As a result of the Tender Offer, we increased our ownership percentage to 86.2% of the share capital of Genkyotex. Collectively, the transactions above are referred to as the "Acquisition."

The following unaudited pro forma condensed combined financial information was prepared using the acquisition method of accounting under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and adopted by us and gives effect to the Acquisition. The transaction will be accounted for as an acquisition, and we will be deemed the acquiring company for accounting purposes as we own a controlling interest of the share capital and voting rights.

The following unaudited pro forma condensed combined financial statements are based on our historical financial statements and Genkyotex's historical financial statements as adjusted to give effect to our acquisition of Genkyotex. The unaudited pro forma condensed combined statement of operations gives effect to the acquisition of Genkyotex as if it had occurred on January 1, 2019, which is the earliest year for which pro forma condensed combined financial statements are required to be presented. The unaudited pro forma condensed combined statement of financial position gives effect to the acquisition of Genkyotex as if it had occurred on September 30, 2020. This information should be read in conjunction with our and Genkyotex's respective audited and unaudited financial statements and related notes included in in this filing.

Genkyotex's assets and liabilities will be measured and recognized at their fair values as of the acquisition date, and combined our assets, liabilities and results of operations after the consummation of the Acquisition.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. The application of the acquisition method of accounting is dependent upon certain valuations and other studies that have yet to be completed. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed, and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. There can be no assurances that the final valuations will not result in material changes to the preliminary estimated purchase price allocation. The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, any anticipated synergies, operating efficiencies or cost savings that may result from the Acquisition or any integration costs. Additionally, the unaudited pro forma condensed combined statement of operations does not include certain nonrecurring charges resulting directly from the Acquisition as described in the accompanying notes.

The unaudited pro forma condensed combined financial information is preliminary and has been prepared for illustrative purposes only and is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had we and Genkyotex been a combined company during the specified periods. The actual results reported in periods following the transaction may differ significantly from those reflected in this unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences between the assumptions used to prepare this unaudited pro forma condensed combined financial information.

The assumptions and estimates underlying the unaudited adjustments to the pro forma condensed combined financial statements are described in the accompanying notes, which should be read together with the unaudited pro forma condensed combined financial statements.

The unaudited pro forma condensed combined financial statements should be read together with our historical financial statements, which are included herein.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF FINANCIAL POSITION

AS OF SEPTEMBER 30, 2020

(in thousands)

	CALLIDITAS THERAPEUTICS AB (Historical)	GENKYOTEX S.A. (Historical)		Pro Forma Adjustments	Note 4	Pro Forma Combined
	(in SEK)	(in EUR)	(in SEK)	(in SEK)		(in SEK)
ASSETS						
Non-current assets						
Intangible assets	16,066	2,801	29,393	386,927	(a)	432,386
Goodwill	—	—	—	47,595	(a)	47,595
Equipment	89	10	105	—		194
Right-of-use assets	4,144	208	2,183	—		6,327
Non-current financial assets	2,111	36	378	—		2,489
Total non-current assets	22,410	3,055	32,059	434,522		488,991
Current assets						
Other current assets	4,106	668	7,010	—		11,116
Prepaid expenses	16,798	179	1,878	—		18,676
Cash and cash equivalents	1,396,869	3,590	37,674	(287,568)	(a)	1,146,975
Total current assets	1,417,773	4,437	46,562	(287,568)		1,767,767
TOTAL ASSETS	1,440,183	7,492	78,621	146,954		1,665,758
SHAREHOLDERS' EQUITY AND LIABILITIES						
Share capital	1,998	11,549	121,196	(121,196)	(a)	1,998
Additional paid-in capital	2,126,016	4,747	49,815	(44,576)	(a)	2,131,255
Reserves	(66)	(2,752)	(28,880)	28,880	(a)	(66)
Accumulated other comprehensive loss	—	(647)	(6,790)	6,790	(a)	—
Retained earnings, including net loss for the period	(751,160)	(8,350)	(87,625)	69,248	(a), (e)	(769,537)
Noncontrolling interest	—	—	—	51,171	(a)	51,171
Total equity attributable to shareholders of the Parent Company	1,376,788	4,547	47,716	(9,683)		1,414,821
Non-current liabilities						
Employee benefit obligations	—	960	10,074	—		10,074
Acquisition liability	—	—	—	51,200	(a)	51,200
Deferred tax liability	—	—	—	87,060	(a)	87,060
Provisions	1,931	—	—	—		1,931
Other non-current liabilities	1,034	63	661	—		1,695
Total non-current liabilities	2,965	1,023	10,735	138,260		151,960
Current liabilities						
Accounts payable	19,872	656	6,884	—		26,756
Current tax liabilities	15	258	2,708	—		2,723
Current financial liabilities	—	146	1,532	—		1,532
Other current liabilities	3,907	54	567	—		4,474
Accrued expenses and deferred revenue	36,636	808	8,479	18,377	(e)	63,492
Total current liabilities	60,430	1,922	20,170	18,377		98,977
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES	1,440,183	7,492	78,621	146,954		1,665,758

The accompanying notes are an integral part of these unaudited pro forma condensed combined financial statements.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

NINE MONTHS ENDED SEPTEMBER 30, 2020
(in thousands, except share and per share amounts)

	CALLIDITAS THERAPEUTICS AB (Historical)	GENKYOTEX S.A. (Historical)		Pro Forma Adjustments	Note 4	Pro Forma Combined
	(in SEK)	(in EUR)	(in SEK)	(in SEK)		(in SEK)
Net sales	474	—	—	—		474
Operating expenses:						
Research and development	(167,379)	(9,271)	(97,978)	65,124	(b)	(200,233)
Administrative and selling	(77,843)	(1,757)	(18,568)	4,162	(c), (d)	(92,249)
Other operating income	969	35	370	—		1,339
Operating loss	(243,779)	(10,993)	(116,176)	69,286		(290,669)
Financial income	504	12	127	—		631
Financial expenses	(19,603)	(101)	(1,067)	—		(20,670)
Change in fair value of derivative instruments	—	64	676	—		676
Loss before income tax	(262,878)	(11,018)	(116,440)	69,286		(310,032)
Income tax expense	(185)	—	—	—	(f)	(185)
Loss for the year attributable to shareholders of the Parent Company and noncontrolling interest	(263,063)	(11,018)	(116,440)	69,286		(310,217)
Whereof:						
Loss for the year attributable to noncontrolling interest	—	—	—	(6,660)	(g)	(6,660)
Loss for the year attributable to shareholders of the Parent Company	(263,063)	(11,018)	(116,440)	75,946		(303,557)
Loss per share before and after dilution attributable to Parent Company	(6.09)					(7.03)
Weighted average shares outstanding	43,165,505					43,165,505

The accompanying notes are an integral part of these unaudited pro forma condensed combined financial statements.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS

YEAR ENDED DECEMBER 31, 2019
(in thousands, except share and per share amounts)

	CALLIDITAS THERAPEUTICS AB (Historical)	GENKYOTEX S.A. (Historical)		Pro Forma Adjustments	Note 4	Pro Forma Combined
	(in SEK)	(in EUR)	(in SEK)	(in SEK)		(in SEK)
Net sales	184,829	—	—	—		184,829
Operating expenses:						
Research and development	(149,826)	(5,406)	(57,248)	4,276	(b)	(202,798)
Administrative and selling	(62,882)	(2,160)	(22,874)	64	(c)	(85,692)
Other operating income	4,385	142	1,504	—		5,889
Other operating expenses	(4,525)	—	—	—		(4,525)
Operating loss	(28,019)	(7,424)	(78,618)	4,340		(102,297)
Financial income	926	348	3,685	—		4,611
Financial expenses	(5,408)	(190)	(2,012)	—		(7,420)
Change in fair value of derivative instruments	—	64	678	—		678
Loss before income tax	(32,501)	(7,202)	(76,267)	4,340		(104,428)
Income tax expense	(77)	—	—	—	(f)	(77)
Loss for the year attributable to shareholders of the Parent Company and noncontrolling interests	(32,578)	(7,202)	(76,267)	4,340		(104,505)
Whereof:						
Loss for the year attributable to noncontrolling interest	—	—	—	(9,926)	(g)	(9,926)
Loss for the year attributable to shareholders of the Parent Company	(32,578)	(7,202)	(76,267)	14,266		(94,579)
Loss per share before and after dilution attributable to Parent Company	(0.88)					(2.56)
Weighted average shares outstanding	36,940,587					36,940,587

The accompanying notes are an integral part of these unaudited pro forma condensed combined financial statements.

Notes to the Unaudited Pro Forma Condensed Combined Financial Information

Note 1—Description of Transaction and Basis of Presentation

The unaudited pro forma condensed combined financial information was prepared in accordance with IFRS as issued by IASB and pursuant to the rules and regulations of SEC Regulation S-X, and present the pro forma financial position and results of operations of the combined companies based upon Genkyotex's and our historical data.

Description of Transaction

On November 3, 2020 and pursuant to the Initial Acquisition, we acquired 62.7% of the share capital in Genkyotex, a biopharmaceutical company specializing in NOX therapies with offices in France and Switzerland. The transaction comprised of the acquisition of 7,236,515 shares of Genkyotex's outstanding shares at EUR 2.73 per share, or an initial purchase price of EUR of 19.7 million (SEK 207.3 million, converted at the September 30, 2020 exchange rate of 10.494052). On November 26, 2020, we submitted a simplified public mandatory cash offer to the remaining shareholders in Genkyotex. The Tender Offer closed on December 11, 2020 and as a result, we purchased an additional 2,885,161 shares at EUR 2.80 per share (SEK 84.8 million converted at the September 30, 2020 exchange rate) and increased our ownership percentage to 86.2%.

In addition to the fixed purchase price above, the transaction stipulates the following contingent consideration if certain milestones are achieved:

1) 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.

2) 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.

3) 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.

Basis of Presentation

Genkyotex's and our historical financial statements have been adjusted to give pro forma effect to events that are (i) directly attributable to the acquisition, (ii) factually supportable, and (iii) with respect to the unaudited pro forma condensed combined consolidated statement of operations, expected to have a continuing impact on the combined results.

We have preliminarily concluded that the transaction represents a business combination pursuant to IFRS 3, *Business Combinations*. We have not yet finalized an external valuation analysis of the fair market value of Genkyotex's assets acquired and liabilities assumed. Using the estimated total consideration for the transaction, we have estimated the allocations to such assets and liabilities. This preliminary purchase price allocation has been used to prepare pro forma adjustments in the unaudited pro forma condensed combined statement of financial position. The final purchase price allocation will be determined when we have determined the final consideration and completed the detailed valuations and necessary calculations. The final purchase price allocation could differ materially from the preliminary purchase price allocation used to prepare the pro forma adjustments. The final purchase price allocation may include (i) changes in allocations to intangible assets or goodwill based on the results of certain valuations that have yet to be finalized, (ii) changes in the fair value of contingent consideration, and (ii) other changes to assets and liabilities.

Under the acquisition method, acquisition-related transaction costs (e.g., advisory, legal, valuation and other professional fees) are not included as consideration transferred but are accounted for as expenses in the periods in which the costs are incurred. These costs are not presented in the unaudited pro forma condensed combined statement of operations because they will not have a continuing impact on the combined results.

This unaudited pro forma condensed combined financial information is not intended to reflect the results which would have actually resulted had the acquisition been effected on the dates indicated. Further,

the pro forma results of operations are not necessarily indicative of the results of operations that may be obtained in the future.

Note 2—Foreign currency adjustments

The historical financial information of Genkyotex was translated from EUR to SEK using the following historical exchange rates:

	Exchange Rate
Period end exchange rate as of September 30, 2020 (statement of financial position)	10.494052
Average exchange rate for the nine months ended September 30, 2020 (statement of operations)	10.568175
Average exchange rate for the year ended December 31, 2019 (statement of operations)	10.589781

Note 3—Preliminary purchase price allocation

Under the acquisition method of accounting, the total purchase price is allocated to the acquired tangible and intangible assets and assumed liabilities of Genkyotex based on their estimated fair values as of the Initial Acquisition date, the date we obtained control over Genkyotex. The excess of the acquisition consideration paid and the fair value of noncontrolling interest in Genkyotex over the estimated fair values of net assets acquired will be recorded as goodwill in the combined statement of financial position. The allocation is dependent upon certain valuation and other studies that have not yet been finalized. Accordingly, the pro forma purchase price allocation is subject to further adjustment as additional information becomes available and as additional analyses and final valuations are completed, and such differences could be material.

The Initial Acquisition closed on November 3, 2020, with the completion of the Tender Offer on December 11, 2020. The acquisition of an additional interest of 23.5% in Genkyotex is a transaction with non-controlling interests that does not result in a loss of control. Transactions with equity owners are accounted for as an adjustment between the carrying amounts of the controlling and non-controlling interests to reflect their relative interests in the subsidiary. Any difference between the amount of the adjustment to non-controlling interests and any consideration paid or received is recognized within equity attributable to owners of the parent company.

The following table sets forth a preliminary pro forma allocation of the purchase price to the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed of Genkyotex using Genkyotex's consolidated statement of financial position as of September 30, 2020, with the excess recorded to goodwill:

(in thousands)	EUR	SEK
Cash and cash equivalents	3,590	37,674
Other current assets	668	7,010
Prepaid expenses	179	1,878
Equipment	10	105
Right of use assets	208	2,183
Other non-current assets	36	378
Intangible assets	2,801	29,393
Acquired identifiable intangible assets (see Note 4)	36,871	386,927
Noncontrolling interest (see Note 4)	(13,022)	(136,658)
Accounts payable	(656)	(6,884)
Accrued expenses	(808)	(8,479)
Current tax liabilities	(258)	(2,708)
Current financial liabilities	(146)	(1,532)

(in thousands)	EUR	SEK
Other current liabilities	(54)	(567)
Deferred tax liabilities	(8,296)	(87,060)
Employee benefit obligations	(960)	(10,074)
Other non-current liabilities	(63)	(661)
Net assets acquired (a)	20,100	210,925
Estimated consideration transferred (b)	24,635	258,520
Estimated goodwill (b) - (a)	4,535	47,595

We also recorded a liability, or Acquisition Liability, representing the fair value of contingent consideration that we may owe to shareholders of Genkyotex if the milestones outlined in Note 1 are achieved within ten years of the tender offer closing (i.e., December 11, 2030). The total Acquisition Liability is EUR 55 million (SEK 577 million). We have determined that the probability of achieving Milestones 1 to 3 is 15.21%. Based on this probability assessment along with a 10% discount rate utilized to determine the present value, we determined the fair value of the contingent consideration to be EUR 4.9 million (SEK 51.2 million) as of the acquisition date. We will remeasure the Acquisition Liability at fair value each reporting period based on updated facts and circumstances surrounding the probability of the milestones to be achieved.

Goodwill represents the excess of consideration transferred and the fair value of noncontrolling interest in Genkyotex over the fair value of the underlying net assets acquired. Goodwill is not amortized but assessed for impairment annually, or more frequently, if an event occurs or circumstances change. Goodwill is attributable to the assembled workforce of Genkyotex and synergies expected to be achieved from combining our operations with Genkyotex.

The deferred tax liabilities represent the deferred tax impact associated with the differences in book and tax basis, including incremental differences created from the preliminary purchase price allocation and acquired net operating losses. Deferred taxes associated with estimated fair value adjustments reflect an estimated Swiss long-term corporate tax rate. The effective tax rate of the combined company could be significantly different (either higher or lower) depending on post-merger activities, including cash needs, the geographical mix of income, and changes in tax law.

Note 4—Pro forma adjustments

The pro forma adjustments are based on our preliminary estimates and assumptions that are subject to change. The following adjustments have been reflected in the unaudited pro forma condensed combined financial information:

(a) Represents the elimination of the historical equity of Genkyotex and the initial allocation of excess purchase price to goodwill:

(in thousands)	EUR	SEK
Total consideration transferred	24,635	258,520[(i)]
Fair value of noncontrolling interest	13,022	136,658[(ii)]
Less:		
Share capital	11,549	121,196
Additional paid-in capital	4,747	49,815
Accumulated other comprehensive income	(647)	(6,790)
Reserves	(2,752)	(28,880)
Retained earnings, including net loss for the period	(8,350)	(87,625)
Acquired identifiable intangible assets	36,871	386,927
Deferred tax liability	(8,296)	(87,060)
Goodwill–related to the Acquisition	4,535	47,595

(i) Consideration of SEK 258,520 represents the acquisition of 7.2 million shares at a negotiated share price of EUR 2.73 per share plus the fair value contingent consideration of EUR 4.9 million, converted to SEK at an exchange rate of 10.494052.

(ii) Fair value of noncontrolling interest was determined as follows:

Noncontrolling interest in connection with Initial Acquisition

(in thousands, except shares and per share amounts)	
Remaining outstanding shares	4,312,047
Price per share (EUR)	3.02
Total fair value of noncontrolling interest (EUR)	13,022
Total fair value of noncontrolling interest (SEK)	136,658

Additionally, Genkyotex issued 187,612 shares in connection with the exercise of warrants between November 3, 2020 and December 11, 2020, the proceeds of which were allocated to the noncontrolling interest.

(in thousands, except shares and per share amounts)	
Shares exercised	187,612
Exercise price per share (EUR)	2.30
Total cash proceeds (EUR)	432
Total cash proceeds (SEK)	4,528

In connection with the Tender Offer, we retained our controlling financial interest in Genkyotex. As such, the transaction is accounted for as an equity transaction.

Noncontrolling interest in connection with Tender Offer

(in thousands, except shares and per share amounts)	
Shares tendered	2,885,161
Price per share (EUR)	2.80
Total cash paid for Tender Offer (EUR)	8,078
Total cash paid for Tender Offer (SEK)	84,776[(i)]
Fair value of noncontrolling interest from Initial Acquisition (SEK)	136,658
Noncontrolling interest in connection with exercise of warrants (SEK)	4,528
Noncontrolling interest before Tender Offer (SEK)	141,186
Less: adjustment to carrying value of noncontrolling interest in connection with Tender Offer	(90,015)[(i)]
Carrying value of noncontrolling interest subsequent to Tender Offer (SEK)	51,171

(i) Adjustment to carrying value was calculated in proportion to the percentage we acquired.

(b) Represents the adjustment of intangible assets acquired to their estimated fair values. As part of the preliminary valuation analysis, we identified an intangible asset relating to technology — NOX 1&4 Platform. The fair value of the technology was determined using the multi-period excess earnings method. The principle behind this method is that the value of an intangible asset is equal to the present value of the incremental after-tax cash flows attributable only to the subject intangible asset after deducting contributory asset charges. The incremental after-tax cash flows attributable to the subject intangible asset are then discounted to their present value. The fair value of the existing SIL Vaxiclase Platform was determined to approximate book value at the date of acquisition.

The following table summarizes the estimated fair values of Genkyotex's identifiable intangible assets, their estimated useful lives and amortization expense under the straight-line method:

			Amortization Expenses	
(Amounts in thousands SEK)	Estimated Fair Value	Estimated Useful Life in Years	Nine Months Ended September 30, 2020	Year Ended December 31, 2019
Technology – NOX 1 & 4 Platform	386,927	15	—	—
Technology – SIL Vaxiclase Platform	29,394	17	1,297	1,729
Historical impairment charges			(61,919)	—
Historical amortization expense			(4,502)	(6,005)
Pro forma adjustments to amortization expense			(65,124)	(4,276)

A pro forma adjustment for amortization expense on the technology — NOX 1 & 4 Platform was not recorded on the unaudited pro forma condensed combined statement of operations as we do not expect to launch the platform until 2026. The identifiable intangible assets are preliminary and are based on management's estimates after consideration of similar transactions. As discussed above, the amount that will ultimately be allocated to identifiable intangible assets, may differ materially from this preliminary allocation. In addition, the amortization impacts will ultimately be based upon the periods in which the associated economic benefits or detriments are expected to be derived. Therefore, the amount of amortization following the acquisition may differ significantly between periods based upon the final value assigned and amortization methodology used for each identifiable intangible asset.

(c) Represents the adjustment to recognize depreciation expense related to acquired equipment, calculated on a straight-line basis over their remaining estimated useful life of one year.

	Depreciation Expenses	
(Amounts in thousands SEK)	Nine Months Ended September 30, 2020	Year Ended December 31, 2019
Estimated depreciation expense	—	(105)
Historical depreciation expense	85	169
Pro forma adjustments to depreciation expense	85	64

(d) Represents the exclusion of 4,077 SEK nonrecurring transaction costs incurred during the nine-month period ended September 30, 2020 that are directly related to the acquisition of Genkyotex.

(e) Represents the accrual for estimated transaction costs of 18,377 SEK that are directly related to the acquisition of Genkyotex.

(f) Due to our history of net operating losses in the jurisdictions in which we operate, our expected blended tax rate is estimated to be zero.

(g) Represents the adjustment to recognize the portion of the loss that is attributable to Genkyotex's noncontrolling interest.

	Net loss attributable to noncontrolling interest	
(Amounts in thousands SEK)	Nine Months Ended September 30, 2020	Year Ended December 31, 2019
Net loss for Genkyotex	(116,440)	(76,267)
Pro forma adjustments[1]	68,178	4,340
Adjusted net loss for Genkyotex	(48,262)	(71,927)
Noncontrolling interest percentage[2]	13.8%	13.8%
Net loss attributable to noncontrolling interest	(6,660)	(9,926)

(1) Excludes transaction costs of 1,108 SEK that we incurred during the nine months ended September 30, 2020.

(2) Represents Genkyotex's noncontrolling interest percentage subsequent to the warrant exercise and completion of the Tender Offer.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations in conjunction with the "Selected Consolidated Financial Data" and our audited consolidated financial statements as of and for the years ended December 31, 2019 and 2018 and the related notes thereto and our unaudited interim condensed consolidated financial statements as of and for the nine months ended September 30, 2020 and 2019 and the related notes thereto included elsewhere in this prospectus. In addition to historical information, the following discussion and analysis contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results and the timing of events could differ materially from those anticipated in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in sections titled "Risk Factors" and "Special Note Regarding Forward-Looking Statements." The consolidated financial statements as of and for the years ended December 31, 2019 and 2018 and our unaudited interim condensed consolidated financial statements as of and for the nine months ended September 30, 2020 and 2019 were prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. As permitted by the rules of the Securities and Exchange Commission for foreign private issuers, we do not reconcile our consolidated financial statements to U.S. generally accepted accounting principles.

Overview

We are a clinical-stage biopharmaceutical 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. Our lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. IgAN is a progressive, chronic disease that over time results in deterioration of kidney function in patients, many of whom end up at risk of developing end-stage renal disease, or ESRD, with the need for dialysis or kidney transplant. Nefecon is currently the only pharmaceutical candidate in development for IgAN that is intended to be disease-modifying. Nefecon targets the ileum, the distal region of the small intestine, which is the presumed origin of IgAN due to the ileum being the location of the highest concentration of the Peyer's patches, which are responsible for the production of secretory immunoglobulin A, or IgA, antibodies. Nefecon is the only compound in development for IgAN that has met the primary and key secondary endpoints in a randomized, double-blind, placebo-controlled Phase 3 clinical trial. Nefecon has been granted orphan drug designation for the treatment of IgAN in the United States and the European Union. We also recently acquired Genkyotex S.A., or Genkyotex, providing us with access to a novel platform of nicotinamide adenine dinucleotide phosphate oxidase, or NOX, inhibitors, which we intend to primarily develop for orphan diseases with fibrotic components, with a main focus on kidney and liver diseases.

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 9 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 9 months compared to a 0.17 ml/min/1.73m^2 decline in the treatment arm. In addition, the trial showed that Nefecon was generally well-tolerated On the basis of the positive results of Part A of NeflgArd, we intend to submit a New Drug Application, or NDA, in the first quarter of 2021 for accelerated approval by the FDA followed by a Marketing Authorisation Application, or MAA, for conditional approval by the EMA in the first half of 2021. In January 2021, we completed the enrollment of all 360 patients in NefIgArd, which includes 200 patients previously enrolled in Part A and another 160 patients enrolled in Part B. We intend to report data from Part B in early 2023, subject to any further impact from the COVID-19 pandemic to our business. We also previously conducted a Phase 2b trial with 150 patients, which also met the identical primary and key secondary endpoint.

Although we observed a statistically significant and clinically meaningful reduction of proteinuria, the United States Food and Drug Administration, or the FDA, and the European Medicines Agency, or the EMA, have not provided a specific level of reduction of proteinuria that would be required to obtain marketing approvals. Accordingly, there can be no assurance that the level of reduction of proteinuria that we observed in our Phase 3 clinical trial will be sufficient to satisfy the FDA and EMA. The FDA accelerated approval pathway, and the conditional approval process of the EMA, 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 approved, we expect that Nefecon will be the first treatment on the market indicated for IgAN. We believe that if Nefecon can successfully treat IgAN patients, their kidney function will be preserved. We retain worldwide rights to Nefecon other than in Greater China and Singapore where we have established a strategic collaboration.

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, 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 and the upfront payment from the out-license of Nefecon to Everest Medicines, or Everest. Through September 30, 2020, we had received net proceeds of SEK 2,124.4 million from the issuance of equity securities. In June and July 2020, we completed a new share issuance of 9.2 million shares, in connection with the U.S. IPO and concurrent private placement, for gross proceeds of SEK 891.4 million from U.S. 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 the net proceeds from the global offering, together with our cash as of September 30, 2020, will be sufficient to fund our operations and capital expenditure requirements until we are cash flow positive, which is expected in the first half of 2023, subject to Nefecon being approved by regulatory authorities for marketing and sale and successfully commercialized. 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 regulatory authorities, or that we will be successful in marketing Nefecon, if approved. See “Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—Even if the global offering is successful, we will 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, 2019 and December 31, 2018, we had a net loss of SEK 32.6 million and SEK 132.0 million, respectively. For the nine months ended September 30, 2020 and September 30, 2019, we had a net loss of SEK 263.1 million and SEK 9.5 million, respectively. As of December 31, 2019 and December 31, 2018, we had an accumulated loss of SEK 488.1 million and SEK 455.5 million, respectively. As of September 30, 2020, we had an accumulated loss of SEK 751.2 million. 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 increasing operating losses for the foreseeable future, and we expect our expenses to increase in connection with our ongoing development and planned commercialization activities.

In June 2019, we received an upfront payment from Everest in connection with the execution of the license agreement, as discussed below under “—License Agreement with Everest Medicines.” We do not expect to generate substantial revenue from product sales or otherwise unless and until we successfully complete clinical development of and obtain regulatory approval for Nefecon or our other product candidates. In addition, if we obtain regulatory approval for Nefecon, 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 significant 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.

License Agreement with Everest Medicines

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, and Singapore, which we collectively refer to as the Territories.

Under the terms of the agreement, we received an initial upfront payment of $15.0 million upon signing the agreement, and we are eligible to receive future payments upon the satisfaction of specific clinical, regulatory and commercial milestones of up to an additional $106.0 million, inclusive of option payments for the development of Nefecon in other potential indications. In December 2019, we announced that of the milestone payments described above, a $5.0 million milestone payment from Everest was triggered upon approval of Everest's investigational new drug application, or IND, in China. Everest is also required to pay typical tiered royalties on annual net sales of the Licensed Product, subject to customary reductions. See "Business—License Agreement with Everest Medicines."

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 U.S. 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.

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. We acquired 7,236,515 ordinary shares of Genkyotex from Genkyotex's largest shareholders and management team, or the Block Sellers, representing 62.7% of the share capital and voting rights for EUR 19.7 million in cash at EUR 2.73 per share. On November 26, 2020, we submitted a simplified public mandatory cash offer, or the Tender Offer, to the remaining shareholders in Genkyotex. The Tender Offer closed on December 11, 2020. As a result of the Tender Offer, we increased our ownership percentage to 86.2% of the share capital of Genkyotex.

The Acquisition costs, excluding transaction costs, amounted to EUR 27.8 million. In addition, we may owe shareholders of Genkyotex consideration of up to EUR 55 million, based on all shares of Genkyotex outstanding, contingent upon the achievement of certain milestones related to regulatory approvals of setanaxib in the U.S. and Europe. See "Description of Transaction" in Note 1 to the unaudited pro forma condensed combined financial information for more information.

Components of our Results of Operations

Revenue

From inception through September 30, 2020, we have not generated revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. In 2019, we recognized revenue in connection with the execution of the license agreement with Everest and additionally upon triggering a payment to us resulting from the satisfaction of a regulatory milestone under such agreement, and we are eligible to receive future payments upon the satisfaction of specific clinical, regulatory and commercial milestones, as well as typical tiered royalties. We refer to revenue received from our license agreement with

Everest as "net sales" in our consolidated financial statements. If our development efforts for Nefecon 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, we may generate revenue in the future from a combination of product sales or payments such collaboration or 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 through September 30, 2020, our research and development expenses have primarily been for the development of Nefecon for the treatment of IgAN. 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:

- advance Nefecon for the treatment of IgAN through Phase 3 clinical development, including both Part A and Part B of our NefIgArd trial;
- seek marketing approvals for Nefecon in the United States and the European Union;
- prepare for and potentially initiate clinical trials for additional product candidates that apply Nefecon or its active ingredient and/or setanaxib for other indications such as PBC and AIH;
- improve the efficiency and scalability of our manufacturing processes and supply chain, including in preparation for commercialization of Nefecon, if approved;
- continue to in-license or otherwise acquire and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development.

Our expenses may also increase if we encounter delays or setbacks in the enrollment or conduct of our clinical trials for our product candidates due to the COVID-19 pandemic. 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 "—Contractual Obligations and Commitments."

Administrative and Selling Expenses

Administrative and selling expenses consist of salaries and other related costs for personnel in our executive, finance, corporate, commercialization and business development and administrative functions. Administrative and selling 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 and selling expenses will increase in the future as we increase our headcount to support our continued development and potential commercialization of our portfolio of product candidates. We also expect 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 gains and losses on operating receivables and liabilities.

Financial Income

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

Financial Expenses

Financial expenses consist primarily of realized and unrealized losses on foreign exchange derivative instruments 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 for one of 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 is recorded as a credit against research and development expenses. The Swedish 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 a result, we have recorded the entire benefit from the Swedish research and development tax credit on social security costs for personnel within research and development as a reduction to research and development expenses and is not reflected as part of the income tax provision.

As of September 30, 2020, we had SEK 933.0 million of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position. 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 the Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Years Ended December 31,	
	2019	2018
	(SEK in thousands, except per share amounts)	
Consolidated Statement of Income Data:		
Net sales	184,829	—
Operating expenses		
Research and development	(149,826)	(99,260)
Administrative and selling	(62,882)	(31,132)
Other operating income	4,385	—
Other operating expenses	(4,525)	(2,090)
Operating loss	(28,019)	(132,482)
Financial income	926	441
Financial expenses	(5,408)	(8)
Loss before income tax	(32,501)	(132,049)
Income taxes	(77)	—
Net loss for the year attributable to shareholders	(32,578)	(132,049)
Loss per share before and after dilution	(0.88)	(5.09)

Net Sales

Net sales for the year ended December 31, 2019 was SEK 184.8 million, relating to the license agreement entered into with Everest Medicines in 2019. The license agreement granted Everest Medicines an exclusive license to develop and commercialize Nefecon for the treatment of IgAN in Greater China and Singapore. No net sales were recognized for the year ended December 31, 2018.

Research and Development Expenses

Research and development expenses increased by SEK 50.6 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase was primarily due to increased costs for clinical trials of SEK 23.4 million and product development of SEK 16.9 million. Additionally, we had a SEK 5.1 million increase in personnel costs due to increased headcount for personnel engaged in research and development functions.

Administrative and Selling Expenses

Administrative and selling expenses increased by SEK 31.8 million for the year ended December 31, 2019 compared to the year ended December 31, 2018. This increase was primarily due to an increase in third-party professional fees of SEK 16.4 million related to costs for pre-commercial activities for Nefecon in the United States and the license agreement with Everest Medicines. Additionally, we had a SEK 9.8 million increase in personnel costs due to increased headcount and associated recruitment costs and a SEK 1.8 million increase in rent expense as a result of our new leased facility in Sweden.

Other Operating Income

Other operating income increased by SEK 4.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to more favorable exchange rates on operating receivables.

Other Operating Expenses

Other operating expenses increased by SEK 2.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to less favorable exchange rates on operating liabilities.

Financial Income

Financial income increased by SEK 0.5 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to interest income earned on cash accounts.

Financial Expenses

Financial expenses increased by SEK 5.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to realized and unrealized losses on foreign exchange derivative instruments entered into during 2019 and less favorable exchange rates on financial receivables and liabilities.

Income Taxes

Income tax expense was SEK 0.1 million for the year ended December 31, 2019 for income taxes relating to our subsidiary in the United States. No income tax expense was recorded for the year ended December 31, 2018.

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September,	
	2020	2019
	(SEK in thousands, except per share amounts)	
Consolidated Statement of Income Data:		
Net sales	474	138,243
Operating expenses		
Research and development	(167,379)	(108,117)
Administrative and selling	(77,843)	(39,092)
Other operating income	969	3,515
Other operating expenses	—	(4,525)
Operating loss	(243,779)	(9,976)
Financial income	504	2,158
Financial expenses	(19,603)	(1,710)
Loss before income tax	(262,878)	(9,528)
Income taxes	(185)	—
Net loss for the period attributable to shareholders	(263,063)	(9,528)
Loss per share before and after dilution	(6.09)	(0.26)

Net Sales

Net sales decreased by SEK 137.8 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This decrease was mainly due to the out-licensing of Nefecon for China as part of the license agreement with Everest Medicines, which occurred in 2019.

Research and Development Expenses

Research and development expenses increased by SEK 59.3 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This increase was primarily

due to increased cost for product development of SEK 11.6 million and increased cost for clinical trials of SEK 30.1 million. Additionally, we had a SEK 10.7 million increase in third party consultant costs engaged in research and development functions and a SEK 4.1 million increase in personnel costs due to increased headcount for personnel engaged in research and development functions.

Administrative and Selling Expenses

Administrative and selling expenses increased by SEK 38.8 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This increase was primarily due to a SEK 10.2 million increase in costs related to U.S. listing fees and insurances. Additionally, we had a SEK 8.7 million increase in costs for our pre-commercial activities incl. personnel in the U.S. and a SEK 7.3 million increase in costs for non-U.S. personnel.

Other Operating Income

Other operating income decreased by SEK 2.5 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019, primarily due to disadvantageous exchange rate development on operating receivables and liabilities.

Other Operating Expenses

Other operating expenses decreased by SEK 4.5 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019, primarily due to favorable exchange rate development on operating liabilities.

Financial Income

Financial income decreased by SEK 1.7 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019, primarily due to reduced unrealized foreign currency transaction gains on cash accounts.

Financial Expenses

Financial expenses increased by SEK 17.9 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019, primarily due to SEK 15.4 million in unrealized foreign currency transaction losses on cash accounts due to a weakened USD against SEK.

Income Taxes

Income tax expense was SEK 0.2 million for the nine months ended September 30, 2020 for income taxes relating to our subsidiary in the United States. No income tax expense was recorded for the nine months ended September 30, 2019.

Change in Accounting Principle

Beginning on January 1, 2019, we switched to presenting costs in our income statements based on function instead of cost by nature. The purpose of the change is to provide more relevant information about our financial results, as a function-divided presentation better reflects the practice in the industry in which we operate. The change constitutes a voluntary change of accounting principle and has been applied retrospectively. The change in accounting principle had no effect on our consolidated financial position, results of operations, or liquidity.

Liquidity and Capital Resources

From inception through September 30, 2020, we have not generated revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. In June 2019, we received the upfront payment of $15.0 million from Everest in connection with the execution of the license agreement, and we are eligible to receive future payments upon the satisfaction of specific clinical, regulatory and commercial milestones, as well as typical tiered royalties. In December 2019, we announced that a $5.0 million milestone payment from Everest was triggered upon approval of Everest's IND in China. If our development

efforts for Nefecon and future product candidates are successful and result in approved and marketed products, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements.

Through September 30, 2020, we had received net proceeds of SEK 2,124.4 million from the issuance of equity securities. In June and July 2020, we completed a new share issuance of 9.2 million shares, in connection with the U.S. IPO and a concurrent private placement, for gross proceeds of SEK 891.4 million from U.S. 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 the net proceeds from this offering, together with our cash as of September 30, 2020, will be sufficient to fund our operations and capital expenditure requirements until we are cash flow positive, which is expected in the first half of 2023, subject to Nefecon being approved by regulatory authorities for marketing and sale and successfully commercialized. There can be no assurance that Nefecon will be approved by regulatory authorities, or that we will be successful in marketing Nefecon, if approved. See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—Even if the global offering is successful, we will 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 currently 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, other than our lease obligations described below under "—Contractual Obligations and Commitments."

In addition to the foregoing, based on our current assessment, we do not expect any material impact on our long-term liquidity due to the COVID-19 pandemic. However, we will continue to assess the effect of the pandemic to our operations. The extent to which the COVID-19 pandemic will impact our business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, any restrictions on the ability of hospitals and trial sites to conduct trials that are not designed to address the COVID-19 pandemic and the perceived effectiveness of actions taken in the United States and other countries to contain and treat the disease. While the potential economic impact brought by COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital in the future. In addition, a recession or long-term market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Years Ended December 31,		Nine Months Ended September 30,	
	2019	2018	2020	2019
	(SEK in thousands)			
Cash used in operating activities	(71,011)	(128,191)	(189,107)	(25,576)
Cash used in investing activities	(18,072)	—	(2)	(17,781)
Cash used in/provided by financing activities	198,835	716,572	847,882	200,088
Net increase (decrease) in cash	109,752	588,381	658,773	156,731

Operating Activities

During the nine months ended September 30, 2020, net cash used in operating activities was SEK 189.1 million, primarily resulting from our operating loss of SEK 243.8 million and positive net cash changes in our operating assets and liabilities of SEK 48.6 million. Net changes in our operating assets and liabilities for the nine months ended September 30, 2020 consisted mainly of a SEK 46.6 million decrease in account receivables due to payments received from Everest.

During the nine months ended September 30, 2019, net cash used in operating activities was SEK 25.6 million, primarily resulting from our operating loss of SEK 10.0 million and negative net cash changes in our operating assets and liabilities of SEK 16.8 million.

During the year ended December 31, 2019, net cash used in operating activities was SEK 71.0 million, primarily resulting from our operating loss of SEK 28.0 million and negative net cash changes in our operating assets and liabilities of SEK 45.9 million. Net changes in our operating assets and liabilities for the year ended December 31, 2019 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.

During the year ended December 31, 2018, net cash used in operating activities was SEK 128.2 million, primarily resulting from our operating loss of SEK 132.5 million, offset by net cash changes in our operating assets and liabilities of SEK 4.2 million. Net changes in our operating assets and liabilities for the year ended December 31, 2018 consisted of a SEK 2.6 million decrease in VAT receivables and a SEK 1.6 million increase in accounts payables and accrued expenses due to an increase in research and development expenses and timing of payments.

Investing Activities

During the nine months ended September 30, 2020 and 2019, we used insignificant cash from investing activities.

During the year ended December 31, 2019, net cash used for investing activities was SEK 18.1 million, consisting of SEK 16.1 million for the acquisition of a license from Dr. Falk Pharma to develop a product in the United States, SEK 1.9 million for a lease security deposit and SEK 0.1 million in capital expenditures.

During the year ended December 31, 2018, we did use insignificant cash from investing activities.

Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was SEK 847.9 million, mainly consisting of net SEK 795.5 million from our IPO in the United States and SEK 54.9 million from exercise of warrants from our Warrant Program 2017/2020.

During the nine months ended September 30, 2019, net cash provided by financing activities was SEK 200.1 million, mainly consisting of a new share issue of net SEK 199.4 million.

During the year ended December 31, 2019, net cash provided by financing activities was SEK 198.8 million, primarily consisting of SEK 199.4 million net proceeds from a new share issuance and SEK 2.8 million attributable to warrant premiums from our Warrant Program 2019/2022, partially offset by paid transaction costs of SEK 1.7 million and lease payments of SEK 1.7 million.

During the year ended December 31, 2018, net cash provided by financing activities was SEK 716.6 million, consisting of SEK 684.2 million net proceeds from our initial public offering on the Nasdaq Stockholm exchange in June 2018, SEK 30.0 million from shareholder contributions prior to such initial public offering and SEK 2.8 million attributable to warrant premiums from our Warrant Program 2018/2022 offset by a repayment of a shareholder loan of SEK 0.5 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities. We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses 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 the net proceeds from this offering, together with our cash as of September 30, 2020, will be sufficient to fund our operations and capital expenditure requirements until we are cash flow positive,

which is expected in the first half of 2023, subject to Nefecon being approved by regulatory authorities for marketing and sale and successfully commercialized. 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 regulatory authorities, or that we will be successful in marketing Nefecon, if approved. See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—Even if the global offering is successful, we will 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 our:

- conducting and fully enrolling clinical trials in the development of Nefecon and our other product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete registrational clinical trials that achieve their primary and/or secondary endpoints;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval by acquiring sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- completing development of our product candidates and in-licensing or otherwise acquiring new product candidates;
- qualifying for and maintaining, adequate coverage and reimbursement by government and payors for our product candidates for which we obtain marketing approval;
- 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;
- obtaining market acceptance of our product candidates, if approved, as viable treatment options with acceptable safety profiles;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure, as needed, including robust quality systems and compliance systems;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- 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

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by Period				
	Total	Less than 1 Year	1-3 years	4-5 Years	More than 5 years
			(in thousands)		
Operating lease obligations[1]	6,655	3,816	2,839	—	—
Total	6,655	3,816	2,839	—	—

(1) Amounts reflect minimum payments due for our office space lease as of December 31, 2019. We had one office lease in Stockholm, Sweden under operating leases that was scheduled to expire in March 2022. In May 2019, we terminated the office lease and signed a new office lease agreement in Stockholm, Sweden, with a term through May 2022. The annual rental commitment for the current office space is SEK 2.8 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 all products, including Nefecon, 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 potential milestone payments totaling up to €38.5 million upon our achievement of specific clinical, 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with International Financial Reporting Standards, or IFRS, issued by the International Accounting Standards Board, or IASB. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the

disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our consolidated financial statements appearing at the end of this prospectus, the following accounting policies are the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and communicating with our personnel to identify services that have been performed on our behalf by third-party service providers and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our third-party service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing clinical trials on our behalf;
- CMOs in connection with the production of clinical trial materials;
- investigative sites or other service providers in connection with clinical trials;
- vendors in connection with clinical development activities; and
- vendors related to product manufacturing and development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs, CMOs and vendors that supply, conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Intangible Assets

Development expenditures are capitalized when they meet the criteria for capitalization. The most important criteria for capitalization are that the final product of the development process has a probable future earnings or cost-savings capacity, and that the technical and financial conditions exist for completing the development work. Research and development expenditures are otherwise expensed as operating expenses. We capitalize expenditures for the development of pharmaceuticals to the extent that it is expected to meet the criteria in accordance with IAS 38. 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). Our expenditures for the development

of pharmaceuticals were not deemed to meet the capitalization criteria for the nine months ended September 30, 2020 or fiscal years ended December 31, 2019 and 2018 and were thus expensed. Capitalization of expenditures for the development of pharmaceuticals typically takes place late in Phase 3 clinical trials, or alternatively in conjunction with the initiation of pivotal trials, 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. Market approval has not yet been obtained for any products and, accordingly, the conditions for capitalizing development expenditures are not met.

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. We have acquired licenses and similar rights connected to Budenofalk. Since the asset has been acquired, it has been recognized as an intangible asset in the consolidated statement of financial position according to IAS 38. We will include potential future one-off payments in the acquisition cost if and when a decision has been made to take the measures that triggers additional payment, meaning only payments we have control over if they will occur, are included in the acquisition cost of intangible assets.

Amortization of the 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 our management. We expect the finite useful life for the Budenofalk product candidate to be 15 years. Until market approval from regulatory authorities has been granted, amortization on the expected useful life will not commence. As market approval has not yet been obtained, no other costs have been capitalized. Following market approval from regulatory authorities, it 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, or when there is an indication that the asset may be impaired.

Revenue

Revenue is recognized when a promised product or service is transferred to the counterparty, which can be done over time or at a point in time. Revenue is the amount that we expect to receive as compensation for transferred goods or services.

Revenue for out-licensing is recognized at a point in time that occurs when control over the intangible asset is transferred to the counterparty. 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. Revenue attributable to the sale of approved products recognized at the point in time when control of the goods is transferred to the counterparty.

Income Tax

Income tax comprises current tax and deferred tax. Income tax is recognized in net profit for the period, 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 are decided or decided in practice on the closing date. Current tax also includes adjustments of current tax attributable to prior periods. Deferred tax is calculated based on temporary differences between the tax bases of assets and liabilities and their carrying amounts. Temporary differences attributable to participations in subsidiaries that are not expected to be reversed in the foreseeable future are not taken into account. Deferred tax is calculated 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 likely that it will be possible to utilize these. The value of deferred tax assets is reduced when it is no longer deemed likely that they can be utilized. Our loss carryforwards have

not been measured and are not recognized as a deferred tax asset. Loss carryforwards are measured when we have established a level of earnings that management is certain will result in a tax surplus.

Warrants

Accounting for warrants requires us to make significant judgments, estimates and assumptions. We estimate the fair value of warrants granted using the Black-Scholes option-pricing model, which requires the input of subjective assumptions, including volatility, risk-free interest rate, expected dividends, and expected term. We have only issued warrants that were transferred at fair value. Premiums received for warrants granted to acquire our shares are recognized as an addition to equity, based on the warrant premium, at the date when the warrant was transferred to the counterparty.

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 our functional currency at the exchange rate on the date of the transaction. Monetary assets and liabilities in foreign currency are translated to our functional currency at the exchange rate that applies on the closing date. Foreign exchange gains and losses on operating receivables and liabilities are recognized in operating profit (loss), 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 Swedish Kronor 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' currencies are recognized in other comprehensive income. We recorded foreign currency transaction losses of SEK 0.1 million and SEK 2.1 million for the years ended December 31, 2019 and 2018, respectively. We recorded foreign currency transaction gains of SEK 1.0 million and foreign currency transaction losses of SEK 1.0 million for the nine months ended September 30, 2020 and 2019, respectively. These foreign currency transaction gains and losses are included in other operating income and other operating expenses in our consolidated financial statements.

Transaction Exposure

Our transaction exposure from contracted payment flows in foreign currency is limited. The table below sets forth our exposure in each currency for the years ended December 31, 2019 and December 31, 2018 and the nine months ended September 30, 2020 and September 30, 2019.

Currency Exposure 2019 (%)	Revenue	Operating expenses
USD	100%	22%
EUR	—	54%
GBP	—	3%
SEK	—	21%

Currency Exposure 2018 (%)	Revenue	Operating expenses
USD	100%	10%
EUR	—	52%

Currency Exposure 2018 (%)	Revenue	Operating expenses
GBP	—	2%
SEK	—	36%

Our primary transaction exposure is in Euros and U.S. dollars. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 10.2 million and SEK 6.0 million for 2019 and 2018, respectively. A 10% stronger U.S. dollar against the Swedish Krona would have a positive impact on profit after tax and equity of approximately SEK 14.4 million and negative impact of SEK 1.1 million for 2019 and 2018, respectively.

Currency Exposure for the nine months ended September 30, 2020 (%)	Revenue	Operating expenses
USD	—	32%
EUR	—	40%
GBP	—	5%
SEK	—	23%

Currency Exposure for the nine months ended September 30, 2019 (%)	Revenue	Operating expenses
USD	—	17%
EUR	—	62%
GBP	—	3%
SEK	—	19%

Our primary transaction exposure is in Euros and U.S. dollars. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 8.3 million and SEK 8.6 million for the nine months ended September 30, 2020 and September 30, 2019, 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 6.6 million and SEK 2.3 million for the nine months ended September 30, 2020 and September 30, 2019, respectively.

Interest Rate Risk

We are currently not exposed to significant interest rate risk. Our only variable interest-bearing financial assets are cash at Swedish banks. Certain European countries have recently experienced (or currently are expected to experience) negative interest rates on certain fixed-income instruments, and similar interest rate conditions may be experienced in other regions. Negative interest rates may magnify our susceptibility to interest rate risk and diminish yield and performance on our investments. Changing interest rates may have unpredictable effects on securities markets in general, directly or indirectly impacting our investments and yield.

Given the short-term nature of these investments, the sensitivity towards interest rate fluctuations is deemed not to be significant. Therefore, the effect of an increase or decrease in interest rates would only have an immaterial effect on our financial results.

As of September 30, 2020, December 31, 2019 and December 31, 2018, we had no debt outstanding and are therefore not subject to interest rate risk related to debt.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC, as of or during the periods presented.

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 Note 1 to our consolidated financial statements appearing at the end of this prospectus.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. Subject to certain conditions set forth in the JOBS Act, we are entitled to rely on certain exemptions as an "emerging growth company." We are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis) and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of the global offering or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Internal Control Over Financial Reporting

As a public company listed on Nasdaq, the Sarbanes-Oxley Act will require, among other things, that we assess the effectiveness of our internal control over financial reporting at the end of each fiscal year. We anticipate being first required to issue management's assessment of internal control over financial reporting pursuant to Section 404(a) of the Sarbanes-Oxley Act in connection with issuing our consolidated financial statements as of and for the year ending December 31, 2021.

In connection with our financial statement preparation process for the years ended December 31, 2019 and 2018, our independent registered public accounting firm has identified a material weakness as defined under the Exchange Act and by the Public Company Accounting Oversight Board (United States), or PCAOB, in our internal control over financial reporting. Under the standards established by the PCAOB, 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. The material weakness related to our financial statement closing process, primarily related to the lack of sufficient skilled personnel with SEC reporting knowledge and experience for purposes of timely and reliable financial reporting. Specifically, the material weakness identified relates 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.

We intend to implement measures designed to remediate this material weakness, including hiring or engaging additional accounting personnel with knowledge and experience in SEC reporting requirements in order to timely and reliably report our financial results in accordance with the requirements of the SEC. However, the implementation of these measures may not fully address these material weaknesses in our internal control over financial reporting in which case we would not be able to conclude that they have been fully remedied. Our failure to correct this material weakness 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.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical 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. Our lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. IgAN is a progressive, chronic disease that over time results in deterioration of kidney function in patients, many of whom end up at risk of developing end-stage renal disease, or ESRD, with the need for dialysis or kidney transplant. Nefecon is currently the only pharmaceutical candidate in development for IgAN that is intended to be disease-modifying. Nefecon targets the ileum, the distal region of the small intestine, which is the presumed origin of IgAN due to the ileum being the location of the highest concentration of the Peyer's patches, which are responsible for the production of secretory immunoglobulin A, or IgA, antibodies. Nefecon is the only compound in development for IgAN that has met the primary and key secondary endpoints in a randomized, double-blind, placebo-controlled Phase 3 clinical trial. Nefecon has been granted orphan drug designation for the treatment of IgAN in the United States and the European Union. We also recently acquired a controlling interest in Genkyotex S.A., or Genkyotex, providing us with access to a novel platform of Nicotinamide adenine dinucleotide phosphate, oxidase, or NOX, inhibitors, which we intend to primarily develop for orphan diseases with fibrotic components, with a main focus on kidney and liver diseases.

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 9 months compared to a 0.17 ml/min/1.73m^2 decline in the treatment arm. In addition, the trial showed that Nefecon was generally well-tolerated. On the basis of the positive results of Part A of NefIgArd, we intend to submit a New Drug Application, or NDA, in the first quarter of 2021 for accelerated approval by the FDA followed by a Marketing Authorisation Application, or MAA, for conditional approval by the EMA in the first half of 2021. In January 2021, we completed the enrollment of all 360 patients in NefIgArd, which includes 200 patients previously enrolled in Part A and another 160 patients enrolled in Part B. We also previously conducted a Phase 2b trial with 150 patients, which also met the identical primary and key secondary endpoint.

Although we observed a statistically significant and clinically meaningful reduction of proteinuria, the FDA and EMA have not provided a specific level of reduction of proteinuria that would be required to obtain marketing approvals. Accordingly, there can be no assurance that the level of reduction of proteinuria that we observed in our Phase 3 clinical trial will be sufficient to satisfy the FDA and EMA. The FDA accelerated approval pathway, and the conditional approval process of the EMA, 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 approved, we expect that Nefecon will be the first treatment on the market indicated for IgAN. We believe that if Nefecon can successfully treat IgAN patients, their kidney function will be preserved. We retain worldwide rights to Nefecon other than in Greater China and Singapore where we have established a strategic collaboration.

IgAN, sometimes referred to as Berger's disease, is a serious progressive autoimmune disease of the kidney in which up to 50% of patients end up 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 has been observed in Asia, including in Greater China, where IgAN has historically been a leading cause of ESRD. We estimate that IgAN affects approximately two million

people in Greater China and approximately 180,000 people in Japan. We estimate the U.S. market opportunity for IgAN to be approximately $9.0 billion to $10.0 billion annually, based on our estimate of the prevalence of the disease in the United States and primary market research conducted by IQVIA that we commissioned to assess preliminary reimbursement levels perceived acceptable by U.S.-based payors. In this market, we intend to primarily focus on treating those IgAN patients that are at risk of progressing to ESRD.

Although IgAN manifests in the kidney, most scientific studies have found that the pathogenesis of IgAN begins in the ileum. Masses of lymphatic tissue, known as Peyer's patches, are predominantly found 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 and 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, leading 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 membranes of the glomeruli, the kidney's filtration apparatus. These trapped immune complexes initiate an inflammatory cascade that damages the membranes, 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, resulting in potentially life-threatening complications that in many patients will lead to the need for dialysis or kidney transplant.

Despite a need for new therapies, there have been few new drugs developed for chronic kidney diseases during the last decade and there is no approved therapy for IgAN. Patients with IgAN are typically initially given antihypertensive medications as recommended by the non-profit organization Kidney Disease: Improving Global Outcome consortium, or KDIGO. This treatment regimen initially attempts to manage the symptoms of IgAN by decreasing blood pressure and reducing proteinuria but does not address the underlying cause of IgAN. Over time, physicians attempt to control disease progression with a variety of off-label treatments, as a significant proportion of patients experience continued deterioration of kidney function, with no approved treatment options currently available. 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, this high dosing of systemic corticosteroids is also associated with a wide range of adverse events, including high blood pressure, weight gain, diabetes, serious infections and osteoporosis.

Nefecon is currently the only pharmaceutical candidate in development that is designed to target the ileum, with the goal of being a disease-modifying treatment. Nefecon is designed to release a high dose of a locally acting immunosuppressive agent in the ileum, where the highest concentration of Peyer's patches exists, to reduce the formation of secretory galactose-deficient IgA antibodies and their appearance in the blood.

Nefecon's active ingredient is budesonide, an established, highly potent locally acting corticosteroid. After the active ingredient has been released and has had its effect in the intestinal mucosa, it enters the liver, where 90% is cleared in first pass metabolism, resulting in the inactivation of a majority of the active ingredient before the substance reaches the systemic circulation. This high metabolism may limit systemic immunosuppressive activity and decrease the significant side effects associated with systemic corticosteroids that are currently used off-label to treat IgAN, of which only 20% to 30% are cleared in first pass metabolism. Other locally delivered approved therapies where budesonide is the active ingredient include those for asthma, allergic rhinitis, Crohn's disease and ulcerative colitis. Based on the written minutes from our End-of-Phase 2 meeting, the FDA has indicated alignment on a pathway toward accelerated approval in the United States based on the evaluation of a surrogate endpoint rather than a clinical outcome endpoint. We have received similar feedback from the EMA on a conditional market access pathway in the European Union.

Additionally, since Nefecon is a reformulation of the active ingredient in an existing approved drug, we are pursuing the Section 505(b)(2) pathway for regulatory approval by the FDA in the United States and the hybrid application pathway for conditional approval by the EMA in the European Union.

Nefecon Phase 3 Clinical Trial Results

Nefecon is the most advanced clinical-stage product candidate for the treatment of IgAN. In November 2020, we reported positive topline data from our global, pivotal Phase 3 clinical trial in IgAN, which we refer to as NefIgArd. NefIgArd is designed to evaluate reduction of the surrogate marker proteinuria as its primary endpoint, which is the same endpoint used in our previously completed NEFIGAN clinical trial. We randomized our first patient in NefIgArd in November 2018. NefIgArd is a double-blind, placebo-controlled, two-part Phase 3 clinical trial. The first part of NefIgArd, which we refer to as Part A, is a pivotal efficacy and safety trial. The primary endpoint of Part A is the decrease in proteinuria in the first 200 randomized and dosed patients. In addition, a secondary endpoint of Part A is the difference in kidney function between treated and placebo patients as measured by eGFR. The key secondary endpoint in Part A, which is a measure of eGFR over a nine-month period, is also expected to be informative of the primary endpoint of Part B, as discussed below. On the basis of the positive Part A results, we intend to submit an NDA in the first quarter of 2021 for accelerated approval by the FDA followed by an MAA for conditional approval by the EMA in the first half of 2021.

The second part, which we refer to as Part B, is a post-approval confirmatory trial designed to provide evidence of long term renal benefit. Following completion of enrollment in Part A in December 2019, completed enrollment in Part B of another 160 patients in January 2020 and the beginning of 2021 in order to power Part B to assess the difference in kidney function between treated and placebo patients as measured by eGFR over a two-year period from the start of dosing of each patient. We experienced a reduced enrollment rate over the past several months due to the impact of the COVID-19 pandemic, and we did not complete full enrollment until January of 2021. Having successfully completed enrollment, we expect to report data from Part B in early 2023. Across both parts, NefIgArd will enroll a total of 360 patients and generate nine months of dosing data, as well as an aggregate of 15 months of follow-up data from Parts A and B. If approved by the FDA, we intend to market and commercialize Nefecon in the United States as a treatment specifically designed to have a disease-modifying effect for IgAN by preserving kidney function and thereby avoiding progression to ESRD.

In our completed pan-European Phase 2b clinical trial, Nefecon was also observed to statistically significantly reduce proteinuria and to provide clinical benefit by preserving kidney function, as measured by estimated glomerular filtration rate, eGFR, which is considered a key metric for measuring kidney disease progression. This trial, known as NEFIGAN, was a double-blind, placebo-controlled trial in 150 patients 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. NEFIGAN achieved its primary endpoint of reduction in proteinuria for the 16 mg dose cohort. As measured by the urine protein creatinine ratio, or UPCR, patients in the placebo cohort exhibited an increase in proteinuria of 2.7%, while patients in the 16 mg dose cohort also exhibited statistically significant and clinically meaningful reductions in proteinuria of 27.3%. Patients treated with Nefecon also exhibited stabilization of eGFR, reflecting preservation of kidney function, while patients administered with placebo continued to show deterioration.

Nefecon Phase 2 Clinical Trial Results

In order to approve a drug, the FDA generally requires one or more clinical trials demonstrating that the product candidate meets an endpoint that represents a direct clinical outcome, such as survival, decreased pain or the absence of disease, which we refer to as a clinical endpoint. However, in certain circumstances, the FDA selectively allows the use of surrogate endpoints that are reasonably likely to predict clinical benefit in clinical trials to permit a more rapid development and approval path of treatments for serious or life-threatening diseases. For treatments related to chronic kidney disease, clinical trials have generally relied on clinical endpoints such as time to dialysis or transplantation. Due to the significant expense associated with the large patient numbers and extended clinical trial duration required to adequately measure such clinical endpoints, few new therapeutic drug candidates have emerged over the past two decades to treat renal disease. In 2012, the FDA and the American Society of Nephrology, or ASN, founded the Kidney Health Initiative, or KHI, with the goal of supporting research and innovation for the development of safe and efficacious

treatments for kidney disease. We funded a collaboration with Tufts University and the University of Utah to conduct a meta-analysis based on selected, well-defined clinical trials in IgAN patients in order to provide regulatory authorities with a data-driven basis to accept a novel surrogate marker for potentially accelerated approval of treatments for IgAN. The final analytical framework from this collaboration showed a robust statistical relationship between reduction in proteinuria and reduction of the risk of progression to ESRD. We believe that this framework, together with the research and analysis conducted by the KHI and spearheaded by ASN, the National Kidney Foundation and the FDA, led to the FDA's acceptance of an accelerated approval pathway at our End-of-Phase 2 meeting in January 2017. This change in regulatory approach was fundamental to our decision to commence our ongoing Phase 3 clinical trial for Nefecon in IgAN.

Genkyotex Acquisition

In 2020, we acquired a controlling interest in Genkyotex, which provides us with access to a novel platform of NOX inhibitors that we intend to develop for orphan diseases with fibrotic components, primarily focused on kidney and liver disease. Examples of fibrotic indications include primary biliary cholangitis, or PBC, primary sclerosing cholangitis, or PSC, and idiopathic pulmonary fibrosis, or IPF, and non-alcoholic steatohepatitis, or NASH. The lead compound, setanaxib has shown clinically relevant activity across a variety of biomarkers related to fibrosis as well as Fibroscan in a recently completed Phase 2 trial in PBC, despite not achieving its primary endpoint. In addition, two investigator led studies are underway, exploring setanaxib in IPF and diabetic kidney disease, or DKD. In January 2021, Genkyotex reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to 1,600 mg/day. Based on this positive data, Genkyotex plans to initiate a Phase 2/3 trial in PBC in the second half of 2021. In addition, Genkyotex plans to initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021.

Clinical Development Plans for Nefecon and Setanaxib

Beyond IgAN, we are exploring applications of Nefecon or its active ingredient for other autoimmune diseases in which it may have therapeutic potential, such as PBC and autoimmune hepatitis, or AIH. We are planning to evaluate setanaxib as our first candidate in PBC, but will also continue to evaluate Nefecon for the treatment of PBC, a progressive and chronic autoimmune disease of the liver, that causes damage to the small bile ducts that drain bile from the liver, which can result in cholestasis and ultimately destruction of the bile ducts, leading to liver cell damage and ultimately liver failure, resulting in the need for a liver transplant. There are currently no approved therapies that specifically address the autoimmune response that is believed to drive PBC or the inflammatory consequences of the autoimmune response. Nefecon is designed to deliver high peak concentrations of its active ingredient to the intestine, which is then transported directly to the liver in order to locally reduce the autoimmune processes that drive PBC. We have received orphan drug designation for the treatment of PBC by the FDA. In addition, through our recent acquisition of a controlling interest in Genkyotex, we have acquired access to a novel NOX inhibitor platform from which the lead compound, setanaxib, has completed a Phase 2 trial in PBC and recently received orphan drug designation for the treatment of PBC in the U.S. and Europe. Based on its Phase 2 results indicating clinically relevant anti-fibrotic activity despite not achieving its primary endpoint in a trial in PBC, Genkyotex had interactions with the FDA during 2020 regarding the clinical development pathway for setanaxib in PBC. In January 2021, Genkyotex reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to 1,600 mg/day. Based on this positive data, Genkyotex plans to initiate a Phase 2/3 trial in PBC, incorporating higher dosing than that used in the Phase 2 trial and using alkaline phosphatase, or ALP, as a primary endpoint. The final design and protocol are subject to further feedback and commentary by the FDA. Genkyotex plans to initiate the trial in the second half of 2021. In addition, Genkyotex plans to initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021 which will study administration of setanaxib in conjunction with immunotherapy targeting cancer associated fibroblasts, or CAFs.

We have also in-licensed Budenofalk 3 mg oral capsules from the German pharmaceutical company Dr. Falk Pharma GmbH, or Falk Pharma, in order to obtain regulatory approval and commercialize Budenofalk in the United States for the treatment of AIH, another rare immune inflammatory liver indication. 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. Budenofalk is a formulation of budesonide originally developed to treat Crohn's disease. We believe Budenofalk has the potential to complement our activities in the United States. We have received orphan drug designation for the treatment of AIH using budesonide by the FDA. We discussed our development plans with the FDA for AIH during 2020 and have received helpful feedback as to the potential regulatory pathway forward. However, we expect to have further interactions with FDA in 2021 before we are in a position to affirmatively decide on the design and timing of a clinical program.

If approved by the FDA, we intend to commercialize Nefecon independently in the United States by establishing a targeted commercial sales infrastructure with a primary focus on IgAN patients at risk of progressing to ESRD. We intend to launch Nefecon in the United States in the first half of 2022, if approved. We are currently focused on disease education, interaction with patient advocacy groups and market access, with the goal of educating physicians about the disease origin, understanding patient needs and preparing our market access strategy for Nefecon. We believe this market can be addressed by a small and dedicated number of marketing and medical sales specialists, initially approximately 40, to efficiently cover the approximately 3,700 nephrologists focused on our target patient population in the United States.

In 2019, we entered into an agreement with Everest Medicines, or Everest, pursuant to which we granted Everest an exclusive license to develop and commercialize Nefecon for IgAN in Greater China and Singapore. In other key territories such as Europe, we intend to commercialize Nefecon through either a broad regional partnership or on a country-by-country basis.

NOX inhibitors is a fairly new drug class focused on inhibiting the overproduction of reactive oxygen species, or ROS, which can drive fibrogenesis across multiple organs. We believe that this platform has several potential applications across orphan indications, focusing on anti-fibrotic and anti-inflammatory applications. Setanaxib is the lead compound, complemented by a research effort focused on developing follow up compounds. Potential indications include PBC, PSC, IPF, NASH and various kidney indications with a fibrotic component. There is also a potential to explore oncology indications, using setanaxib administered with checkpoint inhibitors to address tumor drug resistance related to fibroblasts.

Our Company and Management Team

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.

COVID-19 Pandemic

As of the date of this prospectus, the impact of the COVID-19 pandemic to our business has been limited. To date, we do not anticipate that the COVID-19 pandemic will significantly impact the ongoing clinical activities related to NefIgArd, our Phase 3 pivotal trial in IgAN. We reported topline results from Part A of NefIgArd in the fourth quarter of 2020. We fully recruited Part A in December 2019, and because 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, the impact of the COVID-19 pandemic to Part A of the trial has been limited to date. With sites in 19 countries participating in the trial, there are several geographies facing challenging situations in their healthcare systems, but we believe we have been 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 all 360 patients in NefIgArd, which includes 200 patients previously enrolled in Part A and another 160 patients enrolled in Part B. Having completed enrollment, we intend to report data from Part B in early 2023, subject to any further

impact from the COVID-19 pandemic to our business. There are, however, still uncertainties with regard to the continued development of COVID-19 and its implications, such as the potential inability of regulatory authorities to conduct pre-approval inspections of our manufacturing facilities, if required, and we will continue to assess the situation and seek to put in place relevant mitigating measures where necessary.

Although we believe we have implemented strategies to potentially minimize the impact of the COVID-19 pandemic to our business, we expect that we may experience delays with respect to the initiation of certain additional trials, including our extended dosing trial for Nefecon. The extent to which the COVID-19 outbreak impacts the timing of these additional trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, any restrictions on the ability of hospitals and trial sites to conduct trials that are not designed to address the COVID-19 pandemic and the perceived effectiveness of actions taken in the United States and other countries to contain and treat the disease. We will continue to evaluate the impact of the COVID-19 pandemic to our business.

Our Strategy

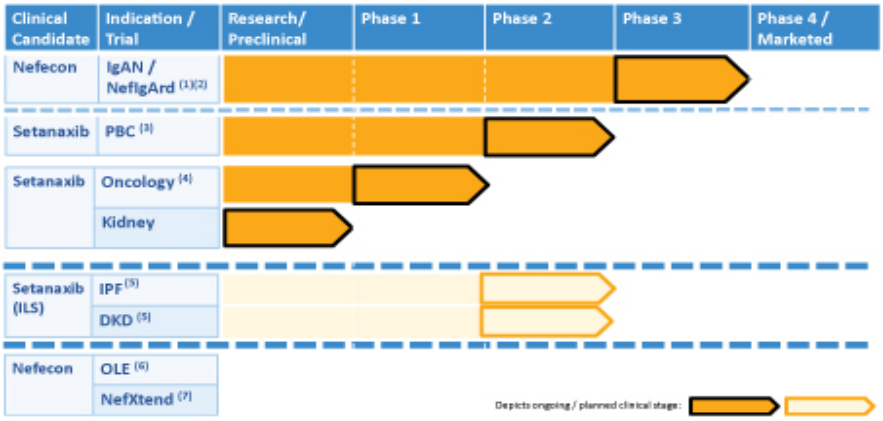
We aim to apply our interdisciplinary expertise in pharmaceutical product development to identify, develop and commercialize novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. To achieve this objective, we intend to pursue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

- **Rapidly and efficiently advance Nefecon through Phase 3 clinical development and regulatory approval in order to establish a new standard of care for IgAN**. We reported positive topline results from Part A of NefIgArd in November of 2020, where the trial met the primary and key secondary endpoint. On the basis of the positive results of Part A of NefIgArd, we intend to submit an NDA in the first quarter of 2021 for accelerated approval by the FDA followed by an MAA for conditional approval by the EMA in the first half of 2021. In January 2021, we completed enrollment for Part B of the trial to assess the difference in kidney function between treated and placebo patients as measured by eGFR to confirm long-term renal benefit. We expect to report data from Part B in early 2023, subject to the impact of the COVID-19 pandemic.
- **Maximize the potential of Nefecon, if approved, through commercialization independently and through opportunistic collaborations with third parties**. We retain worldwide rights to Nefecon other than in Greater China and Singapore. If approved by the FDA, we intend to commercialize Nefecon independently in the United States by establishing a targeted commercial sales infrastructure with a primary focus on IgAN patients at risk of progressing to ESRD. We intend to launch Nefecon in the United States in the first half of 2022, if approved. Based on third party research we commissioned to assess the U.S. 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 3,700 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 other key territories such as Europe, we intend to commercialize Nefecon through either a broad regional partnership or on a country-by-country basis.
- **Leverage our existing pipeline, proprietary formulations and significant experience with drug release technology to explore treatments in select orphan hepatic diseases**. We believe that our proprietary technology has the 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 to apply Nefecon or its active ingredient, and are prioritizing conditions in which there is a strong scientific and clinical rationale and an attractive commercial opportunity, such as PBC and AIH. There are currently no approved therapies that specifically address the autoimmune response that is believed to drive PBC or the inflammatory consequences of the autoimmune response. In addition, there are 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. However, we expect to have further interactions with FDA in 2021 before we are in a position to affirmatively decide on a clinical program.

- **Leverage and enhance our product pipeline complemented by selective acquisitions or in-licensing of product candidates focused on nephrology or orphan diseases.** In addition to building partnerships to enhance broad commercialization of Nefecon, we actively seek to exploit and leverage our existing pipeline as well as acquire or in-license 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 and can be rapidly advanced to market approval. We currently focus on, and we expect to continue to focus on, nephrology and orphan diseases for our clinical development efforts. In 2020, we acquired a controlling interest in Genkyotex, a leader in NOX inhibition therapies. Genkyotex's lead product candidate, setanaxib, is an example of a late stage asset with potential for application in a variety of orphan indications, which adds to and complements our focus on inflammatory disease and provides us with a platform with anti-fibrotic and anti-inflammatory compounds.

Our Pipeline

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



(1) Pursuing accelerated approval pathway in the United States, an expedited pathway, and conditional approval pathway in the European Union.

(2) Pursuing under the Section 505(b)(2) pathway in the United States and, as applicable, the hybrid application pathway in the European Union.

(3) Phase 2/3 trial planned in the second half of 2021.

(4) Phase 2 trial in head and neck cancer planned in 2021.

(5) Investigator-led trial. Not controlled or funded by Calliditas.

(6) Open label extension of the NefIgArd study.

(7) Open label extended dosing trial with Nefecon.

We plan to submit an NDA for Nefecon for accelerated approval by the FDA in the first quarter of 2021, followed by an MAA for conditional approval by the EMA in the first half of 2021.

In addition, we have in-licensed Budenofalk 3 mg oral capsules and intend to develop Budenofalk in the United States for the treatment of AIH, subject to regulatory feedback. We have discussed the

development plans with the FDA for AIH during 2020, but additional interaction is required before establishing any definitive clinical development plans.

Genkyotex's lead product candidate, setanaxib, was granted orphan drug designation by the FDA in October 2020, and by the European Commission in December 2020, in each case for the treatment of PBC. Genkyotex is currently discussing its registration strategy for setanaxib in PBC with the FDA and the EMA.

Our Product Candidates

Nefecon for the Treatment of IgAN

Our lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of IgAN, for which there are no approved treatments. Nefecon, which is the most advanced clinical-stage product candidate for the treatment of IgAN, has been granted orphan drug designation. Nefecon is designed to slow the progression of IgAN and delay kidney failure in patients affected by the disease. Nefecon is currently the only pharmaceutical candidate in development that is intended to be disease-modifying. Nefecon is the only compound in development for IgAN that has met the primary and key secondary endpoint in a randomized, double-blind, placebo-controlled Phase 3 clinical trial. In November, we reported positive topline data of this global, pivotal Phase 3 clinical trial, which we refer to as NefIgArd. In this trial, 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. We also previously conducted a Phase 2b trial with 150 patients, which also met the identical primary and key secondary endpoint. We believe that if Nefecon can successfully treat IgAN patients, their kidney function will be preserved.

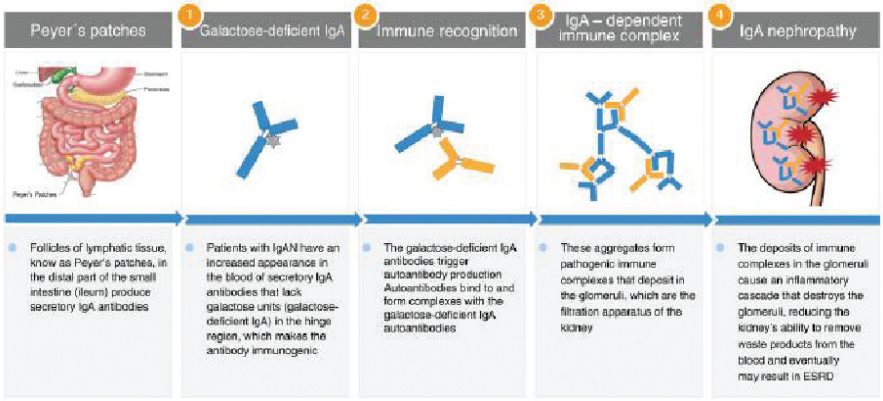
IgAN Disease Background

IgAN is a serious progressive autoimmune disease of the kidney, in which up to 50% of patients end up 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 two million people in Greater China and 180,000 people in Japan. These estimates 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 Greater China and Japan. According to large Chinese epidemiology studies, IgAN represents around 40% of renal biopsies in China.

Although IgAN manifests in the kidney, most scientific studies have found that the pathogenesis of IgAN begins in the ileum, the distal part of the small intestine. The intestine represents the largest component of the immune system in the body, a site of continuous exposure to antigens and pathogens. Masses of lymphatic tissue, known as Peyer's patches, are predominantly found 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 membranes of the glomeruli, the kidney's filtration apparatus. These trapped immune complexes initiate an inflammatory cascade that damages the membranes, resulting in protein and blood leaking into the urine. Ultimately the glomeruli will be 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 will accumulate and will lead to potentially life-threatening complications that in many patients will lead to the need for dialysis or kidney transplant. Dialysis is estimated to cost between $70,000 and $200,000 per patient per year, with a total estimated annual hemodialysis cost in the United States of $42.0 billion. The average cost of a kidney transplant is approximately $415,000 with a total estimated annual cost in the United States of $7.0 billion. The graphic below shows 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

There are currently no approved treatment options for IgAN. KDIGO recommends the use of blood pressure-lowering agents that inhibit or block the renin-angiotensin system, or RAS, using either 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, physicians attempt to control disease progression with a variety of off-label treatments, as a significant proportion of patients experience continued deterioration of kidney function, with no approved treatment options currently available.

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, high dosing of systemic corticosteroids is also associated with a wide range of adverse events, including high blood pressure, weight gain, diabetes, serious infections and osteoporosis.

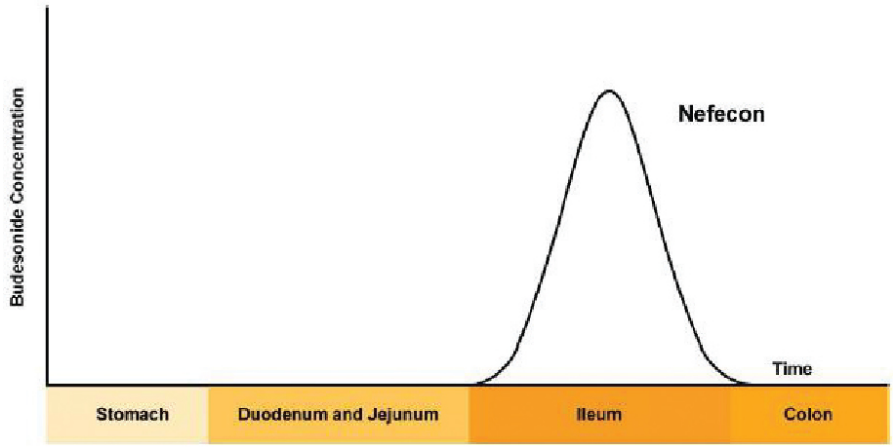
The seriousness of these adverse events in patients with IgAN has been documented in two independent clinical trials investigating the safety and efficacy of systemic corticosteroids in IgAN. In the Therapeutic Evaluation of Steroids in IgA Nephropathy Global, or TESTING, clinical trial conducted by 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 the systemic corticosteroid methylprednisolone or placebo. A significantly higher rate of serious infections and two infection-related deaths were observed in patients receiving methylprednisolone, leading to the suspension of the trial. While patients receiving methylprednisolone appeared to have improved outcomes compared to those receiving placebo, the early termination of the trial prevented a full efficacy analysis. 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, there was also an increase in the rate of serious infections in the 82 patients who received the systemic corticosteroid prednisolone, as well as one infection-related death in the treatment cohort. In this trial, high-dose systemic

corticosteroids 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 immunosuppression, including systemic corticosteroids, to comprehensive supportive care was not beneficial in IgAN.

Our Solution: Nefecon

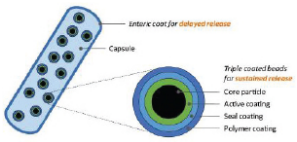
Nefecon is a proprietary, novel oral formulation of budesonide, designed to deliver a targeted and highly concentrated dose directly to the Peyer's patches that are predominantly found in the ileum. The high first pass metabolism of the active ingredient limits the adverse events typically associated with systemic corticosteroids, due to its limited spillover to the circulation. We have formulated Nefecon as a capsule with an enteric coating that prevents dissolution or disintegration in the gastric environment. The capsules are designed to travel intact through the stomach and intestine until they reach the ileum. Upon reaching the ileum, chemical and physical changes, such as acidity, trigger the disintegration of the Nefecon capsules and the release of the capsule's contents.

Nefecon is designed to release a locally acting immunosuppressant in the ileum to provide peak drug concentrations to immune cells in the Peyer's patches.



As illustrated below, Nefecon capsules contain triple coated sustained-release beads that are designed to provide a potent exposure of the active ingredient when it is released in the ileum, which we believe will locally suppress IgA antibody formation in the Peyer's patches and impair the appearance of the immune complexes in the blood. Nefecon is designed to block the initial step in the development of IgAN by preventing the formation of immune complexes that would otherwise become trapped in the glomerular membranes of the kidney, thereby having a disease-modifying effect and preserving kidney function.

Nefecon has two components: an enteric-coated capsule to deliver a local immunosuppressant to the ileum and sustained release beads that provide highly targeted local exposure of the active ingredient.



Budesonide is an established, highly potent locally acting corticosteroid that can be used for local treatment with limited systemic side effects. This active ingredient was selected because of its local potency

and high metabolization by the liver, with 90% being cleared in first pass metabolism, resulting in the inactivation of a majority of the active ingredient before the substance reaches the systemic circulation. This high metabolism limits systemic immunosuppressive activity and avoids the significant side effects associated with systemic corticosteroids that are currently used off-label to treat IgAN, of which only 20% to 30% are cleared in first pass metabolism.

Nefecon is differentiated in its properties, profile and mechanism of action as compared to certain currently marketed products that deliver budesonide to the intestine. Uceris is formulated to deliver a 9 mg tablet of budesonide specifically to the colon for the treatment of ulcerative colitis. Entocort is formulated to deliver 3 mg capsules 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 capable of, delivering the required concentration of budesonide to the ileum to treat the cause of IgAN. 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, which may result in significant side effects. 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 designation in the United States and the European Union, which will provide marketing exclusivity for seven and ten years after approval, respectively. In December 2019, we received a positive opinion from the EMA's Paediatric Committee on the pediatric investigation plan for Nefecon for the treatment of IgAN. If the pediatric investigation plan is successfully completed, Nefecon, if approved, would be eligible for an additional two years of marketing exclusivity in the European Union, on top of the potential ten years of market exclusivity provided by orphan drug designation in the European Union.

Genkyotex's Product Candidates

Genkyotex's lead product candidate, setanaxib, or GKT831, targets inhibition of NOX 1 and NOX 4, which are major drivers of fibrogenesis in multiple organs. They produce reactive oxygen species, or ROS, and modulate signaling by oxidizing signaling proteins, which drive multiple inflammatory and fibrogenic pathways. Setanaxib has shown clinically relevant anti-fibrotic activity in a Phase 2 clinical trial in PBC, a fibrotic orphan disease, despite not achieving its primary endpoint. Based on its Phase 2 results, Genkyotex had interactions with the FDA during 2020 regarding the clinical development pathway for setanaxib in PBC, resulting in a confirmed regulatory pathway in the form of a pivotal and potentially registrational Phase 2/3 design incorporating higher dosing than that used in the Phase 2 trial, using alkaline phosphatase, or ALP, as a primary endpoint. The final design and protocol are subject to further feedback and commentary by the FDA. Genkyotex plans to initiate the Phase 2/3 trial in the second half of 2021.

Setanaxib is also being evaluated in a Phase 2 clinical trial initiated by researchers investigating type 1 diabetes and diabetic kidney disease, or DKD. A grant from the United States National Institutes of Health, or NIH, of $8.9 million was also awarded to Professor Victor Thannickal at 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 lung disease that results in fibrosis of the lungs. The core component of this program is a Phase 2 trial with setanaxib in patients suffering from IPF for which the enrollment of a first patient was announced in September 2020. In October 2020, setanaxib was granted orphan drug designation by the FDA, and in December 2020, setanaxib was granted orphan drug designation by the European Commission, in each case for the treatment of PBC.

Based on preclinical animal models, setanaxib has also shown promising results in combination with immunotherapies, specifically checkpoint inhibitors targeting PD-1. The studies have investigated the ability of setanaxib to affect cancer associated fibroblasts, or CAFs, which has resulted in publications of study results indicating that setanaxib might be used to reduce the negative effects of CAFs in certain tumors, including in head and neck cancer. Genkyotex is planning to initiate a Phase 2 proof of concept study in head and neck cancer in 2021, involving approximately 30 to 40 patients in order to further explore setanaxib's anti-fibrotic effects and characteristics related to CAFs.

Genkyotex also has a polyvalent platform, Vaxiclase, which is suited to the development of immunotherapies. Genkyotex has out-licensed all rights for the use of Vaxiclase as an antigen per se, or

GTL003, to Serum Institute of India Pvt. Ltd., or SIIL, the world's largest producer of vaccine doses, for the development by SIIL of cellular multivalent combination vaccines against a variety of infectious diseases.

Clinical Development of Nefecon

Initial Proof of Concept Observed in a Phase 2a Clinical Trial in IgAN Patients

In 2010, we completed a single-cohort, open-label Phase 2a clinical trial at three sites in Sweden. In this trial, 16 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 the presence of the 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 associated with a statistically significant and clinically meaningful effect on albuminuria, serum creatinine and eGFR.

The FDA utilizes the reported statistical measures when evaluating the results of a clinical trial, including statistical significance as measured by p-values, to evaluate the reported evidence of a product candidate's safety and efficacy. A result is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. The conventional method for determining the statistical significance of a result is known as the "p-value," which represents the probability that random chance caused the result (e.g., a p-value=0.05 means that there is a 5% probability that the difference between the control arm and the treatment arm is purely due to random chance). Generally, a p-value less than 0.05 is considered statistically significant and, if not otherwise specified, we have used this conventional standard to define statistical significance for the clinical trials and data presented in this prospectus.

Nefecon was observed to be well tolerated, with no serious adverse events reported. Adverse events reported in the clinical trial included abdominal pain, acne, nausea, sleep disturbances, depression and mood swings. Of the adverse events reported, 76% were classified as mild and 24% were classified as moderate. Of the adverse events reported, 56% were determined by the investigator not to be related to Nefecon. Three patients withdrew from the trial due to adverse events.

Confirmatory Proof of Concept Observed in a Phase 2b Clinical Trial in IgAN Patients

In 2015, we completed a double-blind, placebo-controlled clinical trial, known as NEFIGAN, in 150 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 the largest double-blind trial ever conducted with an investigational candidate in IgAN patients.

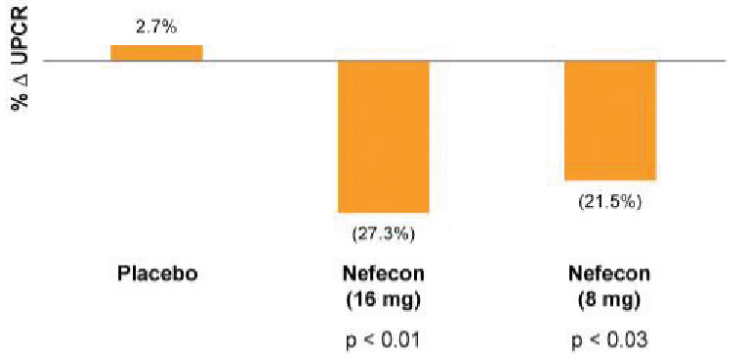
All patients with biopsy-confirmed IgAN were included in a run-in period of six months. During this period, patients were treated with RAS blockade therapies, including ACE inhibitors and ARBs. The objective of this run-in period was to ensure that patients were on an individually optimized and stable dose of RAS blockade therapy sustainable for the duration of the treatment period. The enrolled patients on a stable dose were then re-screened based on specific inclusion criteria, including, among other things, proteinuria and eGFR levels, in order to be randomized into the trial. The trial was initially designed to include 90 patients, based on an expected conversion ratio of 40% to 45% from enrollment in the run-in period to randomization into the trial. However, the actual conversion ratio was 70% to 75%, resulting in 150 patients being randomized, as optimization of RAS blockade therapies had less impact than initially expected. The patients were then randomized to receive 8 mg Nefecon, 16 mg Nefecon or placebo once a day for nine months. At the end of nine months, treatment was discontinued and the patients were observed for an additional three months.

The primary endpoint evaluated in NEFIGAN was mean reduction in proteinuria as measured by UPCR. As contemplated by the trial design, we conducted a predefined analysis after the first 90 patients had completed their nine-month treatment phase. This predefined analysis was conducted on 149 randomized patients in the trial who received at least one dose of Nefecon or placebo and underwent at least one post-dose efficacy measurement (one patient randomized into the trial was unable to swallow the capsule containing

the study drug). For those patients who had not yet completed the nine months in the trial, we conducted the predefined analysis using an industry-standard statistics approach, known as the Mixed-Effect Model Repeated Measure model, or MMRM. MMRM is a statistical technique that is often utilized by trial sponsors, where necessary, in data packages submitted to both the FDA and the EMA in cases where the full dataset is not available for analysis. This approach used the data from the completed cohorts to impute data for those not yet completed in order to arrive at statistically validated results that would have been expected to be observed had such individuals completed the full nine months of dosing.

The primary endpoint was achieved during this planned predefined analysis, and under the predefined protocol, no further analysis of the primary endpoint was to be conducted. In the interim analysis, patients in the placebo cohort exhibited an increase in proteinuria of 2.7%. Results from the 16 mg dose cohort, indicated that Nefecon was associated with statistically significant and clinically meaningful reductions in proteinuria. Results from the 16 mg dose cohort indicated that Nefecon was associated with a reduction in proteinuria of 27.3% ($p<0.01$). Based on these results, we selected 16 mg as the dose for our Phase 3 clinical trial. Patients in the 8 mg dose cohort also exhibited a reduction in proteinuria of 21.5% ($p<0.03$), but this reduction was not statistically significant for purposes of the predefined analysis. The total availability of p-value for this analysis was 0.025, or half of the typical 0.05, as it was designed as a one-sided test. This availability had no impact on the approach, as all numerical results can be doubled to achieve the typical 0.05 p-value test. As it was unknown as to whether the predefined analysis would achieve statistical significance, or whether a subsequent analysis of the complete population would be required, the alpha was split, resulting in a lower p-value of 0.0158 to define statistical significance rather than the conventional 0.025. Despite this higher hurdle for statistical significance, the predefined analysis met the endpoint.

In the interim analysis of the primary endpoint for NEFIGAN, 16 mg of Nefecon was associated with statistically significant and clinically meaningful reductions in UPCR compared to placebo in NEFIGAN at nine months.

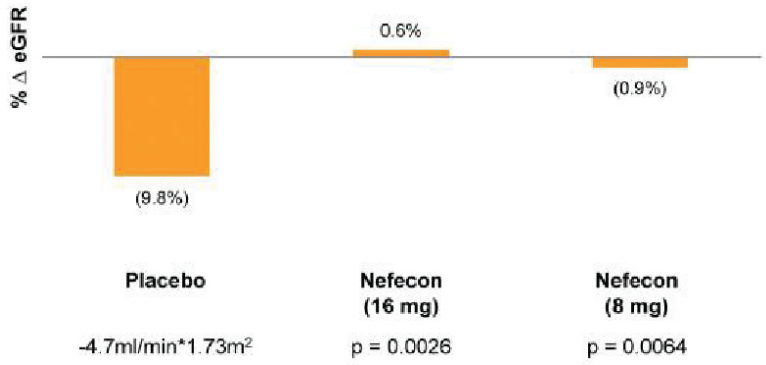


After all subjects had completed the trial, we analyzed secondary and tertiary endpoints, such as eGFR, based on the complete data set. We also performed an analysis of the full UPCR data. Results from this dataset conducted in accordance with the statistical plan indicated that patients from the 16 mg dose cohort exhibited a statistically significant and clinically meaningful reduction of 32.0% ($p=0.0005$) at 12 months, which was three months after the discontinuation of dosing. Results analyzed outside of the statistical plan indicated that patients from this cohort exhibited a reduction in proteinuria of 25.4% at nine months.

Key secondary endpoints, including change in 24-hour urine protein, urine albumin creatinine ratio, or UACR, 24-hour urine albumin and eGFR, were also met. As a measure of kidney function, statistically significant and clinically meaningful differences in eGFR between Nefecon and the placebo groups were observed. Patients in the placebo group exhibited a 9.8% decrease in eGFR, corresponding to -4.7 ml/min*1.73m^2, which reflects the worsening of kidney function during the nine months of placebo dosing, while eGFR was stabilized in Nefecon-treated patients. The 16 mg Nefecon cohort had an increase in eGFR of

0.6%, which reflected a difference from placebo of 10.4% (p=0.0026) and the 8 mg Nefecon cohort had a decrease in eGFR of 0.9% (p=0.0064, compared to placebo). The eGFR levels in patients that received the 16 mg Nefecon dose remained stable during the three-month follow-up period post treatment. In contrast, the placebo cohort, over the same time period, exhibited a continuous decline to 10.7% in eGFR levels compared to baseline, which represented a difference versus the 16 mg cohort of 11.4% (p=0.0134). Nefecon was associated with stabilization of kidney function during the trial, which supports our belief that Nefecon may have a disease-modifying effect.

Nefecon was associated with a stabilization of eGFR in NEFIGAN.



As illustrated in the table below, results observed in additional tertiary endpoints evaluated in NEFIGAN were consistent with the results observed in the primary endpoint of proteinuria reduction.

Change from baseline in proteinuria variables, p-creatinine and microhematuria proportion in NEFIGAN after nine months.

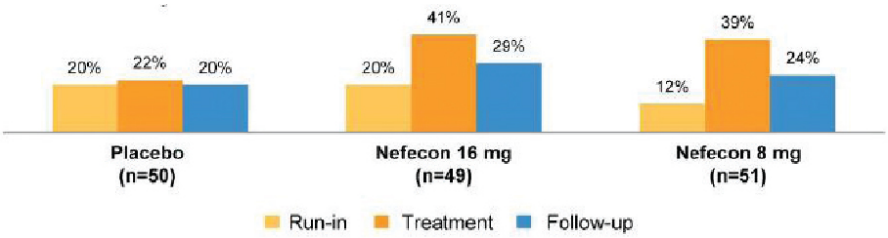
	9 Months		
	Placebo	Nefecon (16 mg)	Nefecon (8 mg)
UPCR (interim)	3%	(27%)	(22%)
Total 24-hour urine protein	1%	(30%)	(20%)
UACR	6%	(28%)	(14%)
Total 24-hour urine albumin	2%	(33%)	(18%)
P-Creatinine	7%	(2%)	(1%)
Microhematuria proportion	86%	63%	82%

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).

To collect safety data, we used solicited adverse event reporting in addition to the typical spontaneous adverse event reporting, which is known to result in some degree of overreporting of adverse events as compared to spontaneous adverse event reporting. In the trial, all patients completed a questionnaire with several questions related to potential steroid-related side effects and gastrointestinal side effects at every visit, including during the run-in and follow-up periods when no active drug was administered. As illustrated in the graphic below, approximately 20% of patients in both the placebo and treatment cohorts reported

corticosteroid-related side effects in the run-in period when no active drug was administered. This response data was consistent in the run-in, treatment and follow-up periods for the placebo cohort. An incremental 20% of patients reported side effects in the 8 mg and 16 mg treatment cohorts during the treatment period.

Summary of solicited corticosteroid-related adverse events observed in NEFIGAN.



Adverse events observed in NEFIGAN were consistent with those known to be associated with non-systemic corticosteroids such as budesonide. The most commonly reported adverse events in the treatment cohorts included nasopharyngitis, acne, joint swelling, cushingoid, insomnia, muscle spasms, dyspepsia, headache, peripheral edema, mood swings and hypertension. Of these events, 75.8% were categorized as mild, 22.6% as moderate and 1.6% as severe.

In the treatment cohorts, eight patients experienced serious treatment emergent adverse events: seven patients in the 16 mg group reported eight serious adverse events (aggravated condition, nephrotic syndrome, aortic dissection, deep vein thrombosis, menorrhagia, proteinuria, appendicitis and spinal pain) and one patient in the 8 mg group reported a serious adverse event (aggravated condition). In the placebo cohorts, three patients reported four serious adverse events (two events of proteinuria, sciatica and aggravated condition).

All serious adverse events in the treatment cohorts were determined by the investigator to be unrelated to Nefecon, except for one 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 one patient in the 8 mg treatment cohort with aggravation of renal condition, which was classified by the investigator as possibly being treatment-related. In the placebo cohort, two serious adverse events (proteinuria and aggravated condition) were classified by the investigator as possibly being treatment-related at the time when the safety results were blinded.

Patient discontinuations were higher among patients in the Nefecon 16 mg cohort as compared to the 8 mg cohort. Most of the patients who discontinued treatment experienced mild to moderate symptoms including, most frequently, acne and other transitory cosmetic side effects.

We believe that the results of the NEFIGAN trial support the further development of Nefecon for the treatment of IgAN. We discussed these results with the FDA in our End-of-Phase 2 meeting in January 2017 and, based on the FDA's positive feedback on the use of decrease in proteinuria at nine months as compared to baseline as a surrogate endpoint, we proceeded to initiate our Phase 3 clinical trial for Nefecon.

Phase 3 Clinical Development

Proteinuria as a Surrogate Marker for IgAN

In order to approve a drug, the FDA generally requires one or more clinical trials demonstrating that the product candidate meets an endpoint that represents a direct clinical outcome, such as survival, decreased pain or the absence of disease, which we refer to as a clinical endpoint. There are, however, exceptions where the FDA accepts the use of surrogate endpoints rather than clinical endpoints when evaluating a product candidate for approval. The FDA selectively allows the use of surrogate endpoints in clinical trials to permit a more rapid development and approval path of treatments for serious or life-threatening diseases. The FDA permits the use of such surrogate endpoints only if they are reasonably likely to predict clinical

benefit and constitute a clinical endpoint that can be measured earlier than irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability of alternative treatments or lack thereof. When the FDA accepts novel surrogate endpoints for approval in pivotal trials, the pivotal trials are required to be followed by confirmatory post-approval trials to verify the clinical benefit. For treatments related to chronic kidney disease, clinical trials have generally relied on clinical endpoints, such as time to dialysis or transplantation. Due to the significant expense associated with the large patient numbers and extended clinical trial duration required to adequately measure such clinical endpoints, few new therapeutic drug candidates have emerged over the past two decades to treat renal disease.

In 2012, the FDA and the American Society of Nephrology, or ASN, founded the Kidney Health Initiative, or KHI, with the goal of supporting research and innovation for the development of safe and efficacious treatments for kidney disease. We have participated in this initiative since 2014. In 2011, we funded a collaboration with Tufts University and the University of Utah to conduct a meta-analysis based on selected, well-defined clinical trials in IgAN patients in order to provide regulatory authorities with a data-driven basis to accept a novel surrogate marker for potentially accelerated approval of treatments for IgAN. The final analytical framework from this collaboration showed a robust statistical relationship between reduction in proteinuria and reduction of the risk of progression to ESRD. We believe that this framework, together with the research and analysis conducted by the KHI and spearheaded by ASN, the National Kidney Foundation and the FDA, led to the FDA's acceptance of an accelerated approval pathway at our End-of-Phase 2 meeting in January 2017. This change in regulatory approach was fundamental to our decision to commence the Phase 3 trial for Nefecon in IgAN.

Phase 3 Clinical Trial in IgAN Patients

We are currently conducting global pivotal Phase 3 clinical trial in IgAN, which we refer to as NefIgArd. NefIgArd is designed to evaluate reduction of the surrogate marker proteinuria as its primary endpoint, which is the same endpoint used in NEFIGAN. NefIgArd is a randomized, double-blind, placebo-controlled, two-part Phase 3 clinical trial. The first part, which we refer to as Part A, is a pivotal efficacy and safety trial that we expect to form the basis for submissions of an NDA to the FDA and an MAA to the EMA. The primary endpoint of Part A is the decrease in proteinuria in the first 200 randomized and dosed patients. In addition, a secondary endpoint of Part A is the difference in kidney function between treated and placebo patients as measured by eGFR. The secondary endpoint in Part A, which is a measure of eGFR over a nine-month period, is also expected to be informative of the primary endpoint of Part B, as discussed below. We reported positive topline results from Part A in the fourth quarter of 2020, where the trial met the primary and key secondary endpoint. On the basis of the positive Part A results, we intend to submit an NDA in the first quarter of 2021 for accelerated approval by the FDA followed by an MAA for conditional approval by the EMA in the first half of 2021.

The second part of NefIgArd, which we refer to as Part B, is a post-approval confirmatory trial designed to provide evidence of long term renal benefit. Following completion of enrollment in Part A in December 2019, we completed the enrollment of an additional 160 patients in January 2021, in order to power Part B to assess the difference in kidney function between treated and placebo patients as measured by eGFR over a two-year period from the start of dosing of each patient. Having successfully completed enrollment, we expect to report data from Part B in early 2023. Across both parts, NefIgArd will enroll a total of 360 patients and generate nine months of dosing data, as well as an aggregate of 15 months of follow-up data from Parts A and B. If approved, we intend to market and commercialize Nefecon in the United States as a treatment specifically designed to have a disease-modifying effect for IgAN by preserving kidney function and thereby avoiding progression to ESRD.

Originally, 450 patients with biopsy-confirmed IgAN were planned to be enrolled in NefIgArd at approximately 150 sites across 19 countries, including in North America, South America, Europe, Australia and Asia. In September 2019, however, the FDA accepted a protocol design modification that reduced the total trial size from 450 to 360 patients and shortened Part B to a fixed twelve-month follow-up period for each patient, which is expected to reduce the total trial timeline from approximately six years to under four years. In addition, this protocol design modification results in a significantly lower capital spend on the development of Nefecon as compared to the original protocol. Under the amended trial protocol, patients

on optimized ACE and ARB doses are randomized to receive either 16 mg Nefecon or placebo, once daily for nine months. Across both parts, NefIgArd will enroll a total of 360 patients and generate nine months of dosing data as well as an aggregate of 15 months of follow-up data from Parts A and B on all randomized patients.

Phase 3 Clinical Trial Results from Part A of NefIgArd

In November 2020, we reported positive topline results from Part A of NefIgArd. The trial met its primary objective of demonstrating a statistically significant reduction in the urine protein creatinine ratio, or UPCR, after nine months of treatment with 16 mg of Nefecon compared to placebo, with significant continued improvement at 12 months. The trial also met the key secondary endpoint showing a statistically significant difference in eGFR after nine months of treatment with Nefecon compared to placebo. Collectively the efficacy data from nine months, treatment with 16 mg of Nefecon indicated a significant and beneficial effect on key factors correlated to the progression to ESRD for IgAN patients.

Topline Results

The analysis set included 199 patients diagnosed with primary 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.

24-hour UPCR (Proteinuria) Data

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). Based on the trends from the data observed from those patients who had reached 12 months at the time of the database lock, the company would expect the proteinuria reduction versus baseline to end up between 42% and 48% at 12 months for the 16 mg treatment cohort.

eGFR Data

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 represented an absolute decline of 4.04 ml/min/1.73 m^2 in the placebo arm over nine months compared to a 0.17 ml/min/1.73 m^2 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, including no clinically relevant changes in weight, blood pressure or HbA1c in the treatment arm. There were also no severe infections, and overall, it was consistent with the known safety profile of Nefecon's active ingredient, Budesonide. The withdrawal rate in this trial was significantly less than what was seen in the Phase 2b NEFIGAN trial.

On the basis of the positive results of Part A of NefIgArd, we intend to submit an NDA in the first quarter of 2021 for accelerated approval by the FDA, followed by an MAA for conditional approval by the EMA in the first half of 2021.

The NefIgArd trial is continuing on a blinded basis with patients continuing in the observational Part B of the trial for a 12 month period following the completion of Part A. In January 2021, we completed the enrollment of all 360 patients in NefIgArd, which includes 200 patients previously enrolled in Part A and another 160 patients enrolled in Part B. Having successfully completed enrollment, we intend to report data from Part B in early 2023, subject to any further impact from the COVID-19 pandemic to our business.

Additional Trials

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.

Extended Dosing Trial

Subject to discussions with the relevant regulatory authorities, we intend to initiate an open-label dosing trial, or the NefXtend trial, in 2021 to provide safety and efficacy data for treatment with Nefecon, in addition to the nine-month treatment course documented in the NefIgArd trial. All patients enrolled in the NefXtend trial will be on active treatment, starting with 16 mg once daily for nine months of treatment, followed by a maintenance dose. We expect that the inclusion criteria would be similar to those used in the NefIgArd trial and the duration of the maintenance dose will be determined after regulatory feedback.

The continuation of the COVID-19 pandemic may impact our ability to initiate or complete either or both of these additional trials according to plan.

Commercialization Plan

We retain worldwide rights to Nefecon other than in Greater China and Singapore. If approved, we intend to commercialize Nefecon in the United States independently. We estimate the total U.S. market opportunity to be approximately $9.0 billion to $10.0 billion annually, based on our estimate of the prevalence of the disease in the United States and primary market research conducted by IQVIA that we commissioned to assess preliminary reimbursement levels perceived acceptable by U.S.-based payors. Such primary market research indicated that the estimated pricing of a course of treatment of Nefecon could range from $55,000 to $85,000 per patient. In that IQVIA market research, 68% of nephrologists also indicated that they would prescribe Nefecon for their IgAN patients within the first year of commercial availability. A majority of nephrologists also indicated that they would prescribe Nefecon as the first agent after, or in conjunction with, treatment with ACEs or ARBs. Payor feedback from our market research indicated that payors generally did not anticipate managing reimbursement of Nefecon in a different manner from other therapies approved for their indications.

Out of the estimated U.S. IgAN market, we intend to commercialize Nefecon in the United States with a targeted commercial infrastructure and with a primary focus on specialist physicians treating IgAN patients at risk of progressing to ESRD. We intend to launch Nefecon in the United States in the first half of 2022, if approved. We are currently focused on disease education, patient advocacy and market access, with the goal of facilitating access to Nefecon, if approved and commercialized, to the patients for which Nefecon can fulfill an unmet medical need. We believe this market can be addressed by a small and dedicated number of marketing and medical sales specialists, initially approximately 40, to efficiently cover the approximately 3,700 nephrologists focused on our target patient population in the United States. In the United States, we estimate that approximately 200 key opinion leaders have direct, first-degree contacts with 90% of practicing nephrologists in the IgAN community.

In 2019, we entered into an agreement with Everest, pursuant to which we granted Everest an exclusive license to develop and commercialize Nefecon for IgAN in Greater China and Singapore. Everest may exercise its option to develop Nefecon in additional indications subject to additional payment by Everest. We have recently reported positive topline data from the ongoing Phase 3 NefIgArd trial. If Nefecon is approved by Chinese regulatory authorities, we expect to achieve commercial access to the Chinese market could be achieved in 2024, which potentially positions Nefecon to be the first approved medication for IgAN in China. In other key territories such as Europe, we intend to commercialize Nefecon through either a broad regional partnership or on a country-by-country basis.

Setanaxib and Nefecon for Primary Biliary Cholangitis

We are exploring applications of setanaxib and Nefecon for other autoimmune diseases in which it may have therapeutic potential such as primary biliary cholangitis, or PBC, a progressive and chronic autoimmune disease of the liver. Based on available Phase 2 clinical data and recent Phase 1 data, combined with interactions with the FDA related to setanaxib, we presently favor proceeding with setanaxib in this indication and plan to launch a Phase 2/3 trial in the second half of 2021. We believe that setanaxib is differentiated from other approved or late stage development candidates in PBC, due to its effect on fibrosis, inflammation and significant impact on fatigue, as seen in the Phase 2 trial. However, we continue to explore stand alone or combination therapies involving Nefecon in this indication, as there are currently no approved therapies that specifically address the autoimmune response that is believed to drive PBC or the

inflammatory consequences of the autoimmune response. Nefecon is designed to deliver high peak concentrations of the local immunosuppressant budesonide to the intestine, where it is then transported directly to the liver in order to locally suppress the autoimmune response associated with PBC and counteract the inflammation resulting from increased and toxic levels of bile acid. 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 increased bile acid 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 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. Despite adequate dosing of UDCA, approximately one-third of PBC patients do not respond adequately and are at risk of requiring liver transplant. Despite showing improvements in liver values in the blood, Ocaliva has not been proven in clinical testing to delay or avoid the need for liver transplant. Although systemic corticosteroids have been shown to alleviate PBC symptoms, their adverse event profile limits their treatment potential.

Our Solution

Setanaxib is our favored drug candidate to pursue in PBC. NOX inhibitors are a fairly new drug class focused on inhibiting the overproduction of ROS, which can drive fibrogenesis across multiple organs. Based on earlier Phase 2 data and recent positive Phase 1 data, we plan to launch a pivotal and potentially registrational Phase 2/3 trial in PBC in the second half of 2021. We believe that setanaxib is differentiated from other approved or late stage development candidates in PBC, due to its effect on fibrosis, inflammation and significant impact on fatigue, as seen in the Phase 2 trial.

In the Phase 2 trial concluded in 2019, setanaxib did not reach its primary endpoint; however, it showed clinical activity and 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 is well tolerated at the doses tested, with no safety signal or dose-limiting toxicity being identified. Based on this positive data, Genkyotex plans to initiate a Phase 2/3 trial in

PBC in the second half of 2021, incorporating higher dosing than that used in the Phase 2 trial and using alkaline phosphatase, or ALP, as a primary endpoint. The final design and protocol are subject to further feedback and commentary by the FDA.

This platform also has several potential applications across orphan indications, focusing on anti-fibrotic and anti-inflammatory applications. Setanaxib is the lead compound, complemented by a research effort focused on developing follow up compounds. Potential indications include PBC, PSC, IPF, NASH and various kidney indications with a fibrotic component. We also intend to explore oncology indications involving fibrotic components such as CAFs and head and neck cancer using setanaxib administered with checkpoint inhibitors to address tumor drug resistance related to fibroblasts. To this end, Genkyotex plans to initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021, which will study administration of setanaxib in conjunction with immunotherapy targeting CAFs.

We also continue to explore application of Nefecon in PBC, as based on current knowledge of PBC's pathophysiology, we believe that targeted exposure to budesonide in the liver may counteract the original autoimmune response that is believed to drive PBC, as well as the inflammation resulting from increased and toxic levels of bile acid. In addition, while historical trials have shown that systemic corticosteroids may alleviate symptoms and improve biochemical and histologic parameters, no targeted immunosuppressive anti-inflammatory therapy is currently approved for PBC in the United States or Europe. Nefecon is designed to deliver high peak concentrations of budesonide to the intestine that is then transported directly to the liver, where it can have a local anti-inflammatory effect to reduce the inflammation associated with PBC, while minimizing systemic exposure and reducing systemic corticosteroid-related adverse events. We believe that Nefecon can address the significant unmet medical need to improve outcomes for PBC patients as a second line therapy.

Budenofalk for Autoimmune Hepatitis

We have exclusively in-licensed Budenofalk 3 mg oral capsules for the U.S. market from 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 during 2020, but additional interaction is required before establishing any definitive clinical development plans. In these discussions with the FDA, if appropriate, we intend to share the data we obtained pursuant to the license agreement with Falk Pharma to support seeking approval of Budenofalk for AIH in the United States through the Section 505(b)(2) abbreviated approval pathway. If there is limited added value perceived by the FDA with regards to the Budenofalk data related to a regulatory pathway, we will need to assess whether to proceed with Budenofalk or alternatively Nefecon utilizing the Section 505(b)(2) pathway. Without yet having had any discussions with the FDA in this regard, we believe that the time and effort under such a scenario might be identical, irrespective of whether we elect to proceed with Budenofalk or Nefecon.

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 modality 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

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 benefit. We believe that Budenofalk can 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 Medicines

In 2019, we entered into a license agreement with Everest Medicines, or 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.

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. Additionally, Everest is required to pay us aggregate milestone payments of up to $106.0 million upon the achievement of specific clinical, regulatory and commercial milestones. Of the milestone payments described above, a $5.0 million milestone payment from Everest was triggered upon approval of Everest's IND in China in December 2019. 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.

Genkyotex Out-licensing Agreements

Through our acquisition of a controlling interest in Genkyotex, we became a party to a license agreement with Serum Institute of India Pvt. Ltd., or the SIIL, the world's largest producer of vaccine doses, pursuant to which we granted SIIL the use of Vaxiclase as an antigen per se, or GTL003, for the development of cellular multivalent combination vaccines against a variety of infectious diseases. In 2018, Genkyotex and SIIL entered into a revised agreement expanding the territories from emerging pharmaceutical markets to certain developed world territories, including the U.S., Canada, E.U. member states, and the U.K.

Since the beginning of the agreement, Genkyotex has received a total of $2.1 million in upfront and extension payments and from the achievement of a pre-specified development milestone in November 2016. According to the terms of the initial agreement, Genkyotex is eligible to receive $57 million in milestone payments. Following the expansion of the agreement to the developed world territories, Genkyotex becomes eligible to receive an additional €100 million, bringing the overall agreement to approximately €150 million in upfront payment, development and commercial milestones. Genkyotex is also eligible to receive single digit royalties on any future sales.

Manufacturing

We rely on third parties to manufacture Nefecon. We have an agreement with a third-party vendor to produce drug substance and drug product for Nefecon for our 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, but we do not have any formal agreements at this time to cover commercial 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 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, if approved, along with any other product candidates that we successfully develop and commercialize, will compete with approved treatment options, including off-label therapies, and new therapies that may become available in the future. Key considerations that would 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.

While there are no approved therapies for the treatment of IgAN, we are aware that other companies are developing product candidates for this indication, including two product candidates in Phase 3 clinical development. Omeros Corporation is developing narsoplimab, a monoclonal antibody administered through intravenous infusion and Travere (previously Retrophin) is developing sparsentan, an orally-administered small molecule. Chinook has also recently announced their intention to start a Phase 3 trial in 2021 with an orally administered small molecule. In addition, we are aware of product candidates in Phase 2 clinical development. Alnylam is developing cemdisiran, an investigational RNAi therapeutic, Merck KGaA is developing atacicept, a recombinant protein, which has recently been out-licensed to Vera Therapeutics and Novartis is developing LNP023, an orally-administered small molecule and have announced that they plan to start a Phase 3 trial in 2021. Chinook Therapeutics also announced they intend to start a Phase 3 trial of a small orally delivered molecule in 2021. Further, we are aware that Visterra has started a dose-finding Phase 2 trial with a systemic B-cell inhibitor, and that open label Phase 2 trials recently were announced by DiaMedica Therapeutics Inc, Aravive, Inc and Ionis Pharmaceuticals Inc. All of these trials use either intravenous infusion or subcutaneous injection as mode of administration. In addition, Apellis Pharmaceuticals and Reata Pharmaceuticals have conducted smaller open-label Phase 2 clinical trials but have not yet announced any intention to proceed with further development activities in IgAN. We are also aware of several therapies that are used off-label for the treatment of IgAN, including a variety of systemic immunosuppressive agents, including systemic corticosteroids like prednisone, prednisolone and methylprednisolone.

With respect to PBC, UDCA, a generic drug, and obeticholic acid, marketed as Ocaliva by Intercept Pharmaceuticals, are the only FDA-approved treatments for PBC. Additionally, we are aware that other companies are developing product candidates with pharmacologies distinct from Nefecon and setanaxib for this indication, the most advanced being peroxisome proliferator-activating receptor, or PPAR, agonists in Phase 3 clinical development by Cymabay Therapeutics and GENFIT. Intercept Pharmaceuticals and Zydus Pharmaceuticals also have projects exploring PPAR agonists but are in Phase 2 development. Gilead and Novartis are potentially continuing their farnesoid X receptor, or FXR, agonists and are in Phase 2 clinical development. Additionally, systemic corticosteroids, like prednisone, have been shown to alleviate symptoms associated with PBC but is 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 under Phase 2 clinical development by Novartis and a repurposed oral anti-inflammatory small molecule under Phase 2 clinical development by TaiwanJ Pharmaceuticals. The standard of care 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. 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. 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 European Union, 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 three patent families covering various aspects of the setanaxib asset derived from three 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. There are seven further patent families that cover other NOX inhibitors and their use. As these 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.

The vaccine patent estate is a combination of licensed, wholly owned and jointly owned patent families. This estate stems from the French company Genticel S.A., or Genticel, with which Genkyotex entered into a strategic combination. The vaccine technology is based on technologies from Institut Pasteur and Genticel. Later, Genticel entered into a partnership, also covering licenses to technology controlled by Genticel, with the Serum Institute of India, Pvt. Ltd. or SIIL. The partnership with the SIIL was continued and re-negotiated after the Genticel/Genkyotex strategic combination. The vaccine technology covers certain immune-cell targeting and immune system stimulating methods and delivery of certain antigens to antigen presenting cells. The most recent patent family, co-owned by Genkyotex and SIIL, has a projected expiry date in 2035.

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 European Commission following a positive opinion provided by the EMA through the MAA process for a drug falling within the scope of the Centralized procedure or by a national Competent Authority through other MAA processes (National Procedure, Mutual Recognition or Decentralized procedure) before they may be legally marketed in the European Union. 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 U.S. 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;
- 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 is 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.

Section 505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of drugs previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA.

Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This type of application permits reliance for such approvals on literature or on an FDA finding of safety, effectiveness or both for an approved drug product. As such, under Section 505(b)(2), the FDA may rely, for approval of an NDA, on data not developed by the applicant. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for the new indication sought by the 505(b)(2) applicant.

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 disease 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 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.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, which is commonly referred to as Brexit. Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

European Union Regulation for Drug Development and Registration

Preclinical and Clinical Development

In the European Union, 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 European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. The Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. Although the Regulation entered into force on June 16, 2014, it will not be applicable until six months after the full functionality of the IT portal and database envisaged in the Regulation is confirmed. This is not expected to occur until the second part of 2020 and may incur further delays. Until then the Clinical Trials Directive 2001/20/EC will still apply.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected

serious adverse reactions, or SUSARs, to the investigated drug that occur during the clinical trial have to be reported to the NCAs and ECs of the Member States where the clinical trial is conducted.

European Union Drug Review and Approval

In the European Economic Area, or EEA (which is currently still comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein, with the United Kingdom having left the European Union on January 31, 2020), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. Marketing Authorizations may be granted either centrally (EU MA) or nationally (National MA).

The EU MA is issued centrally by the European Commission through the Centralized Procedure, based on the opinion of the CHMP of the EMA. It is valid throughout the entire territory of the European Union and is used by Norway, Iceland and Liechtenstein as a basis to adopt corresponding authorizations for their territory. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs are issued nationally by the competent authorities of the Member States of the European Union and Norway, Iceland and Liechtenstein and only cover their respective territory. National MAs are available for products not falling within the mandatory scope of the Centralized Procedure. We do not foresee that any of our current product candidates will be suitable for a National MA as they fall within the mandatory criteria for the Centralized Procedure. Therefore, our product candidates should be approved through EU MAs.

Under the above-described procedures, before granting the MA, the EMA makes an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Also, pursuant to Regulation (EC) No 1901/2006, all applications for marketing authorization for new medicines must include the results of studies as described in a pediatric investigation plan, or PIP, agreed between the EMA and the applicant, unless the medicine is exempt because of a deferral or waiver. In case of no waiver or deferral, applicants can request that a PIP compliance check is carried out before submitting a marketing-authorization application. Alternatively, a compliance check will be carried out as part of the validation of the application but this may delay the validation phase. The applicant and the EMA may, where such a step is adequately justified, agree to modify a pediatric investigation plan to assist validation. Modifications are not always possible; may take longer to agree than the period of validation permits; and may still require the applicant to withdraw its marketing authorization application and to conduct additional non-clinical and clinical studies.

Orphan Drugs

In the European Union, Regulation (EC) No 141/2000, as amended, states 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 affecting not more than five in ten thousand persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and
- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union 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 an EU 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 drug. 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, among other things, 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 drug 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 European Commission 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.

Regulation (EC) No 847/2000 lays down definitions of the concepts ‘similar drug’ and ‘clinical superiority’. Other incentives available to orphan drugs in the European Union 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.

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 U.S. 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 European Union 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.

The European Commission has issued a proposal for health technology assessment building on efforts of Member States for common health technology assessments on a voluntary basis under the umbrella of the

European Network for Health Technology Assessment. The proposal provides for the mandatory use by Member States of joint clinical assessments conducted at EU level which is considered controversial. It is uncertain if the proposed legislation will be adopted. Health technology assessments are used by most Member States to inform reimbursement decisions. The proposed legislation, if adopted may have an impact on health technology assessment and reimbursement decisions taken at national level.

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.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the outgoing Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole", and increased the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the United States Supreme Court reversed the Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" funding. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. It is also unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

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, including the BBA, will stay in effect through 2030 unless additional Congressional action is taken. The CARES Act suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. Additionally, on January 2, 2013, 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 U.S. Congressional inquiries 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. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. Although a number of these, and other measures may require additional authorization to become effective, and it is unclear whether President Joseph Biden will work to reverse these measures or pursue similar policy initiatives, 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 also expect that additional state and federal healthcare reform measures will be adopted in the future, particularly as a result of the recent presidential election. In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic.

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

- federal civil and criminal false claims laws, including the FCA, which can be enforced by private individuals through civil whistleblower or qui tam actions, and civil monetary penalty laws, which prohibit individuals and entities from, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willingly falsifying, concealing or covering up a material fact or making materially false statements, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items, or services. A person or entity does not have to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which imposes certain requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their business associates, which are individuals and entities that perform functions or activities on behalf of covered entities that involve protected health information as well as their covered subcontractors, relating to the privacy, security and transmission of protected health information; HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of drugs for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians (as defined by such law) and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers, including physician assistants and nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives; 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 U.S. 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 U.S. 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. In March 2020, the California State Attorney General proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in adopting regulations, the California State Attorney General will commence enforcement actions against violators beginning July 1, 2020. 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 U.S. 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

As of September 30, 2020, we had 34 full-time employee equivalents. None of our personnel are covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

As the COVID-19 pandemic continues, we have followed the recommendations of domestic public health authorities calling for employees to work from home if possible. We have supported and implemented a work-from-home policy for our employees, while the office remains open for ongoing necessary activities as permitted by relevant government orders. As our workforce is accustomed to working from home, we have not seen any significant impact of remote working arrangements to our operations to date.

Facilities

Our principal office is located at Kungsbron 1, C8, SE-111 22 Stockholm, Sweden. We lease approximately 4,585 square feet of office space at this location, under one lease agreement, and our leases for this location extend through May 2022. 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.

Legal Proceedings

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. There are currently no claims or actions pending against us that, in the opinion of our management, are likely to have a material adverse effect on our business.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name and position of each of our executive officers, directors and director nominee, as well as their respective ages as of December 30, 2020.

Name	Age	Position(s)
Executive Officers:		
Renée Aguiar-Lucander	58	Chief Executive Officer
Fredrik Johansson	43	Chief Financial Officer
Richard Philipson, M.D.	56	Chief Medical Officer
Andrew Udell	50	Vice President, North America Commercial
Frank Bringstrup, M.D.	61	Vice President Regulatory Affairs
Katayoun Welin-Berger, Ph.D.	52	Vice President Operations
Directors:		
Elmar Schnee[2]	61	Chairman of the Board of Directors
Hilde Furberg[1]	62	Director
Lennart Hansson, Ph.D.[1][2]	64	Director
Diane Parks[2]	68	Director
Molly Henderson[1]	50	Director

(1) Member of audit committee

(2) Member of remuneration committee

Executive Officers

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 is the Chairman of the Board of Directors of Exenta Inc. 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 Vice President, North America Commercial since January 2019. 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.

Katayoun Welin-Berger, Ph.D. has served as our Vice President Operations since January 2020. Prior to that, from January 2014 to December 2019, Dr. Welin-Berger served as Vice President of Operations at BioGaia AB. Prior to that, she served in various development and operations roles at AstraZeneca. Dr. Welin-Berger received her Ph.D. in Pharmacy from Uppsala University in Sweden.

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. Since August 2014, 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. Since April 2017, Mr. Schnee has 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. In addition, he currently serves on the boards of directors of five privately-held life sciences companies, Damian Pharma AG, Noorik Biopharmaceuticals AG, Advanz Plc, Kuste Biopharma 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 Tappin AS, PCI Biotech Holding ASA and OncoZenge. Ms. Furberg previously served on the board of directors of CombiGene, 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.

Lennart Hansson, Ph.D. has severed as a member of our board of directors since May 2009. Dr. Hansson served as Head of Life Science at Industrifonden from 2008 to 2016. Dr. Hansson has also held various leadership roles at KabiGen AB, Symbicom AB, AstraZeneca, Biovitrum AB and as CEO of Arexis AB. Dr. Hansson serves as the chairman of the board of directors of Sixera Pharma AB, Cinclus AB and Ignitus AB. Dr. Hansson serves as a member of the Board of Directors of InDex Pharmaceuticals Holding AB (publ), and Medivir AB (publ). Dr. Hansson received his Ph.D. in Genetics from the University of Umea.

We believe that Dr. Hansson is qualified to serve on our board of directors because of his experience, qualifications, attributes and skills, including his broad experience from leading positions within pharmaceutical development and business development in both 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 U.S. 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 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. Since October 2020, Ms. Henderson has served as the Chief Financial Officer of UroGen, Ms. Henderson has also served as the Chief Financial Officer, Executive Vice President of Advaxis, Inc. from June 2018 to September 2020 and the Chairman and partial owner of WUJU Foods, LLC since August 2016. Prior to her current roles, Ms. Henderson was Chief Financial Officer at Iovance Biotherapeutics, Inc. (formerly Lion Biotechnologies, Inc.) from June 2015 through August 2016. From 2013 to 2015, Ms. Henderson advised start-up companies in Switzerland. Earlier in her career, 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.

Family Relationships

There are no family relationships among any of our executive officers or directors.

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 March 3, 2020 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. For an overview of our corporate governance principles, see the section titled "Description of Share Capital and Articles of Association—Differences in Corporate Law."

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 at least two directors 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.

See "Description of Share Capital and Articles of Association—Articles of Association—Board of Directors."

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 Lennart Hansson, and assists the board of directors in overseeing our accounting and financial reporting processes. Molly Henderson serves as chairperson of the audit committee.

The audit committee consists exclusively of members of our board who are financially literate, and Lennart Hansson 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 will be governed by a charter that complies with Nasdaq rules.

The audit committee's responsibilities will 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.

Remuneration Committee

Our remuneration committee consists of Diane Parks, Elmar Schnee and Lennart Hansson. Elmar Schnee serves as chairman of the remuneration committee.

The Remuneration committee's responsibilities will include:

- identifying, reviewing and proposing policies relevant to the compensation and benefits of our directors and 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.

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 2020 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 2021 annual general meeting, the nomination committee consists of Patrick Sobocki (appointed by Stiftelsen Industrifonden), Spike Loy (appointed by BVF), Karl Tobieson (appointed by Linc AB) and Elmar Schnee (chairman of our board of directors). Patrick Sobocki 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.

Code of Business Conduct and Ethics

Prior to the completion of the global offering, we intend to adopt a Code of Business Conduct and Ethics applicable to our and our subsidiaries' employees, independent contractors, executive officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions.

Compensation of Executive Officers and Directors

For the year ended December 31, 2020, the aggregate compensation accrued or paid to the members of our board of directors and executive officers serving during the year was SEK 17.3 million.

During and for the year ended December 31, 2020, 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 remuneration committee and determined by our board as a whole, 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. As of December 31, 2019, warrants to purchase up to an aggregate of 856,586 common shares were outstanding. The exercise price for these warrants is SEK 74.30 per share. The warrants issued under the 2018 Plan may be exercised from January 1, 2022 until March 31, 2022, or such earlier date as may be determined in accordance with the terms of the Program. All exercise prices must be paid in cash at the time of subscription. The 2018 Program is closed and no further warrants may be issued under this program.

Pursuant to the terms of the 2018 Program, warrantholders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain corporate changes. Events giving rise to an adjustment include, among other things, the issuance of bonus shares, a reverse share

split or share split, issuance of new convertible bonds or warrants and payment of dividends in the form of our equity. Additionally, in the event of a "change of control event" as defined in the 2018 Program, each warrantholder will be permitted to exercise all of his or her warrants regardless of the fact that such warrants would otherwise only be exercisable during the specified subscription period. Any warrants not exercised prior to the change in control event are forfeited.

We may amend the 2018 Program at any time with respect to changes which are required by legislation, court decisions, or decisions by public authorities, or, if in our opinion, any such actions are appropriate or necessary and the rights of any warrantholders are in no way prejudiced without the consent of the affected holder.

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. As of December 31, 2019, warrants to purchase up to an aggregate of 422,500 common shares were outstanding. The exercise price for these warrants is SEK 74.50 per share. The 2019 Program is limited to no more than 25 participants and includes caps on the number of warrants that may be issued to a consultant or certain categories of consultants. The warrants issued under the 2019 Plan may be exercised from October 1, 2022 until December 31, 2022, or such earlier date as may be determined in accordance with the terms of the Program. All exercise prices must be paid in cash at the time of subscription. The 2019 Program has concluded, and no further warrants may be issued under this program.

Pursuant to the terms of the 2019 Program, warrantholders are entitled to an adjustment of the number of warrants issued and/or the exercise price applicable in the event of certain corporate changes. Events giving rise to an adjustment include, among other things, the issuance of bonus shares, a reverse share split or share split, issuance of new convertible bonds or warrants and payment of dividends in the form of our equity. Additionally, in the event of a "change of control event" as defined in the 2019 Program, each warrantholder will be permitted to exercise all of his or her warrants regardless of the fact that such warrants would otherwise only be exercisable during the specified subscription period. Any warrants not exercised prior to the change in control event are forfeited.

We may amend the 2019 Program at any time with respect to changes which are required by legislation, court decisions, or decisions by public authorities, or, if in our opinion, any such actions are appropriate or necessary and the rights of any warrantholders are in no way prejudiced without the consent of the affected holder.

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 September 30, 2020, options to purchase up to an aggregate of 1,089,000 common shares were outstanding. Eligible participants in the ESOP 2020 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 2020 annual general meeting and the date of the 2021 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 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 U.S. sub-plan. Options granted under the U.S. 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 U.S. sub-plan will be classified as "non-qualified stock options" under U.S. federal tax laws. No options granted under the U.S. 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 U.S. 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, we were permitted to grant up to 70,000 shares in the form of Share Awards. As of September 30, 2020, 51,399 Share Awards had been granted. The Share Awards are subject to performance-based vesting, and vest in three equal annual installment based on the performance of our share price during the relevant measurement period, calculated in accordance with the terms of the LTIP 2019, subject to the board member's continued service through the applicable vesting date. Share Awards granted under the LTIP 2019 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 2019, all outstanding Share Awards will vest in their entirety upon the completion of such transaction and the Company shall have a right to repurchase all such Share Awards for fair market value.

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 September 30, 2020, 31,371 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.

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.

RELATED PARTY TRANSACTIONS

Within this section, we have calculated the dollar amounts using the historical exchange rate as of the date of each transaction. Other than compensation arrangements described in "Management" elsewhere in this prospectus, since January 1, 2017, we have engaged in the following 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

In connection with the global offering, 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. This policy will become effective on the date on which the registration statement of which this prospectus is part is declared effective by the SEC.

PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common shares as of December 30, 2020, and following the completion of the global offering for:

- each beneficial owner of 5% or more of our outstanding common shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

We have granted the underwriters an option to purchase 675,000 common shares (including common shares in the form of ADSs) at the public offering price less underwriting discounts and commissions.

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 September 30, 2020. Percentage ownership calculations are based on 49,941,584 common shares outstanding as of September 30, 2020.

The percentage of shares beneficially owned after completion of the global offering is based on 54,441,584 common shares outstanding after the global offering, including 4,500,000 common shares (including common shares in the form of ADSs) issued in connection with the global offering. The table assumes no exercise of the underwriters' option to purchase additional common shares (including common shares in the form of ADSs).

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. Beneficial ownership of shares reflected in the table below also includes shares in the form of ADSs. The information is not necessarily indicative of beneficial ownership for any other purpose.

As of December 30, 2020, 13,752,340 common shares, representing 27.54% of our issued and outstanding shares, were held by 20 U.S. shareholders of record.

Except as otherwise indicated in the table below, addresses of the directors, executive officers and named beneficial owners are in care of Calliditas Therapeutics AB, Kungsbron 1, C8, SE-11 22, Stockholm, Sweden.

Name of beneficial owner	Number of Shares Beneficially Owned Before Global Offering	Percentage of Shares Beneficially Owned	
		Before Offering*	After Offering*
5% or Greater Shareholders:			
BVF Partners LP[1]	6,331,562	12.68%	11.91%
Stiftelsen Industrifonden[2]	5,772,995	11.56%	10.86%
Linc AB[3]	4,836,108	9.68%	9.10%
Handelsbanken Fonder AB[4]	2,634,684	5.28%	4.96%
Executive Officers and Directors:			
Renée Aguiar-Lucander[5]	412,000	0.86%	0.77%
Fredrik Johansson[6]	18,250	0.04%	0.03%
Richard Philipson, M.D.	—	*	*
Andrew Udell	—	*	*
Frank Bringstrup, M.D.	—	*	*
Katayoun Welin-Berger	—	*	*
Elmar Schnee	—	*	*

Name of beneficial owner	Number of Shares Beneficially Owned Before Global Offering	Percentage of Shares Beneficially Owned	
		Before Offering*	After Offering*
Hilde Furberg[7]	44,750	0.09%	*
Lennart Hansson, Ph.D.[8]	12,000	0.03%	*
Diane Parks	—	*	*
Molly Henderson	—	*	*
All current directors and executive officers as a group (12 persons)	487,000	0.98%	0.92%

* Represents beneficial ownership of less than one percent.

(1) Consists of 5,772,995 common shares, held directly by Stiftelsen Industrifonden (of which 233,197 are subject to a call option exercisable by the holder). David Sonnek 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.

(2) Consists of 4,836,108 common shares, held directly by Linc AB and Bengt Julander. Bengt Julander is the Chief Executive Officer of Linc AB and, as a result, may be deemed to have voting and dispositive power with respect to the shares reported in the table above. The address of Linc AB is Cronhamns gata 6A, 185 32 Vaxholm, Sweden.

(3) Based on shareholder voting information in connection with our extraordinary general meeting as of March 3, 2020 and consists of (i) 1,105,041 common shares held by Biotechnology Value Fund, L.P., (ii) 871,328 common shares held by Biotechnology Value Fund II, L.P., and (iii) 154,860 common shares held by Biotechnology Value Trading Fund, OS L.P., but does not reflect an unknown number of warrants granted by Industrifonden and Investinor AS to purchase additional common shares of the Company exercisable within 60 days of September 30, 2020. BVF Partners L.P. is the general partner of all three funds referenced in subclause (i) above, and may be deemed to beneficially own the shares listed above that are beneficially owned by such funds. 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.

(4) Consists of 2,634,684 common shares, held directly by Handelsbanken Fonder AB. Magdalena Wahlqvist Alveskog is the Chief Executive Officer of Handelsbanken Fonder AB and, as a result, may be deemed to have voting and dispositive power with respect to the shares reported in the table above. Voting and dispositive power with respect to such shares are made by the board of directors of Handelsbanken Fonder AB, of whom there are three or more and none of whom individually has the power to direct such decisions. The address of Handelsbanken Fonder AB is SE-10670 Stockholm, Sweden.

(5) Consists of 412,000 common shares.

(6) Consists of 18,250 common shares.

(7) Consists of 44,750 common shares.

(8) Consists of 12,000 common shares.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

Introduction

Set forth below is a summary of certain information concerning our share capital as well, as a description of certain provisions of our articles of association and relevant provisions of the Swedish Companies Act. The summary below contains only material information concerning our share capital and corporate status and does not purport to be complete and is qualified in its entirety by reference to our articles of association and applicable Swedish law. Further, please note that as a holder of ADSs, you will not be treated as one of our shareholders and will not have any shareholder rights.

General

We were founded in accordance with Swedish law 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. Our common shares have been listed for trading on Nasdaq Stockholm since June 29, 2018 under the ticker “CALTX.” Our ADSs have been listed for trading on The Nasdaq Global Select Market since June 5, 2020 under the ticker "CALT."

We have two wholly owned subsidiaries, located in Sweden and the United States. The U.S. subsidiary is Calliditas Therapeutics Inc. and the Swedish subsidiary is Nefecon AB. We have two additional subsidiaries, Genkyotex S.A., located in France, and Genkyotex Suisse S.A., located in Switzerland.

Our registered office is located at Kungsbron 1, C8, SE-111 22, Stockholm, Sweden, and our telephone number is +46 (0) 8 411 3005. Our website address is www.calliditas.com. We have included our website address in this prospectus solely as an inactive textual reference. The information contained on or accessible through our website is not incorporated by reference into this prospectus.

Common Shares

Upon the closing of the global offering, up to 4,500,000 common shares will be issued, each with a quota (par) value SEK 0.04, entailing an increase of our share capital of up to SEK 180,000. All of our outstanding common shares have been validly issued, fully paid and non-assessable, and are not redeemable and do not have any preemptive rights other than under the Swedish Companies Act as described below. In accordance with our articles of association, all of the common shares are in one class of shares, denominated in SEK. As of September 30, 2020, we had issued and outstanding 49,941,584 common shares.

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

There were no special terms or installment payments for any of the transactions listed above. There have been two changes in voting rights since we were listed on Nasdaq Stockholm in 2018 through 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, and the IPO 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. During the period as a listed company, there has not been any reduction of amount of share capital.

At the 2020 annual general meeting held on June 25, 2020, our shareholders resolved that for the period until the 2021 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 20% 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. 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 2020 annual general meeting, we had 47,938,408 shares outstanding. As such, under the authorization, the board of directors is authorized to issue up to 11,984,602 new shares.

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 five members, with no deputy members.

Rights Attached to Shares

All of the common shares have equal rights to our assets and earnings, and are entitled to one vote at the general meeting. At the general meeting, every shareholder may vote to the full extent of their shares held or represented, without limitation. Each common 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 and have equal rights to dividends and any surplus capital upon liquidation. 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.

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 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 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 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 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	*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.

advertisement in a Swedish newspaper, the Swedish Official Gazette, by press release, and on the company's website.	
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. For discussion on our ADSs and ADS holder rights, see "Description of American Depositary Shares" in this prospectus.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

Citibank, N.A. is the depositary bank for the American Depositary Shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. American Depositary Shares are frequently referred to as "ADSs" and represent ownership interests in securities that are on deposit with the depositary bank. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank Europe plc, located at 1 North Wall Quay, Dublin 1, Ireland.

We have appointed Citibank as depositary bank pursuant to a deposit agreement. A copy of the deposit agreement has been filed with the SEC under cover of a registration statement on Form F-6 (File No. 333-238726). You may obtain a copy of the deposit agreement from the SEC's website (www.sec.gov). Please refer to Registration Number 333-238726 when retrieving such copy.

We are providing you with a summary description of the material terms of the ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

Each ADS represents 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.

Issuance of ADSs upon Deposit of Common Shares

After the completion of the global offering, the common shares underlying the ADSs that are being offered for sale in the U.S. offering pursuant to the prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will issue ADSs to the underwriters named in the prospectus.

After the closing of the global offering, the depositary bank may create ADSs on your behalf if you or your broker deposit common shares with the custodian. The depositary bank will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the common shares to the custodian. Your ability to deposit common shares and receive ADSs may be limited by U.S. and Swedish legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary bank or the custodian receives confirmation that all required approvals have been given and that the common shares have been duly transferred to the custodian. The depositary bank will only issue ADSs in whole numbers.

When you make a deposit of common shares, you will be responsible for transferring good and valid title to the depositary bank. As such, you will be deemed to represent and warrant that:

- the common shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained;
- all preemptive (and similar) rights, if any, with respect to such common shares have been validly waived or exercised;
- you are duly authorized to deposit the common shares;
- the common shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement); and
- the common shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary bank may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

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. The voting rights of holders of common shares are described in "Description of Share Capital and Articles of Association—Rights Attached to Shares."

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
• 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.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY BANK.

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.

SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Prior to our initial public offering, there was no market for our common shares or ADSs representing our common shares. Future sales of substantial amounts of our common shares or ADSs representing our common shares in the public market, or the perception that such sales may occur, could adversely affect prevailing market prices of our common shares or ADSs representing our common shares.

Based on the number of common shares outstanding as of September 30, 2020, and assuming (1) no exercise of the underwriters' option to purchase additional common shares (including common shares in the form of ADSs) and (2) no exercise of any of our other outstanding warrants or options, we will have outstanding an aggregate of 54,441,584 common shares (including in the form of ADSs) following the global offering. The 4,500,000 ADSs sold in the U.S. offering will be freely tradable in the U.S. public market without restriction or further registration under the Securities Act, unless the ADSs are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act (subject, in each case, to the terms of the lock-up agreements referred to below, as applicable).

Lock-up Agreements

All of our directors and executive officers have agreed, subject to limited exceptions, with the underwriters not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our ADSs, common shares or such other securities for a period of 90 days after the date of this prospectus, without the prior written consent of Citigroup Global Markets Inc. and Jefferies LLC. See "Underwriting." Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements, all of the ADSs and common shares that are held by these parties as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

As of September 30, 2020, there were 1,279,086 common shares issuable upon the exercise of warrants to purchase common shares issued under our two warrant programs, of which warrants to purchase 856,586 common shares may be exercised between January 1, 2022 and March 31, 2022 and warrants to purchase 422,500 common shares may be exercised between October 1, 2022 and December 31, 2022. Of these warrants, warrants to purchase 645,000 common shares that may be exercised between January 1, 2022 and March 31, 2022 and warrants to purchase 337,500 common shares that may be exercised until October 1, 2022 and December 31, 2022 are subject to the lock-up restrictions described in the paragraph above.

Rule 144

In general, persons who have beneficially owned common shares for at least six months are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of any prior owner other than one of our affiliates;
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of

restricted securities without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

Affiliates

Persons seeking to sell securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above.

They are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of common shares then outstanding (including in the form of ADSs), which will equal approximately 544,415 common shares immediately after the consummation of the global offering based on the number of common shares outstanding as of September 30, 2020; or
- the average weekly trading volume of our common shares in the form of ADSs on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section of this prospectus titled “Underwriting” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Regulation S

Regulation S under the Securities Act, or Regulation S, provides that common shares owned by any person may be sold without registration in the United States, provided that the sale is effected in an offshore transaction and no directed selling efforts are made in the United States (as these terms are defined in Regulation S), subject to certain other conditions. In general, this means that our common shares may be sold outside the United States without registration in the United States being required.

In addition, Regulation S provides that any common shares sold by us outside the United States pursuant thereto may be freely resold into the United States as long as we were a foreign private issuer at the time of issuance, subject to limitations on affiliate resales and contractual lock-up agreements.

MATERIAL INCOME TAX CONSIDERATIONS

The following summary contains a description of material Swedish and U.S. federal income tax consequences of the acquisition, ownership and disposition of our common shares or ADSs. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decision to acquire common shares or ADSs in the global offering.

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following is a description of certain material U.S. federal income tax considerations for U.S. 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 U.S. Holder that is an initial purchaser of the common shares or ADSs pursuant to the global offering and 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 U.S. 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 U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. 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 U.S. 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 U.S. federal income tax purposes is not the U.S. 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 U.S. 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) 5% or more (by vote or value) of our outstanding common shares or ADS.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds common shares or ADSs, the U.S. 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 U.S. 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 U.S.-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 "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of common shares or ADSs and is:

(i) An individual who is a citizen or individual 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 U.S. federal income taxation regardless of its source; or

(iv) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. 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 U.S. 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 U.S. FEDERAL, STATE AND LOCAL TAX LAWS.

PFIC Rules

A non-U.S. 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 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 for U.S. federal income tax purposes, the equity of which we own, directly or indirectly, 25% or more (by value).

A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change from year to year. The total value of our assets for purposes of the asset test generally will be calculated using the market price of the common shares or ADSs, which may fluctuate considerably. Fluctuations in the market price of the common shares or ADSs may result in our being a PFIC for any taxable year. In addition, the composition of our assets will also be affected by how, and how quickly, we spend the cash we raise in any offering, including the global offering. Our income for a taxable year will be affected by whether we receive certain milestone payments in such year, and whether certain gains from foreign currency exchanges are treated as qualifying income for purposes of the PFIC income test. Based upon the value of our assets and the composition of our income and assets, we do not believe we were a PFIC for the 2019 taxable year. It is uncertain whether we will be a PFIC for the 2020 taxable year, 2021 taxable year or any subsequent taxable years.

Our status as a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies that in some circumstances are unclear and subject to varying interpretation. Because of the uncertainties involved in determining our PFIC status, we cannot provide any assurances regarding our PFIC status.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the common shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years

during which the U.S. 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 U.S. Holder has made a "deemed sale" election under the PFIC rules. If the "deemed sale" election is made, a U.S. Holder will be deemed to have sold the common shares or ADSs the U.S. 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 U.S. 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 U.S. Holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. 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 U.S. Holders, U.S. Holders will be subject to special tax rules with respect to any "excess distribution" such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including, under certain circumstances, a pledge) of common shares or ADSs, unless (i) such U.S. Holder makes a "qualified electing fund" election, or QEF Election, with respect to all taxable years during such U.S. Holder's holding period in which we are a PFIC or (ii) our common shares or ADSs constitute "marketable" securities, and such U.S. Holder makes a mark-to-market election as discussed below. Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. 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 U.S. 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 U.S. Holder holds the common shares or ADSs as capital assets. In addition, if we are a PFIC, a U.S. 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 U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

If a U.S. Holder makes an effective QEF Election, the U.S. Holder will be required to include in gross income each year, whether or not we make distributions, as capital gains, such U.S. Holder's pro rata share of our net capital gains and, as ordinary income, such U.S. Holder's pro rata share of our earnings in excess of our net capital gains. However, a U.S. Holder can only make a qualified electing fund election with respect to common shares in a PFIC if such company agrees to furnish such U.S. Holder with certain tax information annually. We do not currently intend to provide U.S. Holders with the information necessary for U.S. 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.

U.S. 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 U.S. stock exchanges or on a foreign stock exchange that meets certain conditions. For these purposes, the common shares or ADSs 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. We intend to list our ADSs on The Nasdaq Global Select Market, which is a qualified exchange

for these purposes. Each U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. Holder validly makes a mark-to-market election with respect to our common shares or ADSs, the U.S. 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 U.S. federal income tax purposes. U.S. 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 U.S. Treasury, each U.S. shareholder of a PFIC is required to make an annual filing containing such information as the U.S. Treasury may require. U.S. 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 U.S. federal income tax principles). Because we do not intend to calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Non-corporate U.S. 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-U.S. 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. We intend to list our ADSs 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 U.S.-Sweden Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-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 PFIC, such dividends will generally be expected to

be "qualified dividend income" in the hands of individual U.S. 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 U.S. Holder.

The amount of any dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. 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 U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-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 U.S.-Sweden Tax Treaty will be creditable against your U.S. federal income tax liability. Swedish income taxes withheld in excess of the applicable t rate under the U.S.-Sweden Tax Treaty will not be eligible for credit against your U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. 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 U.S. 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 U.S. 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 U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. 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 U.S. dollar value of the amount realized in a non-U.S. 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 U.S. dollar amount realized on the date of sale or disposition and the U.S. 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 U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. 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 U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle the U.S. Holder to a refund, provided that the required information is timely furnished to the IRS.

Information with Respect to Foreign Financial Assets

Certain U.S. 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 U.S. financial institutions), by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S. Holder to which the information relates may not close until three years after such information is filed. U.S. 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 U.S.-Sweden Tax Treaty the tax rate on dividends paid to U.S. holders entitled to the benefits of the U.S.-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 U.S.—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 U.S.-Sweden Tax Treaty this rule applies for ten years from the date the private individuals became non-resident of Sweden for tax purposes.

UNDERWRITING

The global offering consists of a total of 4,500,000 common shares, consisting of:

- an offering of a total of common shares in the form of ADSs in the United States, referred to as the U.S. offering; and
- a concurrent private placement of a total of common shares in Europe (including Sweden) and countries outside of the United States, referred to as the European private placement.

Citigroup Global Markets Inc., Jefferies LLC and Stifel, Nicolaus & Company, Incorporated are acting as the global coordinators and joint book-running managers of the global offering. Citigroup Global Markets Inc. and Jefferies LLC are acting as representatives of the underwriters in the U.S. offering. Citigroup Global Markets Limited, Jefferies International Limited and Jefferies GmbH are acting as representatives of the underwriters in the European private placement. As used herein, the term "underwriters" refers to with respect to the U.S. offering, the underwriters offering common shares in the form of ADSs in the United States and, with respect to the European private placement, the underwriters offering common shares in Europe, as the case may be. The underwriters in the U.S. offering and the underwriters in the European private placement are collectively referred to herein as the "underwriters." Sales of shares made outside the United States may be made by affiliates of the underwriters.

We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of ADSs set forth opposite the underwriter's name in the U.S. offering.

Underwriters	Number of ADSs
Citigroup Global Markets Inc.	
Jefferies LLC	
Stifel, Nicolaus & Company, Incorporated	
Kempen & Co U.S.A., Inc.	
LifeSci Capital, LLC	
Total	

Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of common shares set forth opposite the underwriter's name in the European private placement.

Underwriters	Number of Common Shares
Citigroup Global Markets Limited	
Jefferies International Limited/Jefferies GmbH*	
Stifel, Nicolaus & Company, Incorporated	
Kempen & Co U.S.A., Inc.	
LifeSci Capital, LLC	
Carnegie Investment Bank AB (publ)	
Total	

* The division of services between Jefferies International Limited and Jefferies GmbH shall be determined at Jefferies' absolute discretion, whereby regulated services with respect to EU 27 countries and EU 27 investors shall be undertaken by Jefferies GmbH only.

The underwriting agreement provides that the obligations of the underwriters to purchase the common shares or ADSs, as the case may be, included in the global offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all the common shares or ADSs, as the case may be (other than those covered by the option described below) if they purchase any of the common shares or ADSs. The total number of ADSs in the U.S. offering and common shares in the European private placement (including any ADSs or common shares purchased pursuant to the underwriters' option to purchase additional ADSs and common shares described below) is subject to reallocation between these offerings to the extent permitted under applicable law and regulations.

Common shares and ADSs sold by the underwriters to the public will initially be offered at the public offering price set forth on the cover of this prospectus. Any common shares or ADSs sold by the underwriters to securities dealers may be sold at a discount from the public offering price not to exceed SEK per common share or $ per ADS. If all the common shares or ADSs are not sold at the offering price, the underwriters may change the offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to make sales to discretionary accounts.

If the underwriters sell more common shares (including in the form of ADSs) than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 675,000 additional common shares (which may be in the form of ADSs) at the public offering price less the underwriting discount. To the extent the option is exercised, each underwriter must purchase a number of additional common shares (which may be in the form of ADSs) approximately proportionate to that underwriter's initial purchase commitment set forth in the table above. Any common shares or ADSs issued or sold under the option will be issued and sold on the same terms and conditions as the other common shares and ADSs that are the subject of the global offering.

We, our officers and directors have agreed that, for a period of 90 days from the date of this prospectus, we will not, without the prior written consent of Citigroup Global Markets Inc. and Jefferies LLC, offer, sell, contract, pledge or otherwise dispose of or hedge any of our common shares, ADSs, or any securities convertible into, or exercisable or exchangeable for, our common shares. Citigroup Global Markets Inc. and Jefferies LLC in their sole discretion may release any of the securities subject to these lock-up agreements at any time, which, in the case of officers and directors, shall be with notice.

The following table shows the per ADS, per common share and total offering price, underwriting discounts, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional common shares.

	Per ADS		Per Common Share		Total (in thousands)	
	Without Option to Purchase Additional ADSs	With Option to Purchase Additional ADSs	Without Option to Purchase Additional Common Shares	With Option to Purchase Additional Common Shares	Without Option to Purchase Additional ADSs and/or Common Shares	With Option to Purchase Additional ADSs and/or Common Shares
Offering price	$	$	$	$	$	$
Underwriting discounts to be paid by us	$	$	$	$	$	$
Proceeds, before expenses, to us	$	$	$	$	$	$

We estimate that expenses payable by us in connection with the global offering, exclusive of underwriting discounts and commissions, will be approximately $ million. We have also agreed to reimburse the underwriters for expenses in an amount up to $35,000 relating to the clearance of the global offering with the Financial Industry Regulatory Authority, Inc.

In connection with the global offering, the underwriters may purchase and sell ADSs in the open market. Purchases and sales of ADSs in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the underwriters' option to purchase additional common

shares (including in the form of ADSs), and other transactions that would stabilize, maintain or otherwise affect the price of our ADSs and common shares.

- Short sales involve secondary market sales by the underwriters of a greater number of ADSs than they are required to purchase in the global offering.
    - "Covered" short sales are sales of ADSs in an amount up to the number of ADSs represented by the underwriters' option to purchase additional common shares (including in the form of ADSs).
    - "Naked" short sales are sales of ADSs in an amount in excess of the number of ADSs and common shares represented by the underwriters' option to purchase additional common shares (including in the form of ADSs).
- Covering transactions involve purchases of ADSs either pursuant to the underwriters' over-allotment option or in the open market in order to cover short positions.
    - To close a naked short position, the underwriters must purchase ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs and common shares in the open market after pricing that could adversely affect investors who purchase in the global offering.
    - To close a covered short position, the underwriters must purchase ADSs in the open market or must exercise the underwriters' option to purchase additional common shares (including in the form of ADSs). In determining the source of ADSs to close the covered short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase ADSs through the underwriters' option to purchase additional common shares (including in the form of ADSs).
- As an additional means of facilitating the global offering, the underwriters may bid for, and purchase, ADSs, as long as such bids do not exceed a specified maximum, to stabilize the price of the ADSs.

Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the ADSs and common shares. They may also cause the price of the ADSs and common shares to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters intend to conduct the stabilization activities described herein in the U.S securities markets, including on The Nasdaq Global Select Market, in compliance with Regulation M under the Securities Exchange Act of 1934, as amended, subject to applicable regulations. The underwriters do not plan to conduct any stabilization activities on Nasdaq Stockholm. If the underwriters commence any of these transactions, they may discontinue them at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more of the underwriters or their respective affiliates. The representatives may agree with us to allocate a number of ADSs and common shares to underwriters for sale to their online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' or their respective affiliates' websites and any information contained in any other website maintained by any of the underwriters or their respective affiliates is not part of this prospectus, has not been approved or endorsed by us or the underwriters and should not be relied upon by investors in the global offering.

Conflicts of Interest

The underwriters are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. The underwriters and their respective affiliates

may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (which may include bank loans and/or credit default swaps) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area, or EEA Member State, an offer to the public of any of our ADSs or common shares which are the subject of the global offering contemplated by this document may not be made in that EEA Member State except that an offer to the public in that EEA Member State of any of our ADSs or common shares may be made at any time under the following exemptions under the Prospectus Regulation:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), as permitted under the Prospectus Regulation, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ADSs or common shares shall require us or any of underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any member state means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

No ADSs or common shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the ADSs or common shares which has been approved by the Financial Conduct Authority, except that the ADSs and common shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA;

provided in each case that no such offer of the ADSs or common shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus

Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Notice to Prospective Investors in France

Neither this prospectus nor any other offering material relating to the ADSs and common shares described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The ADSs and common shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the ADSs and common shares has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the ADSs and common shares to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint* d'investisseurs), in each case investing for their own account, all as defined in, and in accordance with, articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French *Code* monétaire *et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the

Autorité des Marchés Financiers, does not constitute a public offer (*appel public à l'épargne*).

The ADSs and common shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

Notice to Prospective Investors in Hong Kong

The ADSs and common shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the ADSs or common shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to the ADSs or common shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Notice to Prospective Investors in Japan

The ADSs and common shares offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The ADSs and common shares have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs or common shares may not be circulated or distributed, nor may the ADSs or common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the ADSs or common shares are subscribed or purchased under Section 275 of the SFA by a relevant party which is:

- corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ADSs or common shares pursuant to an offer made under Section 275 of the SFA except:
- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- where no consideration is or will be given for the transfer; or
- where the transfer is by operation of law.

Notice to Prospective Investors in Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase ADSs or common shares under the Israeli Securities Law, 5728-1968, which requires a prospectus to be published and authorized by the Israel Securities Authorities, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728-1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the "Addressed investors"); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728-1968, subject to certain conditions (the "Qualified Investors"). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities law, 5728-1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our ADSs or common shares to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Notice to Prospective Investors in Switzerland

This document is not intended to constitute an offer or solicitation to purchase or invest in the ADSs or common shares described herein. Neither the ADSs or common shares may be publicly offered, sold or advertised, directly or indirectly, in, into or from Switzerland and will not be listed on the SIX Swiss Exchange

or on any other exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the ADSs or common shares constitutes a prospectus as such term is understood pursuant to article 652a or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any other regulated trading facility in Switzerland, and neither this document nor any other offering or marketing material relating to the ADSs or common shares may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, nor the Company nor the ADSs or common shares have been or will be filed with or approved by any Swiss regulatory authority. Neither the ADSs or common shares are subject to the supervision by any Swiss regulatory authority, e.g., the Swiss Financial Markets Supervisory Authority FINMA (FINMA), and investors in the ADSs will not benefit from protection or supervision by such authority.

Notice to Prospective Investors in Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to Section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

EXPENSES OF THE GLOBAL OFFERING

Set forth below is an itemization of the total expenses, excluding the underwriting discounts and commissions, which are expected to be incurred in connection with the sale of common shares and ADSs in the global offering. With the exception of the registration fee payable to the SEC and the filing fee payable to FINRA, all amounts are estimates.

	Amount to be Paid
SEC registration fee	$ 9,294
FINRA filing fee	13,278
Printing expenses	70,000
Legal fees and expenses	417,646
Accounting fees and expenses	591,692
Miscellaneous costs	23,384
Total	**$1,125,294**

LEGAL MATTERS

The validity of our common shares and ADSs and certain other matters of Swedish law and U.S. federal law will be passed upon for us by Advokatfirman Vinge, Stockholm, Sweden and Goodwin Procter LLP, New York, NY, respectively. Legal counsel to the underwriters in connection with the global offering are Cooley LLP, New York, New York and Baker & McKenzie Advokatbyrå KB, Stockholm, Sweden.

EXPERTS

The consolidated financial statements of Calliditas Therapeutics AB and its subsidiaries as of December 31, 2019 and 2018 and for the years ended December 31, 2019 and 2018 appearing in this prospectus and registration statement have been audited by Ernst & Young AB, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The registered business address of Ernst & Young AB is Box 7850, 103 99, Stockholm, Sweden.

The consolidated financial statements of Genkyotex S.A. and its subsidiary as of September 30, 2020 and December 31, 2019 and for the nine months ended September 30, 2020 and the year ended December 31, 2019 have been included herein and in the registration statement in reliance upon the report of KPMG S.A., independent auditors, appearing elsewhere herein, and upon the authority of said firms as experts in accounting and auditing. KPMG S.A.'s report expresses a qualified opinion and includes a Basis for Qualified Opinion paragraph stating that as disclosed in Note 2.1 to the consolidated financial statements, the consolidated financial statements have been prepared to meet the reporting requirements of Rule 3-05 of Regulation S-X for purposes of a filing with the U.S. Securities and Exchange Commission and do not include comparative financial information as required by IAS 1 "Presentation of Financial Statements".

The registered business address of KPMG S.A. is 51 Rue de Saint-Cyr, CS 60409, 69338 Lyon Cedex 9, France.

SERVICE OF PROCESS AND ENFORCEMENT OF LIABILITIES

We are incorporated and currently existing under the laws of Sweden. In addition, certain of our directors and officers reside outside of the United States and substantially all of the assets of our subsidiaries are located outside of the United States. As a result, it may be difficult for investors to effect service of process on us or those persons in the United States or to enforce in the United States judgments obtained in U.S. courts against us or those persons based on the civil liability or other provisions of the U.S securities laws or other laws. In addition, uncertainty exists as to whether the courts of Sweden would:

- recognize or enforce judgments of U.S. courts obtained against us or our directors or officers predicated upon the civil liabilities provisions of the securities laws of the United States or any state in the United States; or
- entertain original actions brought in Sweden against us or our directors or officers predicated upon the securities laws of the United States or any state in the United States.

The United States and Sweden currently do not have a treaty providing for the reciprocal 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 U.S. securities laws, would not automatically be recognized or enforceable in Sweden. In order to obtain a judgment which is enforceable in Sweden, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in Sweden. Such party may submit to the Swedish court the final judgment rendered by the U.S. court. This court will have discretion to attach such weight to the judgment rendered by the relevant U.S. court depending on the circumstances. Circumstances that may be relevant to the Swedish court in deciding to give conclusive effect to a final and enforceable judgment of such court in respect of the contractual obligations thereunder without re-examination or re-litigation of the substantive matters adjudicated upon include whether: (i) the court involved accepted jurisdiction on the basis of internationally recognized grounds to accept jurisdiction, (ii) the proceedings before such court are in compliance with principles of proper procedure, (iii) such judgment is not contrary to the public policy of Sweden and (iv) such judgment is not incompatible with a judgment given between the same parties by a Swedish court or with a prior judgment given between the same parties by a foreign court in a dispute concerning the same subject matter and based on the same cause of action, provided such prior judgment is fulfils the conditions necessary for it to be given binding effect in Sweden. Swedish courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Swedish court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

Swedish civil procedure differs substantially from U.S. civil procedure in a number of respects. Insofar as the production of evidence is concerned, U.S. law and the laws of several other jurisdictions based on common law provide for pre-trial discovery, a process by which parties to the proceedings may prior to trial compel the production of documents by adverse or third parties and the deposition of witnesses. Evidence obtained in this manner may be decisive in the outcome of any proceeding. No such pre-trial discovery process exists under Swedish law.

Subject to the foregoing and service of process in accordance with applicable treaties, investors may be able to enforce in Sweden judgments in civil and commercial matters obtained from U.S. federal or state courts. However, no assurance can be given that those judgments will be enforceable. In addition, it is doubtful whether a Swedish court would accept jurisdiction and impose civil liability in an original action commenced in Sweden and predicated solely upon U.S. federal securities laws.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act with respect to the ADSs offered in this prospectus. We have also filed a related registration statement on Form F-6 (File No. 333-238726) with the SEC to register the ADSs. This prospectus, which forms a part of the registration statement, does not contain all of the information included in the registration statement and the exhibits and schedules to the registration statement. Certain information is omitted and you should refer to the registration statement and its exhibits and schedules for that information. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

The SEC maintains an Internet website (http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers, like us, that file electronically with the SEC. We maintain a corporate website at www.calliditas.com. Information contained in, or that can be accessed through, our website is not a part of, and shall not be incorporated by reference into, this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. Those reports may be inspected without charge at the locations described above. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. We are, however, still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5. Since many of the disclosure obligations required of us as a foreign private issuer are different than those required of U.S. domestic reporting companies, our shareholders, potential shareholders and the investing public in general should not expect to receive information about us in the same amount, or at the same time, as information is received from, or provided by, other U.S. domestic reporting companies. We are only liable for violations of the rules and regulations of the SEC that apply to us as a foreign private issuer.

We will send the depositary a copy of all notices of shareholders meetings and other reports, communications and information that are made generally available to shareholders. The depositary has agreed to mail to all holders of ADSs a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the depositary and will make available to all holders of ADSs such notices and all such other reports and communications received by the depositary.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of income, comprehensive income, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years ended December 31, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

As discussed in Note 1 to the consolidated financial statements, the Company changed the presentation of its costs in the consolidated statement of income for the year ended December 31, 2018.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Ernst & Young AB

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

Stockholm, Sweden

February 28, 2020

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME
(SEK in thousands, except per share amounts)

	Note	Year Ended December 31, 2019	2018
Net sales	*3*	184,829	—
Operating expenses:			
Research and development	*9,10*	(149,826)	(99,260)
Administrative and selling	*6,8,9,10*	(62,882)	(31,132)
Other operating income	*4*	4,385	—
Other operating expenses	*5*	(4,525)	(2,090)
Operating loss	*7*	**(28,019)**	**(132,482)**
Financial income	*11*	926	441
Financial expenses	*12*	(5,408)	(8)
Loss before income tax		**(32,501)**	**(132,049)**
Income tax expense	*13*	(77)	—
Loss for the year attributable to shareholders of the Parent Company		**(32,578)**	**(132,049)**
Loss per share before and after dilution	*14*	(0.88)	(5.09)

The accompanying notes are an integral part of these financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(SEK in thousands)

	Note	Year Ended December 31, 2019	2018
Loss for the year		(32,578)	(132,049)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations	*19,23*	(11)	6
Total other comprehensive income/(loss)		(11)	6
Total comprehensive loss attributable to shareholders of the Parent Company		(32,589)	(132,043)

The accompanying notes are an integral part of these financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
(SEK in thousands)

	Note	December 31, 2019	2018
ASSETS			
Non-current assets			
Intangible assets	*15*	16,066	—
Equipment	*16*	104	107
Right-of-use assets	*8*	5,959	—
Non-current financial assets	*17,18,27*	1,939	341
Total non-current assets		24,068	448
Current assets			
Accounts receivables	*19*	46,586	—
Other current assets	*18*	2,719	1,630
Prepaid expenses	*20*	18,287	164
Cash	*21*	753,540	646,175
Total current assets		821,132	647,969
TOTAL ASSETS		845,200	648,417
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	*23*		
Share capital		1,548	1,408
Additional paid-in capital		1,274,664	1,072,319
Reserves		(45)	(34)
Retained earnings including net loss for the year		(488,096)	(455,518)
Total equity attributable to shareholders of the Parent Company		788,071	618,175
Non-current liabilities			
Provisions	*24*	175	—
Other non-current liabilities	*8,18*	3,584	—
Total non-current liabilities		3,759	—
Current liabilities			
Accounts payable	*18,19*	24,384	22,643
Current tax liabilities		77	—
Other current liabilities	*8,18*	3,394	904
Accrued expenses and deferred revenue	*25*	25,515	6,695
Total current liabilities		53,370	30,242
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		845,200	648,417

The accompanying notes are an integral part of these financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(SEK in thousands, except per share amounts)

	Note	Share Capital	Additional-Paid-in Capital	Translation Reserve	Retained Earnings Including Net Loss for the Year	Total
Opening shareholders' equity January 1, 2018		667	352,959	(40)	(320,410)	33,176
Loss for the year		—	—	—	(132,049)	(132,049)
Other comprehensive income/(loss)		—	—	6	—	6
Total comprehensive income/(loss)		—	—	6	(132,049)	(132,043)
Transactions with owners:						
New share issue		741	737,909	—	—	738,650
Cost attributable to new share issue		—	(54,433)	—	—	(54,433)
Premiums received from warrants	*10*	—	2,826	—	—	2,826
Contributions from shareholders	*23*	—	29,999	—	—	29,999
Interest from capital contributions from shareholders	*23*	—	3,059	—	(3,059)	—
Total transactions with owners		741	719,360	—	(3,059)	717,042
Closing shareholders' equity December 31, 2018		1,408	1,072,319	(34)	(455,518)	618,175
Opening shareholders' equity January 1, 2019		1,408	1,072,319	(34)	(455,518)	618,175
Loss for the year		—	—	—	(32,578)	(32,578)
Other comprehensive income/(loss)		—	—	(11)	—	(11)
Total comprehensive income/(loss)		—	—	(11)	(32,578)	(32,589)
Transactions with owners:						
New share issue		140	210,177	—	—	210,317
Cost attributable to new share issue		—	(10,915)	—	—	(10,915)
Premiums received from warrants	10	—	2,834	—	—	2,834
Share-based payments	10	—	249	—	—	249
Total transactions with owners		140	202,345	—	—	202,485
Closing shareholders' equity December 31, 2019	*10,23*	1,548	1,274,664	(45)	(488,096)	788,071

Equity is fully attributable to the shareholders of Calliditas Therapeutics AB.

The accompanying notes are an integral part of these financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(SEK in thousands)

	Note	Year Ended December 31, 2019	2018
Operating activities:			
Operating loss		(28,019)	(132,482)
Adjustments for non-cash items	*21*	2,308	51
Interest received		926	6
Interest paid		(325)	(8)
Cash flow from operating activities before changes in working capital		(25,110)	(132,433)
Cash flow from changes in working capital:			
Changes in operating receivables		(53,546)	2,642
Changes in operating liabilities		7,645	1,600
Cash flow from operating activities		(71,011)	(128,191)
Investing activities:			
Purchase of equipment	*16*	(118)	—
Investments in non-current financial assets	*17*	(1,888)	—
Purchase of intangible assets	*15*	(16,066)	—
Cash flow from investing activities		(18,072)	—
Financing activities:			
New share issue		210,317	738,650
Cost attributable to new share issue		(10,915)	(54,433)
Repayment of loans		(1,652)	(470)
Premiums received from warrants		2,834	2,826
Transaction costs, paid		(1,748)	—
Contributions from shareholders		—	29,999
Cash flow from financing activities		198,835	716,572
Net increase (decrease) in cash		109,752	588,381
Cash at beginning of the year		646,175	57,352
Exchange-rate difference in cash		(2,387)	442
Cash at the end of the year	*21*	753,540	646,175

The accompanying notes are an integral part of these financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except 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 activities in pharmaceuticals. These consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the year ended December 31, 2019 and December 31, 2018. Calliditas is clinical-stage biopharmaceutical 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, C8, 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, 2019, Calliditas is the Parent Company of three wholly owned subsidiaries located in Sweden, Norway and in the United States. The Swedish subsidiary is Nefecon AB and the Norwegian subsidiary is Pharmalink Oncology AS. There were no operating activities in these subsidiaries. During February 2019, the Group established a new subsidiary in the United States (Calliditas Therapeutics Inc.) and during May 2019, the Group completed a merger of Busulipo AB and Pharmalink Nordic AB with the Parent Company.

The Board of Directors (the "Board") approved, and authorized for issuance, these consolidated financial statements on February 28, 2020.

New Issue and Listing on Nasdaq Stockholm

In July 2019, Calliditas completed a directed new share issue of 3.5 million shares for gross proceeds of SEK 210,317, before issuance costs of SEK 10,915.

On June 29, 2018, the Parent Company was listed on the main list of Nasdaq Stockholm and completed a share issue, which included the over-allotment option amounting to SEK 738,650, before issuance costs of SEK 54,433.

Emerging Growth Company Status

Calliditas is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Calliditas has elected to take advantage of specified reduced reporting and regulatory requirements in contrast to those otherwise applicable generally to public companies. These provisions include:

- the requirement to have only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure; and
- exemption from the auditor attestation requirement in the assessment of Calliditas's internal control over financial reporting pursuant to Section 404 the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act.

Calliditas will remain an emerging growth company until the earliest of (i) the last day of the first fiscal year (a) following the fifth anniversary of the completion of the global offering, (b) in which its annual gross revenue totals at least $1.07 billion or (c) when Calliditas is deemed to be a large accelerated filer, which means the market value of Calliditas' common shares that is held by non-affiliates exceeds $700.0 million as of the prior June 30th and (ii) the date on which Calliditas has issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies

Basis for Preparation

These consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS), as adopted 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.

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), 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 at December 31, 2019. Control is achieved when the Parent Company has power 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 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

The Group applied for the first time the new and amended standards and interpretations to be applied for the financial year beginning on or after January 1, 2019. The nature and effect of the changes as a result of adoption of the new accounting standards are described below. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

IFRS 16 Leases

From January 1, 2019, IFRS 16 supersedes IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases—Incentives and SIC-27 Evaluating the Substance

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

of Transactions Involving the Legal Form of a Lease. The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to recognize most leases on the consolidated statement of financial position.

The Group adopted IFRS 16 using the modified retrospective method of adoption, meaning that comparative information of previous periods is not presented. The lease liability consists of the discounted remaining lease payments as of January 1, 2019. The right-of-use assets contains all agreements to an amount corresponding to the lease liability adjusted by the amount of any prepaid or accrued lease payments recognized in the consolidated statement of financial position at the date of initial application. Therefore, the transition to IFRS 16 had no effect on equity.

The Group's material lease agreements consist of leased premises. At the transition to IFRS 16, the Group's statement of financial position increased by the right-of-use assets and lease liabilities in the Group's consolidated statement of financial position. Prior to the adoption, lease payments were recognized as administrative expenses in the consolidated statement of income. The presentation of these expenses in the consolidated statement of income in the period prior to adoption was not changed. Subsequent to adoption, lease expenses consist of depreciation on the right-of-use assets, which are recognized as an administrative expense, and interest on the lease liability, which is recognized as a financial expense. Lease payments are recorded as a reduction of the lease liability to the extent they exceed the interest expense. Agreements that ended in 2019, but which originally had a maturity exceeding 12 months, have been taken into account in the calculation of lease liability and right-of-use asset. The Group applies recognition exemptions for lease agreements that, at the commencement date, have a lease term of 12 months or less (short-term lease), and lease agreements for which the underlying asset is of low value (lease of low-value assets). Lease of low-value assets consists mainly of storage and copiers. When assessing the agreements length when there are extension and termination options, both business strategy and contract-specific conditions are considered to determine if the Group is reasonably certain to utilize them. With regard to identified non-leasing components in a leasing agreement, the Group applied the main rule in IFRS 16, i.e. to recognize them separately from the leasing component.

At the transition to IFRS 16, all remaining lease payments have been calculated at present value using the Group's incremental borrowing rate. The weighted-average borrowing rate as of January 1, 2019 was 5.05 percent. The effect of adopting IFRS 16 is as follows:

	December 31, 2018	Adjustments	January 1, 2019
Assets			
Non-current assets			
Equipment	107	—	107
Right-of-use assets	—	1,819	1,819
Non-current financial assets	341	—	341
Total non-current assets	*448*	*1,819*	*2,267*
Current assets	647,969	—	647,969
Total assets	**648,417**	**1,819**	**650,236**
Shareholders' equity and liabilities			
Shareholders' equity	618,175	—	618,175
Other non-current liabilities	—	1,290	1,290
Current liabilities			
Accounts payable	22,643	—	22,643
Other current liabilities	904	529	1,433

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

	December 31, 2018	Adjustments	January 1, 2019
Accrued expenses	6,695	—	6,695
Total current liabilities	*30,242*	*529*	*30,771*
Total shareholders' equity and liabilities	**648,417**	**1,819**	**650,236**

As a result of the transition to IFRS 16, the Group's assets and liabilities increased by SEK 1,819 as of January 1, 2019.

Reconciliation of operational lease commitments:	
Commitments for operating leases as of December 31, 2018	1,983
Discounting effects	(164)
Recorded leasing liabilities as per January 1, 2019	**1,819**

For additional information concerning the transition to IFRS 16 see Note 8 Leases.

IFRIC 23 Uncertainty over Income Tax Treatment

The interpretation addresses the accounting for income taxes when tax treatments involve uncertainty that affects the application of income taxes and is applied from January 1, 2019. The interpretation has not had any significant effects on the Group's financial statements.

Other new or amended standards or interpretations published by the IASB are not expected to have a significant impact on the Group's financial statements.

Change in Accounting Principle

From January 1, 2019, the Group has switched to presenting costs in the consolidated statements of income based on function instead of cost by nature. The purpose of the change is to provide more relevant information about the Group's financial results, as a function-divided presentation better reflects the practice in the industry in which the Group operates. The change constitutes a voluntary change of accounting principle and has been applied retrospectively. Accordingly, the Group has conformed to current year presentation the consolidated statement of income for the year ended in December 31, 2018 to reflect the changes adopted for the year ended December 31, 2019. The change in accounting principle had no effect on the Group's consolidated statement of financial position, results of operations or liquidity. Below are the effects of the previously issued consolidated statement of income that were reclassified for the year ended December 31, 2018 in the Group:

	Year Ended December 31, 2018		
	Before adjustments	Adjustments	After adjustments
Research and development expenses	—	(99,260)	(99,260)
Administrative and selling expenses	—	(31,132)	(31,132)
Other operating income	715	(715)	—
Other operating expenses	—	(2,090)	(2,090)
Other external expenses	(114,056)	114,056	—
Personnel cost	(19,090)	19,090	—
Depreciation	(51)	51	—
Total operating expenses	**(132,482)**	—	**(132,482)**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

Revenue

The Group recognizes revenue as the identified performance obligations are performed. The Group's revenue for the financial year relates to the out-licensing of intellectual property rights with respect to Nefecon to Everest Medicines. Revenue for out-licensing 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 agreement with Everest Medicines was signed. Variable remuneration (for example, attributable to future regulatory milestones) is not included in the transaction price while there is significant uncertainty as to whether these will occur. Revenue is recognized when these milestones 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. Revenue attributable to the supply of drug is recognized at a point in time when the control of the goods is transferred to the counterparty.

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 asset's 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.

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. Swedish research and development tax credits on social security costs are recorded as an offset to research and development expenses.

Administrative and Selling

Administrative and selling expenses consist of salaries and other related costs for personnel in the Group's executive, finance, corporate and business development and administrative functions. Administrative and selling 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's pension obligations consist solely of defined-contribution 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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

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.

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 warrant programs and a performance-based share award program, 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 warrants is determined at the allotment date using the Black-Scholes model for pricing of warrants. 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

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.

Until December 31, 2018, the Group classified leasing as operational, meaning leases whereby the lessor essentially retains all risks and rewards associated with ownership of the asset. Any incentives received when signing leases were included in the calculation of the total expense of the agreement. Lease payments were expensed through the statement of income on a straight-line basis over the contract period.

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 is currently three years for the Group's only lease.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

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 Other non-current liabilities and Other current liabilities (see Notes 8 Leases and 18 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 12 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 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 subsidiaries that are not expected to be reversed in the foreseeable future are not taken into account.

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. 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

Licenses and similar rights

The Group has acquired licenses and similar rights connected to the product candidate Budenofalk 3 mg. Since the asset has been separately acquired, it has been recognized as an intangible asset in the consolidated statement of financial position.

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.

Research and development expense

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 expenses are otherwise recognized as operating expenses. 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—15 years

Until 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, or 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:

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

- Equipment—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

Since amortization has not yet begun for intangible assets, the Group assesses for impairment at each reporting date, or when there is an indication that an asset may be impaired. Equipment that is amortized 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 valuation 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 for the next 15 years from commercialization and does not include calculation of any residual value thereafter. The valuation is a Level 3-valuation and the essential assumptions will be specified, but the most critical assumptions mainly consist of assumptions about the size, market share and probability of the market.

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 long-term receivables, derivatives, other current receivables and cash, all of which, except derivatives, are classified at amortized cost. Derivatives are classified at fair value through profit or loss.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

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

Financial liabilities at amortized costs are initially measured at fair value, net after transaction costs. Subsequently periods are measured at amortized cost using the effective interest ("EIR") method.

The Group's financial liabilities (accounts payable and other current liabilities) are recognized at amortized cost.

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. See Note 19 Financial risks for information on considerations relating to accounts receivable and deposits.

For all items covered by expected credit losses, a three-stage write-down model is applied. Initially, as well as on each balance sheet date, a loss reserve is recorded for the next 12 months, or for a shorter period of time depending on the remaining maturity. The Group's assets have been assessed to be in stage 1, that is, there has been no significant increase in credit risk.

Expected credit losses are valued to the product by probability of default, loss due to default and exposure at default. For credit impaired assets and receivables, an individual assessment is made by taking into account historical, current and forward-looking information. The valuation of expected credit losses takes into account any collateral and other credit enhancements in the form of guarantees.

Cash

Cash are entirely comprised of cash at banks.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

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. During the year ended December 31, 2018, Calliditas raised mandatory convertible bridge loans with required conversion classified as equity in the Group's statement of financial position. Interest expenses on the bridge loans is recorded in equity as a transfer from additional paid-in capital to retained earnings.

Warrants

The Group has only issued warrants that were transferred at fair value. Premiums received for warrants granted to acquire shares in companies within the Group are recorded as an addition to equity, based on the warrant premium, at the date when the warrant was transferred to the counterparty.

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 other 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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. Significant Accounting Policies (continued)

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 and non-current assets are attributable only to Swedish companies and are all located in Sweden.

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 periods if the change affects both the current period and future periods.

(i) 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 was not deemed to meet the capitalization criteria for the year ended December 31, 2019 and was thus expensed. Capitalization of expenditures for the development of pharmaceuticals typically takes place late in Phase 3 (the final stage of clinical trials where the product is given to large groups of people to confirm effectiveness) and subsequent to market approval, or alternatively in conjunction with the initiation of pivotal studies, 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. Market approval has not yet been obtained for any products and, accordingly, the conditions for capitalizing development expenditures are not met.

(ii) 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, 2019. 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 2. Significant Accounting, Judgements, Estimates and Assumptions (continued)

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 during the year consisted of revenues for the out-licensing of Nefecon within the framework of the agreement with Everest Medicines to Greater China and Singapore. Revenue for out-licensing 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 agreement with Everest Medicines was signed. Furthermore, the Group recognized revenue in connection with variable remuneration when the criteria for a regulatory milestone was met, which was in connection with the approval of Everest Medicines IND (Investigational New Drug application) for Nefecon in China.

The Group has identified two performance obligations within the agreement: 1) Out-licensing of the product candidate Nefecon in existing condition at the signing of the agreement and 2) Provision of drugs for conducting clinical trials. The share of the transaction amount attributable to the supply of the drug for clinical trial has not been recognized as revenue and has been measured by the acquisition price based on the cost of the goods, plus a fair market margin. The proportion attributable to out-licensing has been measured as a residual of the remaining transaction price after deduction of other performance obligations, since the product candidate has not been approved for market by the regulatory authorities and no commercial pricing occur.

The Group's remaining performance obligations relate to future deliveries of study-related drugs within the framework of the licensing agreement with Everest Medicine amounting to SEK 874, which is recognized as deferred revenue in the Group's statement of financial position. See also Note 25 Accrued Expenses and Deferred Revenue. The performance obligations are expected to be satisfied during 2020–2021 when the drug will be delivered within the framework of Everest Medicine's study.

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

	Year Ended December 31,	
	2019	2018
Type of goods or service		
Out-licensing	184,829	—
Total	184,829	—

	Year Ended December 31,	
	2019	2018
Geographical markets		
China, Hong Kong, Macau, Taiwan and Singapore	184,829	—
Total	184,829	—

Note 4. Other Operating Income

	Year Ended December 31,	
	2019	2018
Exchange rate differences	4,385	—

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 4. Other Operating Income (continued)

	Year Ended December 31,	
	2019	2018
Total	4,385	—

Note 5. Other Operating Expenses

	Year Ended December 31,	
	2019	2018
Exchange rate differences	4,464	2,090
Net loss on disposal of equipment	61	—
Total	4,525	2,090

Note 6. Auditors' Fee

	Year Ended December 31,	
	2019	2018
Ernst & Young		
Audit services	645	509
Other audit activities	3,343	1,861
Other services	98	—
Total	4,086	2,370

Audit assignments relate to the statutory audit of the financial statements and the accounts, as well as the management of the Board of Directors and the CEO. This includes other responsibilities that it is incumbent upon the company's auditor to perform including providing advice or any other assistance that may result from observations in such review or the conduct of such other responsibilities.

Other auditing activities are those services in accordance with a special agreement on financial statements. Other services include advice on accounting issues and advice on processes and internal control.

Note 7. Costs per Cost Type

	Year Ended December 31,	
	2019	2018
Other external operating expenses	176,729	111,251
Personnel costs	34,157	19,090
Depreciation on equipment and right-of-use assets	1,822	51
Other operating expenses	4,525	2,090
Total	**217,233**	**132,482**

Note 8. Leases

At the transition to IFRS 16, the Group's right-of-use assets and lease liabilities increased by SEK 1,819 as of January 1, 2019. See Note 1 Significant Accounting Policies. Further, due to the adoption of IFRS 16, the Group's operating loss decreased by SEK 196 for the year ended December 31, 2019, and the Group's net loss for the year increased by SEK 111, compared with the corresponding accounting policies from the previous year if they had been applied.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 8. Leases (continued)

The effect of adopting IFRS 16 is as follows:

Impact on the consolidated statement of income (increase/(decrease)) at the year ended December 31, 2019:

	According to Prior Principles	Effect of IFRS 16	Year Ended December 31, 2019
Net sales	184,829	—	184,829
Research and development expenses	(149,826)	—	(149,826)
Administrative and selling expenses	(63,078)	196	(62,882)
Other operating income	4,385	—	4,385
Other operating expenses	(4,525)	—	(4,525)
Operating loss	*(28,215)*	*196*	*(28,019)*
Financial income	926	—	926
Financial expenses	(5,101)	(307)	(5,408)
Income tax expense	(77)	—	(77)
Loss for the year	(32,467)	(111)	(32,578)

Impact on the consolidated statement of financial position (increase/(decrease)) as per December 31, 2019:

	According to Prior Principles	Effect of IFRS 16	December 31, 2019
Assets			
Non-current assets			
Intangible assets	16,066	—	16,066
Equipment	104	—	104
Right-of-use assets	—	5,959	5,959
Non-current financial assets	1,939	—	1,939
Total non-current assets	*18,109*	*5,959*	*24,068*
Current assets	821,132	—	821,132
Total Assets	**839,241**	**5,959**	**845,200**
Total Shareholders' Equity & Liabilities			
Shareholders' equity	788,182	(111)	788,071
Non-current liabilities			
Provisions	175	—	175
Other non-current liabilities	—	3,584	3,584
Total non-current liabilities	*175*	*3,584*	*3,759*
Current liabilities			
Accounts payable	24,384	—	24,384
Current tax liabilities	77	—	77
Other current liabilities	908	2,486	3,394
Accrued expenses and deferred revenue	25,515	—	25,515
Total current liabilities	*50,884*	*2,486*	*53,370*

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 8. Leases (continued)

	According to Prior Principles	Effect of IFRS 16	December 31, 2019
Total Shareholders' Equity & Liabilities	**839,241**	**5,959**	**845,200**

Right-of-use assets

	December 31, 2019
Cost	
At January 1, 2019	1,819
Additional agreement	7,527
Termination of agreement	(1,819)
At December 31, 2019	7,527
Depreciation	
At January 1, 2019	—
Depreciation	(1,778)
Termination of agreement	210
At December 31, 2019	(1,568)
Net book value	5,959

Depreciation on right-of-use assets are included in the consolidated statement of income under Administrative and selling expenses amounted to SEK 1,778.

Lease liabilities

	December 31, 2019
At January 1, 2019	1,819
Additional agreement	7,527
Termination of agreement	(1,624)
Amortization	(1,652)
At December 31, 2019	6,070

Maturity analysis on future lease liabilities

	December 31, 2019
<12 months	3,816
1–2 years	2,306
>2 year	533
	6,655

Changes in liabilities arising from financing activities, see Note 21 Cash for further information on leasing liabilities.

This year's leases consist of leased premises. During the year, a reassessment of the agreement was performed when the lease was terminated prematurely. The Group also entered into additional agreements pertain to lease agreements for premises with a contract period until May 31, 2022. The lease agreement can

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 8. Leases (continued)

be extended by three years unless one of the parties terminates the lease agreement at least nine months before. The Group cannot determine with reasonable certainty whether the extension will take place based on the Group's development and has therefore not expected utilization after May 2022. 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 copiers.

	Year Ended December 31, 2019
Interest expenses attributable to lease liabilities	307
Expenses attributable to short-term lease	265
Expenses attributable to leasing agreements with low value	96
Expenses attributable to variable lease payments that are not included in lease liabilities	187
This year's lease payments in the Group	2,343

Note 9. Employees and Personnel Costs

Average Number of Employees

	Year Ended December 31,			
	2019		2018	
	Number of Employees	Percentage of Male Employees	Number of Employees	Percentage of Male Employees
Parent Company				
Sweden	13	38%	10	30%
	13	38%	10	30%
Subsidiaries				
United States	1	100%	—	—
	1	100%	—	—
Group, total	14	43%	10	30%

Wages and salaries, pension costs and social security costs to the Board, senior executives and other employees

Wages and Salaries

	Year Ended December 31,	
	2019	2018
Parent Company		
Board and senior executives[1]	13,109	9,875
Other employees	6,091	3,789
Subsidiaries		
Board and senior executives	2,973	—
Total	22,173	13,664

(1) Senior executives includes the Board, CEO and other senior executives.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 9. Employees and Personnel Costs (continued)

Social Security Costs and Pension Costs

	Year Ended December 31,	
	2019	2018
Parent Company		
Pension costs for the Board and senior executives	1,644	1,429
Pension costs to other employees	1,180	699
Social security costs	3,008	2,843
Subsidiaries		
Social security costs	299	—
Total	6,131	4,971

Gender Distribution Among Senior Executives

	Year Ended December 31,	
	2019	2018
Percentage of women on the Board	33%	33%
Percentage of men on the Board	67%	67%
Percentage of women among other senior executives	33%	43%
Percentage of men among other senior executives	67%	57%

Disclosures Regarding Total Remuneration of The Board and Senior Executives

	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
Year Ended December 31, 2019						
Board Chairman Elmar Schnee	402	—	—	—	101	503
Board members						
Thomas Eklund	280	—	—	—	37	317
Hilde Furberg	180	—	—	—	37	217
Lennart Hansson	102	—	—	—	37	139
Bengt Julander	102	—	—	—	—	102
Diane Parks	201	—	—	—	37	238
Olav Hellebo (until May 2019)	58	—	—	—	—	58
Senior executives						
CEO	2,634	510	956	—	—	4,100
Other senior executives (8 people)	8,927	1,134	1,991	4,701	—	16,753
of which relates to subsidiaries	*2,382*	—	*591*	—	—	*2,973*
Total	**12,886**	**1,644**	**2,947**	**4,701**	**249**	**22,427**
Year Ended December 31, 2018						
Board Chairman Thomas Eklund	413	—	—	—	—	413
Board members[(1)]						
Olav Hellebø	160	—	—	—	—	160
Hilde Furberg	173	—	—	—	—	173

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 9. Employees and Personnel Costs (continued)

	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
Senior executives						
CEO	2,462	456	692	—	—	3,610
Other senior executives (7 people)	5,301	973	674	6,001	—	12,949
Total	**8,509**	**1,429**	**1,366**	**6,001**	**—**	**17,305**

(1) Bengt Julander and Lennart Hansson received no remuneration for 2018.

Other Remuneration

Other remuneration comprises of fees for services rendered to the Parent Company. Management services purchased from Jedako Consult AB amounted to SEK 3,848 (SEK 3,425) and relate to the functions of a Chief Medical Officer that were outsourced to this entity. Management services purchased from Cordcom Consultants KB amounted to SEK 853 (SEK 951) and relate to the functions of a Head of Communications and Investor Relations that were outsourced to this entity. Management services purchased from Skepparhagen AB amounted to SEK 0. (SEK 1,625).

Remuneration of Senior Executives

Remuneration of the CEO and other senior executives comprises base salary, pension benefits, variable remuneration and remuneration in the form of consultancy fees. Other senior executives comprise the eight individuals who, together with the CEO, comprise Executive Management. Other senior executives are:

Chief Financial Officer, Chief Medical Officer, Vice President North America Commercial, Vice President Regulatory Affairs, Chief Scientific Officer, VP Project Management, VP Pharmaceutical Development and Head of Communications and Investor Relations.

Pensions

All pension commitments are defined-contribution plans. 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 senior executives are between 15% and 20% of base salary. The age of retirement is 65 for all other senior executives. 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 senior executives is 40% according to the guidelines for remuneration to senior executives.

Severance Pay

A notice period of six months applies if employment is terminated by the CEO. A notice period of 12 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 3 to 12 months, with salary paid, applies between the Group and senior executives. No severance pay is paid to Board members.

Note 10. Share-Based Payments

Warrants

The Group has three warrants programs, whereby personnel and certain other employees have purchased warrants at fair value with rights to acquire shares in the Parent Company. When warrant is

(SEK in thousands, except share amounts or as otherwise indicated)

Note 10. Share-Based Payments (continued)

exercised, the holder pays a subscription price and then receives one common share in the Parent Company. For the program initiated in 2017, the warrants can be exercised at any time until their expiration date without having to fulfill any conditions, while the programs initiated in 2018 and 2019 can be exercised between January 1, 2022 and March 31, 2022 and between October 1, 2022 and December 31, 2022, respectively. If the warrant holder leaves the Group prior to exercise, the Group has the option to repurchase a certain number of warrants, depending on the time of leaving, at the lesser of fair value or the purchase price.

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 program initiated in 2017, quoted prices were not available to use when calculating volatility. The volatility was then based on a calculated average for comparable listed companies. 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. A discount was offered in all programs since the warrants are not listed. 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 Program 2017/2020

In 2017, warrants to purchase a total of 1,296,500 shares were issued to certain Board members, employees and key consultants in the Group. For the warrants in the warrants program 2017/2020, warrants to purchase 1,185,250 common shares can be exercised continuously up to and including June 30, 2020, and warrants to purchase 111,250 common shares can be exercised continuously up to and including August 30, 2020, where each warrant entitles the participant to subscribe for a new share in the company at a subscription price of SEK 42.36 per share.

Warrants Program 2018/2022

In 2018, a total of 856,586 warrants were issued to employees and key consultants in the Group. The warrants in the warrants program 2018/2022 can be exercised between January 1, 2022 and March 31, 2022 where each warrant gives the participant the right to subscribe for a new share in the company at a subscription price of SEK 74.30 per share.

Warrants Program 2019/2022

In 2019, a total of 422,500 warrants were issued to employees and key consultants in the Group. The warrants in the warrants program 2019/2022 can be exercised between October 1, 2022 and December 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the company at a subscription price of SEK 74.50 per share.

Allotted Warrants	Accumulated No. of Outstanding	Weighted-Average Exercise Price, SEK
On December 31, 2018	2,518,086	56
On December 31, 2019	2,575,586	58

The allocated weighted-average exercise price for warrants that are outstanding on the opening and closing date amounts to SEK 56 and SEK 58, respectively. During 2019, 365,000 warrants in Warrant program 2015/2019 expired without exercise.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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Note 10. Share-Based Payments (continued)

Outstanding Warrants per Year	Warrants Outstanding as of December 31, 2018	Warrants Outstanding as of December 31, 2019	Inputs used for the Black & Scholes valuation					
			Exercise Price in SEK	Price per warrant in SEK	Value per share in SEK	Risk-Free Rate	Volatility	Expiration date
Warrant program 2015/2019[1]	365,000							Apr 30, 2019
Warrant program 2017/2020	1,296,500	1,296,500	42.36	0.28	21.18	(0.42)%	27%	Jun 30/Aug 30, 2020
Warrant program 2018/2022	856,586	856,586	74.30	3.29	46.50	(0.28)%	33%	Mar 31, 2022
Warrant program 2019/2022	—	422,500	74.50	6.69*	54.39*	(0.55)%*	36%*	Dec 31, 2022
Total	**2,518,086**	**2,575,586**						

* Average value

(1) Warrant program 2015/2019 meets the definition of equity instruments since no vesting period or other features that required any future service from the employees exist.

Changes and holdings of warrants for the Board, CEO, other senior executives and other employee and consultants on the opening and closing dates are presented below.

Holder	Warrants Outstanding as of January 1, 2018	Change	Warrants Outstanding as of December 31, 2018	Change	Warrants Outstanding as of December 31, 2019
CEO Renée Aguiar-Lucander	369,500	350,000	719,500	195,000	914,500
Board member Thomas Eklund	111,250	—	111,250	—	111,250
Board member Hilde Furberg	29,500	—	29,500	—	29,500
Other senior executives	538,500	188,586	727,086	107,500	834,586
Other employees, consultants and external parties	612,750	318,000	930,750	(245,000)	685,750
Total	**1,661,500**	**856,586**	**2,518,086**	**57,500**	**2,575,586**

Share-Based Payments

Board LTIP 2019

This is a performance-based long-term incentive program for some members of the Board of Directors in Calliditas. A total of 57,032 share rights have been granted under the program during the year of 2019. The share rights are gradually vested over three years until the AGM 2022 or June 1, whichever is the earliest, based on the development of Calliditas share price during the period from May 8, 2019 through on June 1, 2022. The share rights 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, the share rights are subject to performance-based vesting based on the development of Calliditas share price. If Calliditas share price has increased by more than 60 per cent, 100 per cent of the share rights shall be earned, and if the share price has increased by 20 per cent, 33 per cent of the share rights shall be vested. In the event of an increase in the share price by between 20 and 60 per cent, vesting will be linear. If the share price has increased by less than 20 per cent, no vesting will take place. Each share right 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.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 10. Share-Based Payments (continued)

The Board's holding of share awards as of the closing day is shown below.

Holder	Share Awards Outstanding as of January 1, 2018	Change	Share Awards Outstanding as of December 31, 2018	Change	Share Awards Outstanding as of December 31, 2019
Elmar Schnee, Chairman of the Board	—	—	—	23,236	23,236
Thomas Eklund, Board member	—	—	—	8,449	8,449
Hilde Furberg, Board member	—	—	—	8,449	8,449
Lennart Hansson, Board member	—	—	—	8,449	8,449
Diane Parks, Board member	—	—	—	**8,449**	**8,449**
Total	—	—	—	**57,032**	**57,032**

Calculation of fair value of share-based payments (Board LTIP 2019)

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).

	Grant Date	Exercise Date	Fair Value at Grant Date	Number of Share Awards
Board LTIP 2019	May 10,2019	June 1,2022	22.49	57,032

The total cost of the outstanding share-based payments is presented below. These costs do not affect the Groups consolidated statement of cash flows. The Group has 70,000 warrants which are set aside to secure the delivery of shares in connection with the utilization of the Board LTIP 2019. For additional information see Note 23 Shareholders' Equity.

	Year Ended December 31,	
	2019	2018
Personnel cost, IFRS 2 Share-based payments	249	—
Provisions attributable to social security costs, IFRS 2 Share-based payments	175	—
	424	—

Note 11. Financial Income

	Year Ended December 31,	
	2019	2018
Interest income	926	6
Exchange rate differences	—	435
Total	**926**	**441**

Note 12. Financial Expense

	Year Ended December 31,	
	2019	2018
Interest on lease liabilities	(307)	—
Other interest expenses	(18)	(8)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 12. Financial Expense (continued)

	Year Ended December 31,	
	2019	2018
Exchange rate differences	(2,383)	—
Changes in FX options measured at fair value	(2,700)	—
Total	**(5,408)**	(8)

Note 13. Income Tax

	Year Ended December 31,	
	2019	2018
Current income taxes	(77)	—
Income tax expense recorded in the statement of income	**(77)**	—
Reconciliation of effective tax rate		
Accounting loss before income tax	(32,501)	(132,049)
Tax in accordance with applicable tax rate in Sweden 21.4% (22.0%)	6,955	29,051
Effect of other tax rates for foreign subsidiaries	2	—
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(6,316)	(29,069)
Non-deductible expenses	(782)	(35)
Non-taxable income	64	53
Income tax expense recorded in the statement of income	(77)	—
At the effective income tax rate	0%	0%

The Group has costs attributable to new share issue amounted to SEK 10,915, which are recognized directly against equity. These costs are however deductible for tax purposes, despite not being charged against the statement of income.

As of December 31, 2019, the Group has SEK 578,117 (SEK 535,802) of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position. 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,	
	2019	2018
Loss per share before and after dilution		
Net loss for the year attributable to shareholders of the Parent Company	(32,578)	(132,049)
Weighted-average number of common shares outstanding	36,940,587	25,948,037
Loss per share before and after dilution	(0.88)	(5.09)

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. 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 2017–2019. 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 warrants with entitlement to

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 14. Earnings Per Share (continued)

subscribe to 2,575,586 shares and 2,518,086 shares, since the Group is in a loss position for the years ended December 31, 2019 and December 31, 2018, respectively. Further, there is no dilution effect for issued share awards with entitlement to receive 57,032 shares, due to performance-based vesting for the year ended December 31, 2019.

For disclosures regarding the number of outstanding shares, refer to Note 23 Shareholders' Equity.

Note 15. Intangible assets

	December 31,	
	2019	2018
Licenses and similar rights		
Cost at opening balance		—
Acquisition for the year	16,066	—
Cost at closing balance	16,066	—
Amortization at closing balance	—	—
Net book value	16,066	—

Acquisition during the year

The Group licensed Budenofalk 3 mg oral capsule from the German pharmaceutical company Dr Falk Pharma GmbH, for development in the United States. The agreement covers all indications for the United States, excluding orphan indications who are not liver related. The Group paid an initial payment of EUR 1.5 million for the license. In addition, one-off payments, which are paid if certain regulatory milestones are achieved and if potential future sales reach certain predetermined milestones, totaling EUR 38.5 million may be paid together with royalties on future sales.

The initial payment of EUR 1.5 million (SEK 16,066) has been recognized as an intangible asset according to IAS 38. The Group will include future one-off payments in the acquisition cost if and when a decision has been made to take the measures that triggers additional payment, meaning only payments the Group has control over if they will occur, are included in the acquisition cost of intangible assets.

Note 16. Equipment

	December 31,	
	2019	2018
Cost at opening balance	813	813
Acquisition for the year	118	—
Disposal for the year	(813)	—
Cost at closing balance	**118**	**813**
Depreciation at opening balance	(706)	(655)
Depreciation for the year	(44)	(51)
Disposal for the year	736	—
Depreciation at closing balance	**(14)**	**(706)**
Net book value	**104**	**107**

Depreciation on equipment included in the consolidated statement of income under Administrative and selling expenses amounted to SEK 44 (SEK 51).

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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Note 17. Non-Current Financial Assets

	December 31,	
	2019	2018
Opening cost	341	341
Bank guarantees granted	1,888	—
Reimbursement security deposit	(290)	—
Net book value	**1,939**	**341**

Non-current financial assets comprise of bank guarantees/deposits paid of SEK 1,938 (SEK 340).

Note 18. Financial and Non-Financial Assets and Liabilities

Financial and non-financial assets and liabilities at December 31, 2019 and December 31, 2018:

December 31, 2019	Financial Assets Measured at Fair Value through Profit or Loss	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Assets				
Fixed assets	—	—	22,129	22,129
Non-current financial assets	—	1,939	—	1,939
Accounts receivables	—	46,586	—	46,586
Other current assets	399	—	2,320	2,719
Prepaid expenses	—	—	18,287	18,287
Cash	—	753,540	—	753,540
	399	802,065	42,736	845,200

	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
Liabilities			
Provisions	—	175	175
Non-current lease liabilities	3,584	—	3,584
Accounts payable	24,384	—	24,384
Current lease liabilities	2,486	—	2,486
Other current liabilities	—	985	985
Accrued expenses and deferred revenue	14,837	10,678	25,515
	45,291	11,838	57,129

December 31, 2018	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Assets			
Equipment	—	107	107
Non-current financial assets	341	—	341

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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Note 18. Financial and Non-Financial Assets and Liabilities (continued)

December 31, 2018	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Other current assets	—	1,630	1,630
Prepaid expenses	—	164	164
Cash	646,175	—	646,175
	646,516	1,901	648,417

	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
Liabilities			
Accounts payable	22,643	—	22,643
Other current liabilities	—	904	904
Accrued expenses	944	5,751	6,695
	23,587	6,655	30,242

Financial assets valued at fair value through profit or loss consist of currency options amounting to SEK 399 (SEK 0). Currency options are valued based on quoted prices in active markets for similar assets and liabilities at year-end.

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 19. 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 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, and accordingly no provision for credit risk is recognized.

Credit risk accounts receivable

The payment terms amount to 20 business days depending on the counterparty.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 19. Financial Risks (continued)

Days past due, but not impaired, receivables on the closing day is given below. There is no reserve for bad debts and no recognized credit losses.

	December 31,	
	2019	2018
Days past due account receivables	—	—
Not due account receivables	46,586	—
Total	**46,586**	—

The credit quality of receivables that are not past due or written down is deemed to be good. The accounts receivable refers to Everest Medicines and was settled after the balance sheet date, see also Note 3 Revenue from Contracts with Customers.

Market Risks

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The type of market risk that impacts the Group is currency risk. The Group does not currently have any loans or holdings that expose the group to interest rate risk or other price risk.

Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The primary exposure derives from the Group's purchases in foreign currencies. This exposure is known as transaction exposure. Currency risk is also found in the translation of the assets and liabilities of foreign operations to the Parent Company's functional currency, known as translation exposure.

Transaction Exposure

Transaction exposure from contracted payment flows in foreign currency is limited in the Group. Refer to the table below for exposure in each currency.

Currency Exposure 2019	Revenue	Operating expenses
USD	100%	22%
EUR	—	54%
GBP	—	3%
SEK	—	21%

Currency Exposure 2018	Revenue	Operating expenses
USD	—	10%
EUR	—	52%
GBP	—	2%
SEK	—	36%

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 10,246 (SEK 6,006). A 10% stronger U.S. dollar against the Swedish Krona would have a positive impact on profit after tax and equity of approximately SEK 14,359 (neg. SEK 1,115).

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 19. Financial Risks (continued)

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. This translation exposure exists against U.S. dollar and amounted to a loss of SEK 359 on the closing date. A 10% stronger Swedish Krona against the U.S. dollar would have a negative impact on equity of approximately SEK 36.

The Group also has a translation exposure arising from the translation of foreign trade debt to the Swedish Kronor. This exposure amounted to SEK 5,866 (SEK 3,202) at the closing date in U.S. dollars and SEK 14,817 (SEK 15,701) in Euros. A 10% stronger U.S. dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 587 (SEK 320). A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 1,482 (SEK 1,570).

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 currently financed by equity and thus is not exposed to risks related to external loan financing. Accordingly, the primary risks pertain to the risk of not securing additional contributions and investments from the owners.

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 day rate. Financial instruments with variable interest rates were measured at the rate on the closing date. Liabilities were included in the earliest period when repayment is required. For future lease payments see Note 8 Leases.

Maturity Analysis

	December 31, 2019		
	< 6 Months	6 – 12 Months	>12 months
Accounts payable	24,384	—	—
Other current liabilities	908	—	—
Accrued expenses	21,982	2,659	—

	December 31, 2018		
	< 6 Months	6 – 12 Months	>12 month
Accounts payable	22,643	—	—
Other current liabilities	904	—	—
Accrued expenses	4,409	2,286	—

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 20. Prepaid Expenses

	December 31,	
	2019	2018
Prepaid rental charges	771	164
Prepaid expenses for research and development	2,854	—
Prepaid transaction costs	14,662	—
Total	18,287	164

Note 21. Cash

	December 31,	
	2019	2018
Available balances	753,540	646,175
Total	**753,540**	**646,175**

Cash refer to cash at banks and are primarily in Swedish Kronor.

	Year Ended December 31,	
Adjustments for non-cash items	2019	2018
Depreciation and amortization	1,822	51
Change in provisions	175	—
Share-based payments	249	—
Other	62	—
Total	2,308	51

Reconciliation of liabilities from financing activities

			Non-Cash Items		
	January 1, 2019	Cash Flow	Additional Agreement	Termination of Agreement	December 31, 2019
Lease liabilities	1,819	(1,652)	7,527	(1,624)	6,070
	1,819	(1,652)	7,527	(1,624)	6,070

			Non-Cash Items		
	January 1, 2018	Cash Flow	Interest on Loan	Offsetting of New Shares	December 31, 2018
Shareholder loans	470	(470)	—	—	—
	470	(470)	—	—	—

Note 22. Group Companies

The consolidated financial statements of the Group include:

Name	Principal Activities	Country of Incorporation	% Equity Interest 2019	% Equity Interest 2018
Parent Company				
Calliditas Therapeutics AB	Research and development of pharmaceuticals	Sweden		

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 22. Group Companies (continued)

Name	Principal Activities	Country of Incorporation	% Equity Interest 2019	% Equity Interest 2018
Nefecon AB	Administration of incentive programs issued by the Parent Company	Sweden	100%	100%
Calliditas Therapeutics Inc.	Pre-commercialization activities in the United States	USA	100%	—
Pharmalink Oncology AS	No activities as of December 31, 2019 and December 31, 2018	Norway	100%	100%

The Group established a new subsidiary in the United States (Calliditas Therapeutics Inc.) and the Group completed a merger of Busulipo AB and Pharmalink Nordic AB with the Parent Company.

Note 23. Shareholders' Equity

Share capital and other contributed capital	Number of Shares	Share Capital	Additional Paid-in Capital
At January 1, 2018	16,673,000	667	352,959
Premiums received from warrants	—	—	2,826
Contributions from shareholders	—	—	29,999
Interest from capital contributions from shareholders	—	—	3,059
Offset issue approved in June 2018	2,114,903	84	(84)
IPO new share issue June, 2018[1]	16,414,444	657	683,560
At December 31, 2018	35,202,347	1,408	1,072,319
Premiums received from warrants	—	—	2,834
Share-based payment	—	—	249
New share issue	3,505,291	140	199,262
At December 31, 2019	38,707,638	1,548	1,274,664

(1) Initial public offering on the Nasdaq Stockholm exchange in June 2018

Share Capital

All shares have been fully paid and no shares are reserved for sale. All shares are common shares, confer the same entitlement to capital, and carry one vote. The quotient value is SEK 0.04 per share. No shares are held in treasury by the Parent Company or its subsidiaries.

Additional Paid-in Capital

Additional paid-in capital is comprised of capital contributed by the Parent Company's owners, in the event of share premiums arising on share subscription, warrants premiums and accounted capital from warrants, and other financing treated as equity.

Bridge Loans

In connection with the listing on June 29, 2018, all outstanding bridge loans of SEK 95.2 million in total, including accrued interest, were converted into shares at a conversion price of SEK 45 per share, which corresponded to the listing price for the Group's share at the Nasdaq Stockholm listing. These loans were subscribed by the company in 2017 and 2018 with a total amount of SEK 91.6 million and an annual interest rate of 8 percent with a maturity of 12 months.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 23. Shareholders' Equity (continued)

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,	
	2019	2018
Balance at January 1	(34)	(40)
Change for the year ended	(11)	6
Balance at December 31	(45)	(34)

Note 24. Provisions

	December 31,	
	2019	2018
Opening balance	—	—
Provisions for the year	175	—
Total	175	—

Refers to social security costs related to share-based payment. There is uncertainty as to when social security costs for share-based payments will be paid in the future, and what amount they will ultimately be adjusted to as it is dependent on market values at the time when performance shares are used.

Note 25. Accrued Expenses and Deferred Revenue

	December 31,	
	2019	2018
Accrued salaries and Board fees	4,726	2,286
Vacation pay liability	1,904	1,347
Social security costs	2,975	2,098
Accrued expenses for research and development	1,176	944
Deferred revenue	874	—
Other accrued expenses	13,860	20
Total	25,515	6,695

Other accrued expenses as of December 31, 2019 are mainly attributable to prepaid transaction costs of SEK 9,716 and amounts owed to external suppliers of SEK 4,144.

Note 26. Related Party Transactions

For information regarding remuneration of senior executives, 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 and 10 Share-Based Payments.

Note 27. 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 all products, including Nefecon, if approved, covered by the license granted to us pursuant to our agreement with Archimedes pursuant to which we were granted

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(SEK in thousands, except share amounts or as otherwise indicated)

Note 27. Pledged Assets, Contingent Liabilities and Other Obligations (continued)

(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 amounting to SEK 1,938 (SEK 340), which consist of restricted bank accounts of SEK 1,938. The Group has no other obligations.

Note 28. Events After the Reporting Period

In January 2020, our Board of Directors determined to investigate whether there are conditions for a potential offering of the company's securities in the United States and a press release with the title "Calliditas submits draft registration statement for the listing of ADSs in the U.S." was published.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(Unaudited)
(SEK in thousands, except per share amounts)

	Notes	Nine Months Ended September 30, 2020	2019
Net sales	4	474	138,243
Operating expenses:			
Research and development		(167,379)	(108,117)
Administrative and selling		(77,843)	(39,092)
Other operating income		969	3,515
Other operating expenses		—	(4,525)
Operating loss		**(243,779)**	**(9,976)**
Financial income		504	2,158
Financial expenses		(19,603)	(1,710)
Loss before income tax		**(262,878)**	**(9,528)**
Income tax expense		(185)	—
Loss for the period attributable to shareholders of the Parent Company		**(263,063)**	**(9,528)**
Loss per share before and after dilution		(6.09)	(0.26)

The accompanying notes are an integral part of these condensed consolidated financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited)
(SEK in thousands)

	Notes	Nine Months Ended September 30, 2020	2019
Loss for the period		(263,063)	(9,528)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		(20)	27
Total other comprehensive income/(loss)		(20)	27
Total comprehensive loss attributable to shareholders of the Parent Company		(263,083)	(9,501)

The accompanying notes are an integral part of these condensed consolidated financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
(Unaudited)
(SEK in thousands)

	Notes	September 30 2020	December 31 2019
ASSETS			
Non-current assets			
Intangible assets		16,066	16,066
Equipment		89	104
Right-of-use assets		4,144	5,959
Non-current financial assets		2,111	1,939
Total non-current assets		22,410	24,068
Current assets			
Accounts receivables		—	46,586
Other current assets	6	4,106	2,719
Prepaid expenses		16,798	18,287
Cash		1,396,869	753,540
Total current assets		1,417,773	821,132
TOTAL ASSETS		1,440,183	845,200
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital		1,998	1,548
Additional paid-in capital		2,126,016	1,274,664
Reserves		(66)	(45)
Retained earnings including net loss for the year		(751,160)	(488,096)
Total equity attributable to shareholders of the Parent Company	7,8	1,376,788	788,071
Non-current liabilities			
Provisions	8	1,931	175
Other non-current liabilities		1,034	3,584
Total non-current liabilities		2,965	3,759
Current liabilities			
Accounts payable		19,872	24,384
Current tax liabilities		15	77
Other current liabilities		3,907	3,394
Accrued expenses and deferred revenue		36,636	25,515
Total current liabilities		60,430	53,370
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,440,183	845,200

The accompanying notes are an integral part of these condensed consolidated financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(Unaudited)
(SEK in thousands)

	Notes	Share Capital	Additional-Paid-in Capital	Translation Reserve	Retained Earnings Including Net Loss for the Period	Total
Opening shareholders' equity January 1, 2019		1,408	1,072,319	(34)	(455,518)	618,175
Loss for the period		—	—	—	(9,528)	(9,528)
Other comprehensive income/ (loss)		—	—	27	—	27
Total comprehensive income/(loss) for the period		—	—	27	(9,528)	(9,501)
Transactions with owners:						
New share issue	7	140	210,177	—	—	210,317
Cost attributable to new share issue	7	—	(10,915)	—	—	(10,915)
Premiums from warrants issuance	8	—	1,749	—	—	1,749
Share-based payments	8	—	142	—	—	142
Total transactions with owners		140	201,153	—	—	201,293
Closing shareholders' equity September 30, 2019		1,548	1,273,473	(7)	(465,046)	809,967
Opening shareholders' equity January 1, 2020		1,548	1,274,664	(45)	(488,096)	788,071
Loss for the period		—	—	—	(263,063)	(263,063)
Other comprehensive income/(loss)		—	—	(20)	—	(20)
Total comprehensive income/(loss) for the period		—	—	(20)	(263,063)	(263,083)
Transactions with owners:						
New share issue	7	398	890,990	—	—	891,388
Cost attributable to new share issue	7	—	(97,686)	—	—	(97,686)
Exercise of warrants	7	52	54,867	—	—	54,919
Premiums from warrants issuance		—	—	—	—	—
Share based payments	8	—	3,179	—	—	3,179
Total transactions with owners		450	851,350	—	—	851,800
Closing shareholders' equity September 30, 2020		1,998	2,126,016	(65)	(751,159)	1,376,788

Equity is fully attributable to the shareholders of Calliditas Therapeutics AB.

The accompanying notes are an integral part of these condensed consolidated financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)
(SEK in thousands)

	Notes	Nine Months Ended September 30, 2020	2019
Operating activities:			
Operating loss		(243,779)	(9,976)
Adjustments for non-cash items		6,866	1,438
Interest paid		(321)	(219)
Income taxes paid		(427)	—
Cash flow used in operating activities before changes in working capital		(237,661)	(8,757)
Cash flow (used in)/from changes in working capital:			
Changes in operating receivables		28,558	(10,784)
Changes in operating liabilities		19,996	(6,035)
Cash flow used in operating activities		(189,107)	(25,576)
Investing activities:			
Cash flow used in investing activities		(2)	(17,781)
Financing activities:			
New share issue		891,388	210,317
Cost attributable to new share issue		(95,937)	(10,915)
Premiums from warrants issuance		54,919	1,749
Repayment of loans		(2,488)	(1,063)
Cash flow from financing activities		847,882	200,088
Net increase/(decrease) in cash		658,773	156,731
Cash at the beginning of the period		753,540	646,175
Net foreign exchange gains/(loss) on cash		(15,444)	2,169
Cash at the end of the period		1,396,869	805,075

The accompanying notes are an integral part of these condensed consolidated financial statements.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(SEK in thousands, except share amounts or as otherwise indicated)

Note 1. 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 activities in pharmaceuticals. These interim condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the nine months ended September 30, 2020 and September 30, 2019. All the Group's significant business operations are conducted in the Parent Company.

Calliditas is a Swedish public limited company registered in and with its registered office in Stockholm. The registered address of the corporate headquarters is Kungsbron 1, C8, Stockholm, Sweden. Calliditas is listed at Nasdaq Stockholm in the Mid Cap segment with ticker CALTX and from June 5, 2020 Calliditas is also listed, in the form of ADSs, on The Nasdaq Global Select Market in the United States under the ticker "CALT".

These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on December 28, 2020.

Emerging Growth Company Status

Calliditas is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The condensed consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Calliditas has elected to take advantage of specified reduced reporting and regulatory requirements in contrast to those otherwise applicable generally to public companies. These provisions include:

- the requirement to have only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure; and
- exemption from the auditor attestation requirement in the assessment of Calliditas's internal control over financial reporting pursuant to Section 404 the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act.

Calliditas will remain an emerging growth company until the earliest of (i) the last day of the first fiscal year (a) following the fifth anniversary of the completion of the global offering, (b) in which its annual gross revenue totals at least $1.07 billion or (c) when Calliditas is deemed to be a large accelerated filer, which means the market value of Calliditas's common shares that is held by non-affiliates exceeds $700.0 million as of the prior June 30th and (ii) the date on which Calliditas has issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Note 2. Significant Accounting Policies

These interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting". The Parent Company applies the Swedish Financial Reporting Board recommendation RFR2, Accounting for legal entities. None of the new or amended standards and interpretations that became effective January 1, 2020, have had a significant impact on the Group's financial reporting. Relevant accounting principles can be found in the 2019 Consolidated Financial Statements.

Unaudited Interim Condensed Consolidated Financial Statements

The interim condensed consolidated statement of financial position as of September 30, 2020, and the interim condensed consolidated statements of income and comprehensive income, changes in shareholders' equity and cash flows for the nine months ended September 30, 2020 and 2019 are unaudited. The

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(SEK in thousands, except share amounts or as otherwise indicated)

Note 2. Significant Accounting Policies (continued)

unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair statement of the Group's financial position as of September 30, 2020 and its results of operations and cash flows for the nine months ended September 30, 2020 and 2019. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the nine-month periods are also unaudited. The condensed consolidated results of operations for the nine months ended September 30, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020 or for any other future annual or interim period. The condensed consolidated statement of financial position as of December 31, 2019 included herein was derived from the audited consolidated financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with the Group's audited consolidated financial statements included elsewhere in this prospectus.

Note 3. Risks and uncertainties

Operational risks

Research and drug development up to product approval and registration is subject to considerable risk and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to the technological risk such as the risk for insufficient efficacy, intolerable side effects or manufacturing problems. Competing pharmaceuticals can capture market share or reach the market faster, or if competing research projects achieve better product profiles, the future value of the product portfolio may be lower than expected. The operations may also be impacted negatively by regulatory decisions, such as decisions on approvals and price changes.

COVID-19

A novel strain coronavirus, known as COVID-19, has rapidly developed from an initial event in Wuhan, China, to a worldwide pandemic and infections have been reported globally. Calliditas has clinical trial sites in the global Phase 3 NefIgArd trial based in areas currently affected by this coronavirus and the future spread of the virus and its impact on global markets, the supply chain, and research sites remains unknown. Calliditas has not yet experienced any major disturbances in the NefIgArd trial. The extent to which the coronavirus impacts the operations and the NefIgArd trial will depend on the type, degree and duration of the various restrictions put in place to contain the virus or treat those affected. This today varies in different geographies, and future developments cannot be predicted with reasonable assurance.

The pandemic may negatively impact our trial as a result of disruptions, such as travel bans, quarantines, and inability of patients to access the trial sites and provide samples as well as interruptions in the supply chain, which could result in delays and impact on the data integrity of the trial.

The continued spread of the coronavirus globally, may negatively impact our operations, including our trials. It could also negatively affect the operations of key governmental agencies, such as the FDA and EMA, which may delay the development of our product candidates, or could result in the inability of our suppliers to deliver components or raw materials on a timely basis, each of which in turn could have a negative impact on our business and results of operations.

Financial risks

Calliditas' financial policy governing the management of financial risks has been designed by the Board of Directors and represents the framework of guidelines and rules in the form of risk mandated and limits for financial activities.

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(SEK in thousands, except share amounts or as otherwise indicated)

Note 3. Risks and uncertainties (continued)

The Group is primarily affected by foreign exchange risk, since the development costs for Nefecon are mainly paid in USD and EUR. Further, the Group carry cash in USD to meet future expected costs in USD in connection with a potential commercialization of Nefecon in United States. Regarding the Group and the Parent Company's financial risk management, the risks are essentially unchanged compared with the description in the 2019 consolidated financial statements.

For more information and full disclosure regarding the operational- and financial risks, reference is made to the 2019 consolidated financial statements included elsewhere in this prospectus.

Note 4. Revenue from contracts with customers

The Group's revenues for the nine months ended September 30, 2020 consisted of revenues for the delivery of study-related drugs within the framework of the out-licensing of Nefecon in connection with the agreement with Everest Medicines to Greater China and Singapore.

Revenue for the provision of drug for conducting clinical trials was recognized at a point in time, which occurred when control over the drug was transferred to Everest Medicines. Calliditas has not completed all performance obligations within the agreement as of the delivery of study-related drugs to Everest Medicines. The remaining performance obligations amounts to SEK 400 thousand and SEK 874 thousand as of September 30, 2020 and 2019, respectively, and are expected to be completed during 2020–2021.

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

	Nine Months Ended September 30,	
	2020	**2019**
Type of good or service		
Out-licensing	—	138,243
Provision of drugs	474	—
Total	474	138,243

	Nine Months Ended September 31,	
	2020	**2019**
Geographical markets		
China, Hong Kong, Macau, Taiwan and Singapore	474	138,243
Total	474	138,243

Note 5. Related-Party Transactions

During the reporting period, no significant related-party transactions have taken place. For information about incentive programs please see Note 8.

Note 6. Financial Instruments

The Groups' financial assets comprise of long-term receivables, derivatives, other current receivables and cash, all of which, except derivatives, are recognized at amortized cost. Derivatives are recognized at fair value through profit or loss, which consist of currency options amounting to SEK 851 and SEK 1,590 as of September 30, 2020 and 2019, respectively. Currency options are presented as "Other current assets" and valued at fair value based on calculation using the Black-Scholes option pricing model (Level 2) as of

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(SEK in thousands, except share amounts or as otherwise indicated)

Note 6. Financial Instruments (continued)

September 30, 2020 and 2019. The Group's financial liabilities comprise of ac-counts payable and other current liabilities, which are recognized at amortized cost. The carrying amount is an approximation of the fair value.

Note 7. Shareholders' Equity

	September 30,	
	2020	2019
Total registered shares at the beginning of the period	38,707,638	35,202,347
New issue of shares during the period	11,233,946	3,505,291
Total registered shares at the end of period	**49,941,584**	**38,707,638**
Share capital at the end of period	1,998	1,548
Shareholders' equity at the end of period	1,376,788	809,967

	Nine Months Ended September 30,	
	2020	2019
Loss per share before and after dilution	(6.09)	(0.26)
Weighted-average number of shares outstanding for the period, before and after dilution	43,165,505	36,345,098

Reserves for translation from foreign operations amounted to (SEK 20) and SEK 27, which are included in shareholders' equity as of September 30, 2020 and 2019, respectively.

In June 2020, Calliditas completed an initial public offering on The Nasdaq Global Select Market in the United States, by way of issuance of 9,230,770 new common shares, consisting of a public offering of 8,306,770 common shares in the form of American Depositary Shares ("ADSs"), with each ADS representing two common shares, and a concurrent private placement of 924,000 common shares. Furthermore, in July 2020, the exercise of the partial over-allotment option from the IPO on The Nasdaq Global Select Market was completed, by way of issuance of 706,676 new common shares in the form of American Depositary Shares ("ADSs"), with each ADS representing two common shares.

In addition, Calliditas has during the period completed a registration of issue of shares of 1,296,500 common shares, which referred to the exercise of the Warrant Program 2017/2020.

Note 8. Incentive programs

Warrant Program 2018/2022

The warrants in Warrant Program 2018/2022 may be exercised from January 1, 2022 until March 31, 2022 and each warrant will entitle the participant to subscribe for one new share in the Parent Company at a subscription price of SEK 74.30 per share. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model.

Warrant Program 2019/2022

The warrants in the Warrant Program 2019/2022 may be exercised between October 1, 2022 and December 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the Parent Company at a subscription price of SEK 74.50 per share. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(SEK in thousands, except share amounts or as otherwise indicated)

Note 8. Incentive programs (continued)

Board LTIP 2019

This is a performance-based long-term incentive program for certain Calliditas Board members. A total of 51,399 share awards were granted under the program during the second quarter of 2019. The share awards are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2019 Annual General Meeting to June 1, 2022.

Board LTIP 2020

This is a performance-based long-term incentive program for certain Calliditas Board members. A total of 31,371 share awards were granted under the program during the second quarter of 2020. The share rights are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2020 Annual General Meeting to July 1, 2023.

ESOP 2020

In 2020, Calliditas implemented an option program for employees and key consultants in Calliditas. The options were allotted free of charge to participants of the program. The options have a three-year vesting period calculated from the allotment date, provided that, with customary exceptions, the participants remain as employees of, or continue to provide ser-vices 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 the weighted average price that the company's shares were traded for on Nasdaq Stockholm during the ten trading days preceding the allotment date. The options have, at the time of issue, been valued according to the Black & Scholes valuation model.

Summary of Outstanding Incentive Programs as of September 30, 2020 and 2019:

Incentive Programs	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding
Warrant program 2018/2022	856,586		—	856,586
Warrant program 2019/2022	422,500		—	422,500
Board LTIP 2019	—		51,399	51,399
Board LTIP 2020	—		31,371	31,371
ESOP 2020	—	1,089,000	—	1,089,000
Total Outstanding as of September 30, 2020	**1,279,086**	**1,089,000**	**82,770**	**2,450,856**

Incentive Programs	Warrants Outstanding	Share Awards Outstanding	Total Outstanding
Warrant program 2017/2020	1,296,500	—	1,296,500
Warrant program 2018/2022	856,586	—	856,586
Warrant program 2019/2022	422,500	—	422,500
Board LTIP 2019	—	57,032	57,032
Total Outstanding as of September 30, 2019	**2,575,586**	**57,032**	**2,632,618**

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(SEK in thousands, except share amounts or as otherwise indicated)

Note 9. Subsequent events

Acquisition of a Controlling Interest in Genkyotex S.A.

In November 2020, Calliditas 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 the product portfolio in orphan diseases. Calliditas acquired 7,236,515 ordinary shares of Genkyotex from Genkyotex's largest shareholders and management team, or the Block Sellers, representing 62.7% of the share capital and voting rights for EUR 19.7 million in cash at EUR 2.73 per share. On November 26, 2020, Calliditas submitted a simplified public mandatory cash offer, or the Tender Offer, at 2.80 EUR per share plus contingent consideration amounting to a maximum of EUR 55 million, based on 100% of Genkyotex shares outstanding, which is contingent upon future regulatory approvals of Setanaxib in the U.S. and Europe, to the shareholders of Genkyotex. The Tender Offer closed on December 11, 2020. As a result of the Tender Offer, Calliditas increased the ownership percentage to 86.2% of the share capital of Genkyotex.

Calliditas acquired control of Genkyotex on November 3, 2020 and the following table sets forth a allocation of the purchase price to the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed of Genkyotex using Genkyotex's consolidated statement of financial position as of November 3, 2020, with the excess recorded to goodwill:

(thousands)	EUR	SEK
Acquired identifiable intangible assets	36,871	382,521
Patents and software	2,785	28,893
Fixed assets	39	405
Right of use assets	196	2,033
Other current assets	966	10,022
Cash and cash equivalents	3,110	32,265
Noncontrolling interest	(13,023)	(135,111)
Deferred taxes liabilities	(7,970)	(82,683)
Interest-bearing provisions	(907)	(9,410)
Lease liability	(196)	(2,033)
Short term debt	(199)	(2,065)
Accounts payables	(810)	(8,403)
Other operating liabilities	(788)	(8,175)
Net assets acquired (a)	20,074	208,259
Total contingent consideration (b)	4,941	51,257
Total consideration transferred (c)	19,747	204,867
Estimated goodwill (b)+(c)-(a)	4,614	47,866

CALLIDITAS THERAPEUTICS AB AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)
(SEK in thousands, except share amounts or as otherwise indicated)

Note 9. Subsequent events (continued)

Phase 3 clinical trial results from Part A of NefIgArd

In November 2020, Calliditas announced positive topline results from Part A of the global Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon versus placebo in pa-tients with primary IgA nephropathy (IgAN). The trial met its primary objective of demonstrating a statistically significant reduction in the urine protein creatinine ratio, or UPCR, after nine months of treatment with 16 mg of Nefecon compared to placebo, with significant continued improvement at 12 months. The trial also met the key secondary endpoint showing a statistically significant difference in estimated glomerular filtration rate or eGFR after nine months of treatment with Nefecon com-pared to placebo. Collectively the efficacy data from nine months treatment with 16 mg of Nefecon indicated a significant and beneficial effect on key factors correlated to the progression to end stage renal disease (ESRD) for IgAN patients. On the basis of these results, Calliditas plans to submit for accelerated approval with the US Food and Drug Administration (FDA) in the first quarter of 2021 followed by a submission for conditional approval with the European Medicines Agency in H1 2021.

GENKYOTEX S.A.

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Independent Auditors' Report

The Board of Directors
Genkyotex S.A.

We have audited the accompanying consolidated financial statements of Genkyotex S.A. and its subsidiary, which comprise the consolidated statements of financial position as of September 30, 2020, and December 31, 2019, and the related consolidated income statements, consolidated statements of comprehensive income (loss) , statements of changes in consolidated shareholders' equity, and consolidated statements of cash flows for the nine month period ended September 30, 2020 and the year ended December 31, 2019, and the related notes to the consolidated financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"); this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our qualified audit opinion.

Basis for Qualified Opinion

As disclosed in Note 2.1 to the consolidated financial statements, the consolidated financial statements have been prepared to meet the reporting requirements of Rule 3-05 of Regulation S-X for purposes of a filing with the U.S. Securities and Exchange Commission and do not include comparative financial information as required by IAS 1 "Presentation of Financial Statements".

Qualified Opinion

In our opinion, except for the effects of the matter described in the Basis for Qualified Opinion paragraph, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Genkyotex S.A. and its subsidiary as of September 30, 2020, and December 31, 2019, and the results of their operations and their cash flows for the nine month period ended September 30, 2020 and the year ended December 31, 2019 in accordance with International Financial Reporting standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Lyon, France
January 25, 2021

KPMG Audit
Division of KPMG S.A.

Stéphane Devin
Partner

Bertrand Roussel
Partner

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(amounts in thousands of euros)	NOTES	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
ASSETS			
Intangible assets	3	9,086	2,801
Property, plant and equipment	4	154	218
Non-current financial assets	5	29	36
Total non-current assets		**9,270**	**3,055**
Other current assets	6	1,349	668
Prepaid expenses	6	151	179
Cash and cash equivalents	7	2,417	3,590
Total current assets		**3,917**	**4,437**
TOTAL ASSETS		**13,186**	**7,492**
SHAREHOLDER'S EQUITY AND LIABILITIES			
Shareholders' equity			
Share capital	8	8,683	11,549
Additional paid-in capital		126,118	4,747
Foreign currency transaction adjustment		(2,732)	(2,752)
Accumulated other comprehensive loss		(697)	(647)
Accumulated deficit–attributable to shareholders of Genkyotex		(114,332)	2,669
Net loss–attributable to shareholders of Genkyotex		(7,203)	(11,017)
Shareholders' equity–attributable to shareholders of Genkyotex		**9,836**	**4,548**
Non-controlling interests		—	—
Total shareholders' equity		**9,836**	**4,548**
Liabilities			
Employee benefit obligations	11	1,348	960
Non-current financial liabilities	10	17	63
Total non-current liabilities		**1,364**	**1,023**
Current financial liabilities	10	848	146
Derivative liabilities	10	64	—
Provisions	12	—	258
Accounts payables		562	656
Tax and social liabilities	12	469	808
Other creditors and miscellaneous liabilities		43	54
Total current liabilities		**1,986**	**1,922**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**13,186**	**7,492**

The accompanying Notes form an integral part of these consolidated financial statements

CONSOLIDATED INCOME STATEMENTS

(amounts in thousands of euros, except share and per share data)	NOTES	December 31, 2019 12 months	September 30, 2020 9 months
Research and development expenses, net			
Research and development expenses	16.1	(6,305)	(9,627)
Research tax credit	16.1	899	356
General and administrative expenses	16.2	(2,160)	(1,757)
Other operating income		142	35
Operating loss		**(7,425)**	**(10,993)**
Financial expenses	18	(190)	(101)
Financial income	18	348	12
Change in fair value of derivative instruments	18	64	64
Net financial expense		**222**	**(25)**
Loss before taxes		**(7,203)**	**(11,017)**
Income taxes benefit		—	—
Net loss for the period		**(7,203)**	**(11,017)**
Attributable to shareholders of Genkyotex		*(7,203)*	*(11,017)*
Non-controlling interests		—	—
Basic and diluted weighted average number of shares outstanding		8,146,178	11,160,072
Basic loss per share (€/share)	20	**(0.88)**	**(0.99)**
Diluted loss per share (€/share)	20	**(0.88)**	**(0.99)**

The accompanying Notes form an integral part of these consolidated financial statements

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(amounts in thousands of euros)	December 31, 2019 12 months	September 30, 2020 9 months
Net loss for the period	**(7,203)**	**(11,017)**
Items that will not be reclassified to profit or loss		
Remeasurements of the defined benefit liability (asset)	(183)	50
Items that will be reclassified to profit or loss		
Foreign currency translation adjustment	(370)	(20)
Other comprehensive income (loss)	**(554)**	**30**
Total comprehensive loss	**(7,757)**	**(10,987)**
Attributable to shareholders of Genkyotex	*(7,757)*	*(10,987)*
Non-controlling interests	—	—

The accompanying Notes form an integral part of these consolidated financial statements

STATEMENTS OF CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY

(amounts in thousands of euros, except share data)	Notes	Share capital–number of shares	Share capital	Additional paid-in capital	Accumulated deficit and net loss	Treasury Shares	Foreign currency translation adjustment	Other comprehensive loss	Shareholders' equity–Attributable to shareholders of Genkyotex	Non-controlling interests	Shareholders' equity
As of January 1, 2019		*79,347,621*	**7,935**	**124,183**	**(114,649)**	**(152)**	**(2,361)**	**(514)**	**14,442**	**—**	**14,442**
Net loss for the twelve-month period			—	—	(7,203)	—	—	—	(7,203)	—	(7,203)
Other comprehensive income (loss)			—	—	—	—	(370)	(183)	(554)	—	(554)
Total comprehensive income (loss)			—	—	**(7,203)**	—	**(370)**	**(183)**	**(7,757)**	—	**(7,757)**
Conversion of convertible bonds		*748,687*	749	1,961	—	—	—	—	2,710	—	2,710
Effect of reverse stock split by 10[2]		*(71,412,859)*	—	—	—	—	—	—	—	—	—
Costs incurred in relation to equity transactions[1]			—	(27)	—	—	—	—	(27)	—	(27)
Treasury shares movements, net			—	—	—	107	—	—	107	—	107
Gains and losses, net related to treasury shares			—	—	(122)	—	—	—	(122)	—	(122)
Equity settled share-based payments	9		—	—	483	—	—	—	483	—	483
As of December 31, 2019		***8,683,449***	**8,683**	**126,118**	**(121,491)**	**(45)**	**(2,732)**	**(697)**	**9,836**	**—**	**9,836**
Net loss for the nine-month period			—	—	(11,017)	—	—	—	(11,017)	—	(11,017)
Other comprehensive income (loss)			—	—	—	—	(20)	50	30	—	30
Total comprehensive income (loss)			—	—	**(11,017)**	—	**(20)**	**50**	**(10,987)**	—	**(10,987)**
Conversion of convertible bonds	**8**	417,816	418	382	—	—	—	—	800	—	800
Capital increase	**8**	2,447,297	2,447	2,496	—	—	—	—	4,944	—	4,944
Costs incurred in relation to equity transactions[1]			—	(323)	—	—	—	—	(323)	—	(323)
Allocation of premiums to retained earnings			—	(123,926)	123,926	—	—	—	—	—	—
Treasury shares movements, net			—	—	—	(1)	—	—	(1)	—	(1)
Gains and losses, net related to treasury shares			—	—	8	—	—	—	8	—	8
Equity settled share-based payments	9		—	—	271	—	—	—	271	—	271
As of September 30, 2020		***11,548,562***	**11,549**	**4,747**	**(8,303)**	**(46)**	**(2,752)**	**(647)**	**4,548**	**—**	**4,548**

(1) Costs directly attributable to the issuance of shares in connection with a capital increase with maintenance of the preferential subscription rights are recognized as a reduction from shareholders' equity.
(2) Refer to note 8

The accompanying Notes form an integral part of these consolidated financial statements

CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands of euros)	NOTES	December 31, 2019 12 months	September 30, 2020 9 months
Cash flows from operating activities			
Net loss for the period		**(7,203)**	**(11,017)**
Adjustments to reconcile net loss to cash flows used in operating activities			
Amortization of intangible assets	3	(567)	(427)
Depreciation of property, plant and equipment	4	(147)	(109)
Impairment on the SIIL contract	3, 17		(5,859)
Unrealized foreign exchange gains or losses		325	4
Provisions for pension commitments	11	(123)	349
Provisions	12	—	(258)
Costs related to share-based payments	9	(483)	(271)
Variation of the fair value of derivative		—	64
Fair value of bond loans	10	—	(75)
Interest expenses		(6)	(3)
Operating cash flows before change in working capital requirements		**(6,201)**	**(4,433)**
Change in working capital requirements (net of depreciation of trade receivables and inventories)		**(1,386)**	**1,098**
Decrease (increase) in other current assets		*673*	*682*
Decrease (increase) in prepaid expenses		*(17)*	*(28)*
(Decrease) increase in Accounts payables		*(1,652)*	*94*
(Decrease) increase in social security liabilities		*(358)*	*446*
(Decrease) increase in tax liabilities		*(16)*	*(107)*
(Decrease) increase in other creditors and miscellaneous liabilities		*(17)*	*11*
Cash flows used in operating activities		**(7,588)**	**(3,335)**
Cash flows used in investing activities			
Acquisition of intangible and tangible assets	3, 4	(1)	(2)
Cash flows used in investing activities		**(1)**	**(2)**
Cash flows from financing activities			
Capital increase		—	4,944
Reduction of financial debt relating to the right of use (IFRS 16)	10.3	(130)	(102)
Financial interest paid		(5)	(3)
Repayment of conditional advances	10.1	(118)	—
Costs paid in relation to equity transactions		(27)	(323)
Cash flows (used in) from financing activities		**(281)**	**4,516**
Net effect of exchange rate changes on cash and cash equivalents		(11)	(5)
Decrease in cash and cash equivalents		**(7,881)**	**1,173**
Cash and cash equivalents at the beginning of the period	7	10,297	2,416
Cash and cash equivalents at the end of the period	7	2,416	3,590

The accompanying Notes form an integral part of these consolidated financial statements

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 1: General information about the Company

1.1 Information about the Company and its activity

Founded in October 2001, Genkyotex is a French company (société anonyme) with the following corporate purpose in France and abroad: research, study, development, manufacturing and distribution of medicines and drug and health products in the field of human and animal health.

The Company's therapeutic approach is primarily based on the selective inhibition of NOX enzymes which amplify many pathological processes such as fibroses, inflammation, the perception of pain, the development of cancer and neurodegeneration.

Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, setanaxib (GKT831), a NOX1 and NOX4 inhibitor has shown evidence of anti-fibrotic activity in a Phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease).

Genkyotex SA has been listed on the Euronext market in Paris and Brussels since April 8, 2014.

Genkyotex has its registered office located 218 avenue Marie Curie—Forum 2 Archamps Technopole, 74166 Saint-Julien-en-Genevois, France (register Number at the company's house: 439 489 022 RCS THONON-LES-BAINS)

Genkyotex SA is hereinafter referred to as the "**Company**." The group formed by Genkyotex SA and Genkyotex Suisse SA is hereinafter referred to as the "**Group**."

The following information constitutes the Notes to the financial statements for the nine-month period ended September 30, 2020 with comparative information for the twelve-month period ended December 31, 2019.

The consolidated financial statements of Genkyotex, or the "**Financial Statements**", have been prepared under the responsibility of management of the Company and were approved and authorized for issuance by the Company's Board of Directors on January 24, 2021.

Note 2: Accounting principles, rules and methods

2.1 Principles used in preparing the Financial Statements

The Financial Statements are presented in thousands of euros unless stated otherwise. Some amounts may be rounded for the calculation of financial information contained in the Financial Statements. Accordingly, the totals in some tables may not be the exact sum of the preceding figures.

The Company's consolidated financial statements have been prepared in accordance with the historical cost principle, with the exception of financial instruments measured at their fair value.

Statement of compliance

These Financial Statements as of and for the year ended December 31, 2019 and the nine-month period ended September 30, 2020 have been prepared to meet the reporting requirements of Rule 3-05 of Regulation S-X for purposes of a filing with the U.S. Securities and Exchange Commission in connection with the acquisition of Genkyotex S.A. by Calliditas Therapeutics AB, a company publicly listed in the United States of America, as of November 3, 2020 (refer to paragraph "Going concern" and note 23). The Company has prepared these Financial Statements in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Boards, or IASB, and, with respect to the nine-month period ended September 30, 2020, in accordance with IAS 34 "Interim financial reporting", except that they do not include comparative financial information as of and for the year ended December 31, 2018 and for the nine-month period ended September 30, 2019 as required by IAS 1 "Presentation of Financial Statements".

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

The term "IFRS" refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (IFRS Interpretations Committee, or IFRS IC, and Standing Interpretations Committee, or SIC), whose application is mandatory for the periods presented.

As of December 31, 2019, and September 30, 2020, all IFRS relevant to the Company that the IASB has published and that are mandatory are the same as those endorsed by the EU and mandatory in the EU.

Going concern

The Company focuses on inventing and developing new treatments. The loss-making position over the reference periods is not unusual for a company at this stage of development.

The Company has managed to finance its operations to date primarily through successive capital fund-raising or convertible bonds.

The Company announced on August 13, 2020 the signing of an agreement for the acquisition of a controlling block in Genkyotex SA, representing 62.7% of the share capital and voting rights of Genkyotex from its main shareholders and its management team.

After receipt of clearance from the French Minister of Economy and Finance was received regarding foreign investments into France, Calliditas Therapeutics closed on November 3, 2020 the off-market block trade for a total consideration of €19.75m in cash (€2.73 per ordinary share*) plus contingent rights payable upon regulatory approvals of setanaxib, Genkyotex's lead asset.

Calliditas Therapeutics filed with the French Financial Market Authority ("Autorité des Marchés Financiers" or the "AMF") a simplified mandatory cash tender offer for the remaining Genkyotex shares at €2.80 per ordinary share plus contingent right payable upon regulatory approvals of setanaxib. Following the tender offer, Calliditas owned 86.24% of the share capital and voting rights of Genkyotex.

On December 9, 2020, the Company received a support letter from Calliditas Therapeutics confirming that it is their intention to continue supporting Genkyotex S.A., so as to enable it to meet its liabilities as they fall due and carry on its normal business without any significant curtailment to its operations. Based on this letter, the Board of Directors approved these financial statements on a going concern basis.

Accounting methods

The accounting principles adopted for the Financial Statements as of and for the nine-month period ended September 30, 2020 are the same as for the year ended December 31, 2019 with the exception of the following new standards, amendments and interpretations whose application is mandatory for the Company as of January 1, 2020:

- Amendments to References to the *Conceptual Framework* in IFRS Standards, issued on March 29, 2018 and whose application is mandatory from January 1, 2020;
- Amendments to IAS 1 and IAS 8: Definition of Material, issued on October 31, 2018 and whose application is mandatory from January 1, 2020;
- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform, issued on September 26, 2019 and whose application is mandatory from January 1, 2020;
- Amendments to IFRS 3 *Business Combinations*, issued on October 22, 2018 and whose application is mandatory from January 1, 2020; and
- Amendment to IFRS 16 *Leases Covid 19- Related Rent Concessions* issued on May 28, 2020 and whose application is for annual reporting periods beginning on or after June 1, 2020; early adoption is permitted.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

Adoptions of these standards have not had a material impact on the Financial Statements.

Recently issued accounting pronouncements by the IASB that may be relevant to the Company's operations but have not yet been adopted by the Company are as follows:

- Amendments to IAS 1 *Presentation of Financial Statements: Classification of Liabilities as Current or Non-current and Classification of Liabilities as Current or Non-current—Deferral of Effective Date* issued on January 23, 2020 and July 15, 2020 respectively and whose application is for annual reporting periods beginning on or after January 1, 2023;
- Amendments to IFRS 3 *Business Combinations*,—References to the Conceptual Framework, IAS 16 *Property, Plant and Equipment*—Proceeds before Intended Use, IAS 37 *Provisions, Contingent Liabilities and Contingent Assets—Onerous Contracts—Cost of Fulfilling a Contract*, Annual Improvements 2018-2020, all issued May 14, 2020 and whose application is for annual reporting periods beginning on or after January 1, 2022;
- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 *Interest Rate Benchmark Reform—Phase 2* issued on August 27, 2020 and whose application is for annual reporting periods beginning on or after January 1, 2021.

The Company has not early adopted when applicable, these new accounting standards, amendments and interpretations.

It currently does not anticipate any significant impact on its Financial Statements at adoption date.

Impacts of the health crisis on the financial statements

In the context of the COVID-19 pandemic, the Company continues to closely monitor changes to the official guidelines and recommendations in order to protect its employees and subcontractors. The Company has also implemented strategies to mitigate the impact of the global crisis on its business and operations.

Accordingly, the Company has asked its employees in France and Switzerland to work from home and organize meetings and events remotely as much as possible.

To date, except for the impact of the delay in the development process of the products using the Vaxiclase platform (SIIL contract refer to note 3), the Company is only anticipating a limited impact from the COVID-19 pandemic on its operations, including the planned discussions with regulatory authorities, the conducting of clinical trials as well as interactions with the scientific community and other stakeholders.

The Company will continue to closely monitor the possible impact of COVID-19 on the conducting of clinical trials and discussions with health authorities and, depending on the evolution of the pandemic and of its potential material impact on such trials and discussions, will report to the markets on any such material impact.

2.2. Scope

According to IFRS 10, subsidiaries are all the entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The subsidiaries are consolidated as from the date on which the Group acquires control. They are deconsolidated as of the date on which control ceases.

In connection with the combination of Genkyotex SA and Genkyotex Suisse SA which took place on February 28, 2017, Genkyotex Suisse SA was considered as the buyer from an accounting standpoint (reverse acquisition).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

The scope of consolidation is as follows:

	AS OF			
	DECEMBER 31, 2019		SEPTEMBER 30, 2020	
	Percent interest	Percent control	Percent interest	Percent control
GENKYOTEX SA	Parent company (from a legal standpoint)			
GENKYOTEX SUISSE SA	100.00%	100.00%	100.00%	100.00%

2.3. Reporting currency

The Group's financial statements are prepared in euros (EUR).

2.4. Translation of the financial statements of foreign subsidiaries

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates as of the date this transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currency are converted into functional currency at the exchange rate on the closing date.

Differences resulting from the settlement or conversion of monetary items are recognized in profit and loss.

The financial statements of companies whose operating currency is not the euro (EUR) are converted as follows:

- Statement of financial position items are converted using the closing rate for the year;
- Items of the statement of consolidated operations are converted at the average exchange rate for the period.

The exchange differences arising on conversion for consolidation are recognized in the "currency translation reserve".

The exchange rates used for the preparation of the Financial Statements are as follows:

	Closing rate AS OF		Average rate for the periods ended AS OF	
EXCHANGE RATE	DECEMBER 31, 2019	SEPTEMBER 30, 2020	DECEMBER 31, 2019 12 months	SEPTEMBER 30, 2020 9 months
CHF	1.0854	1.0804	1.1124	1.0680

2.5. Use of judgments and estimates

To prepare the financial statements in accordance with IFRS, the main judgements and estimates are made by the Group's management based on the assumption of business continuity and on the information available at the time. These estimates are ongoing and are based on past experience as well as various other factors judged to be reasonable and form the basis for assessment of the carrying amount of assets and liabilities. The estimates may be revised if the circumstances on which they are based change or as a result of new information. Actual results may differ significantly from these estimates if the assumptions or conditions change.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

The significant estimates or judgments made by the Group relate to the following:

- Valuation of share subscription options and non-voting shares allocated to employees and executives:
  - The fair value measurement of share-based payments is based on the Black & Scholes option valuation model, which includes assumptions about, the expected volatility of the share price over the lifetime of the instrument, the expected term of the options and the expected forfeitures. There is a high inherent risk of subjectivity when using an option valuation model to measure the fair value of share-based payments in accordance with IFRS 2.
  - The valuation assumptions adopted are disclosed in Note 9.
- Defined benefit plans:
  - Defined benefit plans are reported in the balance sheet based on an actuarial valuation of the obligations at period-end, less the fair value of the plan's assets. This valuation is determined by using the projected unit credit method while taking into account the workforce turnover rate, mortality probability and actuarial assumptions based on management estimates.
  - The valuation assumptions adopted are disclosed in Note 11.
- Impairment test of the intangible asset recognized in connection with the license agreement signed with SIIL (for use of the Vaxiclase platform) and its extensions (hereinafter referred to as the "SIIL contract"):
  - The estimated fair value of the SIIL contract is calculated based on the discounted cash flow (DCF) method. In doing so, the Company's management used estimates to determine:
    - future flows for the period until 2035, corresponding to the life of the patent underlying the license sold to SIIL;
    - the probability of success of the various stages of clinical development;
    - the discount rate;
    - the expected development timeline.
  - The valuation assumptions adopted are disclosed in Note 3.

2.6. Intangible assets

Research and development expenses

Research costs are recognized as expenses when they are incurred. Costs incurred on development projects are recognized as intangible assets when the following criteria are fulfilled:

- it is technically feasible to complete the intangible asset so that it will be available for use or sale,
- management intends to complete the intangible asset and use or sell it,
- it is possible to use or sell the intangible asset,
- it can be demonstrated that the intangible asset will likely generate economic benefits in the future,
- adequate technical, financial and other resources necessary to complete the development and to use or sell the intangible asset are available, and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

Regarding the expenses incurred for developing a medicinal product and due to the risks and uncertainties inherent in the R&D process and in obtaining regulatory authorizations, the six criteria for capitalizing expenses are considered fulfilled only when the medicinal product has received marketing authorization.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

Consequently, internal development expenses are recognized in the statement of consolidated operations when incurred.

SIIL contract

Initial valuation

In connection with the accounting for the combination of Genkyotex SA and Genkyotex Suisse SA on February 28, 2017, the Company recognized as an intangible asset a license agreement and its extensions signed between the Serum Institute of India Pvt. Ltd. (SIIL) and Genkyotex S.A. for the use of the Vaxiclase technology as part of the development by SIIL of acellular and multivalent vaccines containing antigens for whooping cough

In return for access to and use of the Vaxiclase technology in the authorized indications, the Company could receive up to US$57 million in initial payments and development and sales milestone payments based on criteria defined in the terms and conditions of the agreement, as well as royalties as a percentage of net sales.

The SIIL contract was valued to €10,697 thousand as of the acquisition date using the discounted cash flow (DCF) method, the future estimated cash flows being adjusted for the probability of success of the various phases in the development of products using the Vaxiclase technology.

Genkyotex S.A. signed as an extension to the SIIL contract in June 2018. Taking into account this latest extension, the agreement provides for:

- An initial payment of €750 thousand (recognized during the first half of 2018 when the extension was signed),
- Milestone payments for emerging markets for up to US$57 million,
- Milestone payments for industrialized countries for up to €100 million.

The Company is also eligible to receive “single-digit percentage” royalties on sales.

Subsequent impairment testing

- The SIIL contract is tested annually for impairment based on the same valuation method used for its initial valuation. The main assumptions used for the impairment testing are described in note 3.

Software

Software license acquisition costs are posted to assets based on the costs incurred to acquire and bring the software concerned online.

Other intangible assets

In application of the IAS 38 criteria, intangible assets acquired are recognized under assets at their acquisition cost.

Amortization expense and duration

When an asset has a finite useful life, amortization is calculated using the straight-line method to spread the cost over the estimated useful life, specifically:

Items	Amortization period
Software	1 year–straight line
SIIL contract and extensions	19 years–straight line (2017–2035 corresponding to the life of the patent underlying the Vaxiclase technology license sold to SIIL)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

The amortization expense for intangible assets is recognized in the consolidated income statement as:

- "General and administrative expenses" for amortization expenses related to accounting software, and
- "Research and development expenses" for the amortization expenses relating to the SIIL contract and extensions and the software used by the laboratory.

2.7. Property, plant and equipment

Property, plant and equipment are valued initially at their acquisition cost.

Assets are depreciated on a straight-line basis over their useful life.

The following depreciation periods are used:

Items	Depreciation period
Office equipment, furniture and computer equipment	3 to 5 years
Laboratory equipment	5 to 8 years
Right of use	1 to 3 years

The depreciation expense for property, plant and equipment is recognized in the consolidated income statement under:

- "General and administrative expenses" for depreciation of office equipment, furniture and computer equipment; and
- "Research and development expenses" for laboratory equipment and other laboratory assets.

2.8. Non-current financial assets

The Group's non-current financial assets are made up of:

- loans and receivables initially reported at fair value and subsequently evaluated at amortized cost, using the effective interest rate method. Collateral deposits and liquidity contract are included in this category.

Financial assets having a maturity over one year are classified under "Non-current financial assets".

2.9. Other current assets

Research tax credit ("CIR")

Research tax credits are granted to the Group's French companies by the French State as an incentive to conduct technical and scientific research. Companies with expenses that meet the eligibility criteria receive a tax credit that can be used to pay the corporate income tax due in the year in which it is granted, as well as in the following three financial years or, as the case may be, any unused surplus can be reimbursed.

In the absence of taxable income, and in view of the Company's SME status, the CIR receivable from the French State is paid in the year following the year in which it is granted.

The research tax credit is recorded in assets for the year it was granted that corresponds to the year during which eligible expenses giving rise to a tax credit were incurred.

The research tax credit is presented in the consolidated statement of consolidated operations under grants in "Research and development expenses".

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

Grants

Grants received are reported as soon as the corresponding receivable becomes certain, taking into consideration the conditions specified when the subsidy was granted.

2.10. Cash and cash equivalents

Cash and cash equivalents recognized in the balance sheet include cash at banks, cash at hand and short-term deposits with an initial maturity of less than three months.

They are held for meeting short-term cash commitments, are easily convertible into a known amount of cash and exposed to negligible risk that they will change in value.

For cash flow statement purposes, net cash consists of cash and cash equivalents as defined above.

2.11. Capital

Classification as equity depends on the specific analysis of the characteristics of each instrument issued. The Company's ordinary shares are classified as equity instruments.

Costs directly attributable to the issuance of shares are recognized, net of tax, as a reduction from shareholders' equity.

2.12. Share-based payments

The Company has implemented several compensation plans settled in equity instruments in the form of warrants ("BSA") and share subscription options ("Stock-options") attributed to employees and board members.

The grant date fair value of the equity settled share-based payments is recognized as an expense with a corresponding increase to equity over the vesting period of the awards

The fair value of the equity instruments granted to employees is measured using the Black-Scholes option valuation model.

Assumptions used in measuring the fair value of such options are disclosed below:

- The share price used is equal to the stock market price at grant date,
- The risk-free rate is based on the average lifetime of the instruments,
- Expected volatility is calculated with reference to a sample of listed companies in the biotechnology sector, over a period commensurate with the expected term of the option, and
- The expected term and forfeiture rate.

2.13. Borrowings and financial liabilities

Unless otherwise indicated, loans and borrowings are reported after initial recognition at amortized cost, calculated using the effective interest rate ("EIR") method, in accordance with IFRS 9.

The portion of financial debts due within one year is presented as "Current financial debt".

2.14. Conditional advances

The Group benefits from a certain amount of public aid, in the form of conditional advances.

They are reported in accordance with IAS 20. These advances are granted at below market interest and measured at amortized cost, in accordance with IFRS 9:

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

- The initial difference between the advance received and its amortized cost is a grant recorded to income in accordance with IAS 20.
- The financial cost of the conditional advances, calculated at the effective interest rate, is then recorded under financial expenses.

If the project which benefits from the conditional advance fails, the conditional advance is usually forgiven. Any such advance forgiveness would be recorded to income as a grant.

2.15. Convertible bonds

Financial instruments, such as convertible bonds ("OCA") or convertible bonds with stock acquisition rights options ("OCABSA") undergo a specific analysis. Refer to note 10.2

2.16. Employee benefit obligations

The Group provides retirement, death and disability benefits to its employees in line with local customs and requirements through pension payments by social security bodies, which are funded by Group and employee contributions (defined contribution plan) in Switzerland and France, the two countries where the Group operates.

The Group also provides retirement, death and disability benefits to its Swiss and French employees through the following defined-benefit plans:

- For Swiss employees, Genkyotex Suisse SA's compulsory company-wide defined-benefit plan through a program that is funded through employer (50%) and employee (50%) contributions. This company-specific plan has been in place since Genkyotex Suisse SA was founded, and all Swiss employees of this company are beneficiaries of the plan. On retirement, the plan participant will receive his/her accumulated savings, which consist of all contributions paid in by the employer and the employee (net of any withdrawals) and the interest granted on those savings, which are fixed, according to the law for the compulsory part and at the discretion of the Council of the Foundation for the optional part. At retirement age, the plan participant will be entitled to choose between a lump sum payment or an annuity, or a combination of the two.
- Employees of the Group's French companies are entitled to a retirement lump sum payment at the time of retirement.

Pension plans, similar compensation and other employee benefits that qualify as defined benefit plans (in which the Group guarantees an amount or defined level of benefits) are reported in the balance sheet based on an actuarial valuation of the obligations at period end, minus the fair value of the plan's assets.

This valuation is determined by using the projected unit credit method, taking into account staff turnover and mortality probability. Any actuarial differences are reported in equity under "Other comprehensive income."

The Group's payments into defined contribution plans are reported under expenses in the consolidated income statement for the period to which they relate. Retirement expenses (cost of services rendered and interest expense) are presented in operating income (loss).

2.17. Provisions

A provision is recognized if, as a result of a past event, a company has a present legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation.

The amount recognized as a provision is the best estimate of the expenditure required to settle the present obligation at the reporting date.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

2.18. Other current liabilities

The fair value of current liabilities is equivalent to their carrying amount in the balance sheet, taking into account the extremely short deadlines for payment.

2.19. Financial assets and liabilities and impacts on consolidated income statement

The Company has established three categories of financial instruments depending on their valuation methods and uses this classification to disclose some of the information required by IFRS 7:

- Level 1: financial instruments listed on an active market;
- Level 2: financial instruments whose valuation methods rely on observable inputs; and
- Level 3: financial instruments whose valuation methods rely entirely or partly on unobservable inputs, an unobservable input being defined as one whose measurement relies on assumptions or correlations that are not based on the prices of observable market transactions for a given instrument on the valuation date, nor on observable market data on the valuation date.

2.20. Revenue

Revenue is recognized in accordance with IFRS 15, the fundamental principle of which is based on the transfer of control of goods and services to the customer.

The standard sets out a five-step general approach to revenue recognition:

- Step 1: Identify the contract;
- Step 2: Identify the “performance obligations” under the contract. The “performance obligations” serve as a unit of account for the revenue recognition;
- Step 3: Determine the transaction price;
- Step 4: Allocate the transaction price to each “performance obligation”;
- Step 5: Recognize the revenue when the “performance obligation” is satisfied, either on a given date or over time.

The standard specifies how to treat licenses and distinguishes two types:

- those which constitute a right to access intellectual property as it will change over the term of the license as a result of future action taken by the licensor. These licenses are known as “dynamic licenses” or “rights to access” and recognition of the associated income is spread over the term of the license; and
- those which constitute a right to use “fixed” intellectual property, as it exists as of the date on which the license is assigned. These licenses are called “static licenses” or “rights of use”, and the income related to them is recognized on a given date at the time when control of the license is transferred, unless the royalty exception applies, regardless of the type of license.

Variable consideration, except for license royalties is recognized when it is highly probable.

IFRS 15 also provides that the revenue related to intellectual property licenses for which royalties are received should be recognized when the later of the following two events occurs:

- the license is sold or used by the customer (on which the calculation of royalties is based);
- the “performance obligation” to which these royalties have been allocated has been satisfied.

2.21. Details of expenses and products by function

The Group presents its consolidated income statement by function in two categories:

- Research and development expenses;

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 2: Accounting principles, rules and methods (continued)

- General and administrative expenses.

Expenses are broken down on the basis of cost accounting.

The research tax credit and other operating grants are presented as a reduction of the research and development costs. They are recognized in profit or loss on a systematic basis as the entity recognizes as expenses the costs that the grants are intended to compensate.

2.22. Net financial income and expenses

Net financial income includes:

- Expenses related to the financing of the Company: interest paid and unwinding of conditional advances and financial liabilities.
- Interest income from term deposits and the capital bond.
- Changes in fair values of derivative financial instruments.

Gains and losses on currency translation are also reported under financial income (expenses).

2.23. Income taxes

Taxable assets and liabilities are valued at the amount expected to be recovered from or paid to the tax authorities.

The tax rates and tax regulations used to calculate these amounts are those which were enacted or substantively enacted at the end of the reporting period.

Deferred taxes are reported using the variable deferral method for all temporary differences existing at the end of the reporting period between the tax base of assets and liabilities and their carrying amount on the balance sheet.

Deferred tax assets are recognized for unused tax loss carryforward to the extent that taxable temporary differences are available and, beyond, when it is probable that the Company will have future taxable profits to which those unused tax losses could be applied. The measurement of identifiable deferred tax assets requires Management to make estimates about the time period over which the deferred losses will be used up, and about the level of future taxable income, based on the tax strategies adopted.

2.24. Earnings (loss) per share

Basic earnings (loss) per share are calculated by dividing the net income (loss) attributable to the Company shareholders by the weighted average number of the shares outstanding during the period.

Diluted earnings (loss) per share are calculated by adjusting the net income (loss) attributable to the holders of ordinary shares and the weighted average number of ordinary shares outstanding by the effects of all the dilutive potential ordinary shares.

If the inclusion of instruments giving deferred access to capital (warrants or convertible bonds) creates an anti-dilutive effect, those instruments are not taken into account.

2.25. Segment information

The Group operates in only one business segment, the research and development of pharmaceutical products.

Assets, operating losses as well as research and development facilities are located in France and in Switzerland.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 3: Intangible assets

(amounts in thousands of euros)	Software	SIIL Contract and extensions	Total
GROSS AMOUNT			
As of December 31, 2018	**16**	**10,697**	**10,713**
Addition	1	—	1
As of December 31, 2019	**17**	**10,697**	**10,714**
Addition	1	—	1
As of September 30, 2020	**18**	**10,697**	**10,714**
AMORTIZATION AND IMPAIRMENT			
As of December 31, 2018	**16**	**1,043**	**1,060**
Increase	—	567	567
Exchange effect	1	—	1
As of December 31, 2019	**17**	**1,611**	**1,628**
Increase	1	426	427
Impairment		5,859	5,859
As of September 30, 2020	**18**	**7,896**	**7,914**
NET BOOK VALUE			
As of December 31, 2019	**—**	**9,086**	**9,086**
As of September 30, 2020	**—**	**2,801**	**2,801**

The Company carried out an impairment test of the SIIL contract at December 31, 2019 and September 30, 2020 using the same valuation model (risk adjusted discounted cash flows) that was used for the initial accounting of the contract.

The main valuation assumptions used for the assessment of the fair value of the contract at December 31, 2019 and September 30, 2020 are as follows:

- The business plan from the reporting date until 2035, corresponding to the life of the patent for the Vaxiclase technology licensed to SIIL (no terminal value).
- The probability of success of the various stages of clinical development (based on a study conducted by Biomedtracker in 2016 who undertook a retrospective analysis of the probability of success of the various stages of clinical development in 9,985 trials between 2006 and 2015):

	Probability of success of each phase	Overall probability of success
POC[1]	100%	100%
Phase 1	70%	70%
Phase 2	43%	30%
Phase 3	73%	22%
Commercial success	89%	19%

(1) Proof of concept already achieved

- The discount rate of 17% at September 30, 2020 (14.2% at December 31, 2019), was estimated based on a weighted average cost of capital based on the risk premium of the French equity market,

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 3: Intangible assets (continued)

an average beta originating from a sample of biotechnology companies operating in the liver disease and a risk premium specific to the Company. The increase in the discount rate is due to an increase of the risk premium specific to the Company

In addition, at the end of December 2020, SIIL informed the Company that given the Covid-19 situation, it would be difficult for them to focus and develop any other vaccine than Covid. They also indicated that they were facing technical challenges with the technology and were not getting convincing results. As a result the timeline that prevailed at the end of 2019 is no longer valid as of September 30, 2020 and SIIL indicated that they would expect that it would be pushed back by 2 years i.e. the first product to be developed using the Vaxiclase technology is not expected to enter a phase 1 clinical trial before the first quarter of 2024 (compared to the first quarter of 2022 previously).The timeline to develop the products until market authorization was also reassessed and extended in light of the Covid-19 situation, prior delays already experienced and the technical challenges faced.

This impairment test highlighted a loss of value of €(5,859) thousand as of September 30, 2020 (no impairment at December 31, 2019), which has been recognized in research and development expenses. The loss is mainly explained by the delay in the expected development by SIIL of the products using the Vaxiclase technology.

The sensitivity of the assumptions used in the valuation model is as follows at September 30, 2020:

- A 1-point increase in the discount rate would generate an additional impairment loss of €(283) thousands;
- A 2.5-point decrease in the probability of success of different phases would generate an additional impairment loss of €(433) thousands;
- A 10% deterioration in the business plan would generate an additional impairment loss of €(1,004) thousands;
- A one-year delay in the development phases of the project would generate an additional impairment loss of €(767) thousands.

Note 4: Property, plant and equipment

(amounts in thousands of euros)	Laboratory equipment	Office equipment, furniture and computer equipment	Buildings (right of use)	Total
GROSS AMOUNT				
As of January 1, 2019	**538**	**98**	**—**	**636**
IFRS 16 first application impact	—	—	262	262
Disposal	—	1	—	1
Exchange effect	15	3	10	29
As of December 31, 2019	**553**	**102**	**272**	**927**
Addition	—	2	171	173
Disposal	(46)	(11)	—	(57)
Exchange effect	2	1	0	3
As of September 30, 2020	**509**	**94**	**443**	**1,046**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 4: Property, plant and equipment (continued)

(amounts in thousands of euros)	Laboratory equipment	Office equipment, furniture and computer equipment	Buildings (right of use)	Total
DEPRECIATION				
As of January 1, 2019	**508**	**97**	**—**	**605**
IFRS 16 first application impact	—	—	131	131
Increase	15	1	—	16
Decrease	—	—	—	—
Exchange effect	15	3	3	21
As of December 31, 2019	**538**	**101**	**134**	**772**
Increase	7	1	102	109
Decrease	(46)	(11)	—	(57)
Exchange effect	2	1	(0)	3
As of September 30, 2020	**501**	**91**	**235**	**827**
NET BOOK VALUE				
As of December 31, 2019	**15**	**1**	**138**	**154**
As of September 30, 2020	**8**	**2**	**208**	**218**

The increase in right of use in 2020 is due to the renewal of the lease agreement for the Archamps premises for an additional period of 3 years and to an extension of the lease term by 8 months of the Plan-les-Ouates premises.

Except for the impact of the delay in the development process of the products using the Vaxiclase platform (SIIL contract refer to note 3), the COVID-19 pandemic had a limited impact on the company's operations (refer to note 2.1 *Impacts of the health crisis on the financial statements*). No indicators of impairment have been identified on other assets and as a result, no additional impairment test was performed at the closing dates.

Note 5: Non-current financial assets

(amounts in thousands of euros)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Cash reserve related to the liquidity agreement	14	21
Guarantees	15	15
Total non-current financial assets	**29**	**36**

Note 6: Other current assets and prepaid expenses

(amounts in thousands of euros)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Research tax credit[1]	899	356
Value added tax	229	206
Social security receivables	16	71
Suppliers–advances payment and debit balance[2]	75	—
Miscellaneous	131	35
Total other current assets	**1,349**	**668**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 6: Other current assets and prepaid expenses (continued)

(1) Research Tax Credit ("CIR")

CIR research tax credits are payable by the government in the year following its recognition when there is no taxable net income to be offset. The Company does not have taxable net income.

CIR recorded as of December 31, 2019 includes CIR 2019 (€899 thousand), reimbursed by the French Tax Authorities in April 2020.

CIR recorded as of September 30, 2020 includes the CIR estimated for the nine-month period ended September 30, 2020 (€356 thousand).

The CIR is estimated on the basis of the expenses that meet the eligibility criteria.

(2) Suppliers advances payment and debit balance involve installments paid to the Contract Research Organization (CRO) responsible for studies.

(amounts in thousands of euros)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Prepaid expenses	151	179

Prepaid expenses mainly relate to research services provided by an external provider.

Note 7: Cash and cash equivalents

Cash and cash equivalents are broken down as follows:

(amounts in thousands of euros)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Bank accounts	2,417	3,590
Short-term deposits	—	—
Total cash and cash equivalents	**2,417**	**3,590**

Note 8: Share capital

	At the end of the financial periods presented	
SHARE CAPITAL	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Share capital (in thousands of euros)	8,683	11,549
Number of shares	8,683,449	11,548,562
o/w ordinary shares	8,863,449	11,548,562
Par value of shares (in euro)	1.00€	1.00€

Reverse stock split

After closing of the market on March 28, 2019, the old Genkyotex shares (ISIN code: FR0011790542) have been delisted from Euronext and have been replaced by the new Genkyotex shares (ISIN code: FR0013399474) beginning at the start of trading on March 29, 2019. Every 10 shares with a par value of €0.10 of the Company's issued and outstanding common stock have automatically been combined into one share with a par value of €1.00. The number of shares of common stock underlying Genkyotex' options, warrants, convertible securities or other rights to acquire shares of common stock was adjusted accordingly. This technical adjustment is purely arithmetical and has no impact on the value of Genkyotex shares held by the shareholders.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 8: Share capital (continued)

Capital increases

During the nine-month period ended September 30, 2020, 80 bonds were converted for a total of 417,816 new shares with a par value of €1.00, resulting in a €418 thousand capital increase plus an issue premium of €382 thousand.

Furthermore, the Company carried out a capital increase in February 2020 with maintenance of preferential subscription rights ("DPS") at the end of which 2,447,297 new shares were issued, i.e. a capital increase of €2,447 thousand, increased by a premium of €2,496 thousand.

As of September 30, 2020, the share capital of the Company was €11,548,562.00 divided into 11,548,562 fully subscribed ordinary shares with a nominal value of €1.00 per share.

Capital management

The Group's policy is to maintain a sufficient capital base in order to preserve the confidence of investors and creditors and to support the Company's future growth.

Following the Company's IPO on the regulated Euronext market in Paris and Brussels, the Company signed a liquidity contract on April 18, 2014, in order to limit intra-day volatility in the Company's share price. For this purpose, the Company had initially entrusted €200 thousand to Oddo Corporate Finance so that it could carry out purchase and sale transactions on the Company's shares. The contract was transferred to Kepler Cheuvreux on May 7, 2018.

As of September 30, 2020—under the contract—6,632 treasury shares (or €17 thousand) were removed from equity and €21 thousand in cash was entered as non-current financial assets.

As of December 31, 2019—under the contract—7,789 treasury shares (or €16 thousand) were removed from equity and €14 thousand in cash was entered as non-current financial assets.

As of December 31, 2018—under the contract—94,540 treasury shares (or €122 thousand) were removed from equity.

Dividends

The Company paid no dividend in the financial periods presented.

Note 9: Share-based payments

Following the closing of the acquisition by Calliditas Therapeutics of a controlling interest of 62.7% in Genkyotex SA in November 2020 and the subsequent simplified mandatory cash tender offer, the BSA_{022010}, $BSA_{12/2013}$ and $BSA_{09/2014}$ were waived, the stock $option_{012018}$, stock $option_{092018}$ and stock $option_{032019}$ were waived by current employees. The vesting of the stock $option_{062020}$ has been accelerated and all stock $option_{062020}$ have been exercised. Two former employees agreed to waive their stock $options_{012018}$ and stock $option_{032019}$ in case of a squeeze out subsequent to a tender offer.

Warrants

The Company issued warrants to employees in 2010, 2013 and 2014 which were all fully vested by September 30, 2017. The following table summarizes the main features of these warrants which are still outstanding:

		Plan features		
Type	**Grant date**	**Number of warrants granted[1]**	**Maturity date**	**Adjusted exercise price[2]**
BSA 02/2010	02/04/2010	**155,200**	10 years	€ 30.00
BSA 12/2013	12/20/2013	**116,000**	10 years	€ 40.00
BSA 09/2014	09/12/2014	**35,000**	10 years	€ 57.90

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 9: Share-based payments (continued)

(1) After the reverse stock split at the beginning of 2019, the parity is 10 BSAs issued before 2019 for 1 new share.

(2) The exercise price was adjusted to take into account the reverse stock split.

Changes in number of outstanding warrants

Type	Grant date	Number of outstanding warrants					Number of shares which can be subscribed[3]
		At 12/31/2019	Granted	Exercised	Lapsed	At 09/30/2020	
BSA 02/2010	02/04/2010	155,200	—	—	(2,700)	152,500	15,295
BSA 12/2013	12/20/2013	116,000	—	—	—	116,000	11,631
BSA 09/2014	09/12/2014	35,000	—	—	—	35,000	3,509
Total		**306,200**	—	—	**(2,700)**	**303,500**	**30,435**

(3) Following the capital increase which took place on February 6, 2020 (see Note 8), the maximum number of shares that can be subscribed was adjusted to take into account the dilutive effect of maintaining the preferential subscription rights.

Stock Options

The following table summarizes the option plans issued to employees and the assumptions adopted for IFRS 2 valuation:

Type	Grant date	Plan features			Assumptions		
		Number of options granted[1]	Exercise period	Adjusted exercise price[2]	Volatility	Risk-free rate	Total initial IFRS 2 valuation (€ thousands) (Black&Scholes)
Stock option 01/2018	01/09/2018	**1,159,934**	10 years	€ 16.70	60.68%	0.00%	**1,096**
Stock option 10/2018	10/11/2018	**20,000**	10 years	€ 14.90	56.86%	0.11%	**13**
Stock option 03/2019	03/21/2019	**1,336,380**	10 years	€ 9.10	56.80%	-0.27%	**604**
Stock option 06/2020	06/04/2020	**187,612**	10 years	€ 2.30	59,33%	-0.49%	**241**

(1) After the reverse stock split at the beginning of 2019, the exchange ratio was 10 stock options issued before 2019 for 1 new share.

(2) The exercise price was adjusted to take the reverse split into account.

The plans only have service conditions and vest over 4 years by tranche of 25% (graded vesting).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 9: Share-based payments (continued)

Changes in number of outstanding warrants

Type	Grant date	Number of warrants outstanding					Number of shares which can be subscribed[3]
		At 12/31/2019	Granted	Exercised	Lapsed	At 09/30/2020	
Stock option 01/2018	01/09/2018	1,130,153	—	—	(28,294)	1,101,859	110,513
Stock option 10/2018	10/11/2018	20,000	—	—	—	20,000	2,006
Stock option 03/2019	03/21/2019	1,336,380	—	—	(61,750)	1,274,630	127,882
Stock option 06/2020	06/04/2020	—	187,612	—	—	187,612	187,612
TOTAL		**2,486,533**	**187,612**	**—**	**(90,044)**	**2,584,101**	**428,013**

(3) Following the capital increase which took place on February 6, 2020 (see Note 8), the maximum number of shares that can be subscribed was adjusted to take into account the dilutive effect of maintaining the preferential subscription rights.

Stock-based compensation expense recognized for the periods presented

(amounts in thousands of euros)

Type	TWELVE-MONTH PERIOD ENDED DECEMBER 31, 2019				NINE-MONTH PERIOD ENDED SEPTEMBER 30, 2020			
	Probable cost of the plan	Cumulative expenses–beginning of period	Expense for the period	Cumulative expense to date	Probable cost of the plan	Cumulative expenses–beginning of period	Expense for the period	Cumulative expense to date
Stock option 01/2018	1,068	511	250	761	1,041	761	108	869
Stock option 10/2018	13	1	6	7	13	7	2	10
Stock option 03/2019	604	—	228	228	577	228	123	351
Stock option 06/2020	—	—	—	—	241	—	38	38
Total	**1,685**	**512**	**483**	**996**	**1,872**	**996**	**271**	**1,268**

Note 10: Borrowings and financial liabilities

(amounts in thousands of euros)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Conditional advances	—	—
Lease obligations (IFRS 16)	17	63
Non-current financial liabilities	**17**	**63**
Conditional advances	—	—
Lease obligations (IFRS 16)	122	145
Convertible bonds (refer to note 10.2)	725	—
Derivative liabilities	64	—
Bank overdrafts	0	0
Current financial liabilities	**912**	**146**
Total financial liabilities	**928**	**209**

The increase in the lease obligation in 2020 is due to the renewal of the lease agreement for the Archamps premises for an additional period of 3 years and to an extension of the lease term by 8 months of the Plan-les-Ouates premises.

In 2020, the convertible bonds issued to Yorkville were fully converted.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 10: Borrowings and financial liabilities (continued)

Breakdown of financial liabilities by maturity, at value on redemption

The maturity of financial liabilities of the Company is broken down as follows:

(amounts in thousands of euros)	AS OF SEPTEMBER 30, 2020	Current	Non-current	
		< 1 year	1 to 5 years	> 5 years
Conditional advances	—	—	—	—
Lease obligations	208	145	63	—
Convertible bonds	—	—	—	—
Derivative liabilities	—	—	—	—
Bank overdrafts	0	0	—	—
Total financial liabilities	**209**	**145**	**63**	**—**

10.1 Conditional advances

CHANGE IN CONDITIONAL ADVANCES AND SUBSIDIES (amounts in thousands of euros)	OSEO 3– ProCervix (GTL001)	TOTAL
As of January 1, 2019	**118**	**118**
Proceeds from conditional advances	—	—
Repayment	(118)	(118)
Subsidies	—	—
Financial expenses	1	1
As of December 31, 2019	**—**	**—**
Proceeds from conditional advances	—	—
Repayment	—	—
Subsidies	—	—
Financial expenses	—	—
As of September 30, 2020	**—**	**—**

OSEO Innovation conditional advance—OSEO 3

On January 11, 2013, Genkyotex SA (formerly Genticel SA) obtained from OSEO an interest-free conditional advance to "extend the Phase I clinical studies of the ProCervix (GTL001) project" for a total of €849 thousand.

Following confirmation of completion of the program and after obtaining the statement of expenditure incurred on the project financed by OSEO, the conditional advance was reduced to take into account the fact that actual expenditure was less than projected. The aid was thus reduced to €812 thousand, and an amendment was signed on September 5, 2014, to change the repayment dates.

The Company repaid this advance in several installments between September 30, 2014 and June 30, 2019 and there is no remaining outstanding liability at December 31, 2019 and September 30, 2020.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 10: Borrowings and financial liabilities (continued)

10.2 Convertible bonds

CHANGE IN CONVERTIBLE BONDS (amounts in thousands of euros)	2019 YORKVILLE OCABSA	2018 YORKVILLE OCABSA	TOTAL
As of January 1, 2019	**—**	**3,510**	**3,510**
Issuance	1,600	—	1,600
Derivative liabilities	(128)	—	(128)
Amortized cost of debt	53	(260)	(207)
Debt extinction	—	(1,600)	(1,600)
Conversion	(800)	(1,650)	(2,710)
As of December 31, 2019	**725**	**—**	**725**
Cash inflow	—	—	—
Derivative liabilities	—	—	—
Amortized cost of debt	75	—	75
Debt extinction	—	—	—
Conversion	(800)	—	(800)
As of September 30, 2020	**—**	**—**	**—**

Convertible bonds with share subscription warrants ("2018 YORKVILLE OCABSAs") issued to YA II PN Ltd ("Yorkville") on August 20, 2018.

On August 20, 2018, the Company signed a convertible bond (OCA) with stock acquisition rights (BSA) (referred to as the "2018 YORKVILLE OCABSA") agreement with YA II PN Ltd ("Yorkville") to raise up to €7.5 million, at the Company's discretion.

The agreement comprised two tranches:

- A first tranche of 500 OCAs for a nominal amount of €5 million (as of the signature date) ;
- A second tranche consisting of OCAs for a nominal amount of €2.5 million which became null and void on November 23, 2018.

The OCAs have the following features:

- Par value: €10,000
- Subscription price: 98% of par
- Commitment fees: 6% of par value
- Maturity: 12 months
- No interest
- Conversion methods: N = Vn / P where
  - N corresponds to the number of shares that can be subscribed
  - Vn corresponds to the par (nominal) value of the bond
  - P corresponds to 92% of the average share price for the five trading days before the conversion request.

If the OCAs are not converted before the maturity date, they are refundable in cash.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 10: Borrowings and financial liabilities (continued)

The BSAs have the following features:

- Maturity: 5 years
- Exercise price: 115% of the average share price for the five trading days before the tranche is issued.

The Company incurred €410 thousand in fees setting up the bond, including €300 thousand in commitment fees.

Initial Accounting treatment

The OCAs are analyzed as hybrid instruments (the parity for conversion is not fixed and depends on the stock market price) including a non-derivative host (financial debt) and an embedded derivative (conversion option). In accordance with paragraph 4.3.5 of IFRS 9, the Company chose to designate the OCAs at full fair value through profit and loss, therefore not separating the debt and the embedded derivatives.

Because of the fixed exchange parity of the BSA, the Company analyzed them as equity instruments and they were booked to equity for their fair value upon issuance.

As a result, as of the date the agreement was signed and the first tranche was issued, the Company recorded:

- The fair value of the BSAs for €242 thousand
- The fair value of the OCAs amounting to €5,400 thousand, or 108% of their par value;
- a €742 thousand financial expense (day-one loss) representing the difference between 98% of the par value (issuing price) net of the BSA estimated fair value and the fair value of the OCAs,
- The commitment fee amounting to €300 thousand and the other issuance fees amounting to €110 thousand were also recorded to expense.

In the course of 2018, subsequently to the issuance of the first tranche, Yorkville converted 175 OCAs for €1.75 million representing 149,762 shares (share price for conversion purposes ranging from €8.77 to €14.87).

Subsequent accounting of the OCAs

Between January 1, 2019 and July 31, 2019, Yorkville converted 165 additional OCAs for €1.65 million representing 310,721 of new shares (share price for conversion purposes ranging from €3.39 to €7.949).

In August 2019, the Company agreed with Yorkville Advisors Global—the management company of a US investment fund—to extend the conversion period for the remaining €1.6 million of OCA still outstanding at that date.

To this end, on August 19, 2019, Genkyotex signed an agreement to buy back from Yorkville, the remaining €1.6 million of 2018 YORKVILLE OCABSAs maturing on August 20, 2019, and then immediately issued to Yorkville 160 convertible bonds (the "2019 YORKVILLE OCAs") for a total nominal amount of €1.6 million. There was no cash payment in connection with these agreements, the outstanding 2018 YORKVILLE OCABSAs being offset by the 2019 YORKVILLE OCAs.

In accordance with IFRS 9, the redemption of the 2018 YORKVILLE OCABSAs was analyzed by the Company to be a debt extinction.

Convertible bonds ("2019 YORKVILLE OCAs") issued to YA II PN Ltd ("YORKVILLE") on August 19, 2019

The main features of the 2019 YORKVILLE OCAs issued on August 19, 2019 are:

- The nominal unit value of the OCAs is equal to ten thousand euro (€10,000). Each OCA will be issued at a subscription price per OCA equal to 100% of its nominal unit value, a total nominal amount of one million six hundred thousand euro (€1,600,000).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 10: Borrowings and financial liabilities (continued)

- The OCAs (i) are freely assignable or transferable by the Investor to any of its affiliates and (ii) may not be transferred to any other third party without the prior written consent of the Company.
- The OCAs will not be listed or admitted to trading on the regulated markets of Euronext Paris or Euronext Brussels or on any other financial market. Each OCA expires twelve (12) months from its issue (the "Maturity date"). In the event that an OCA is not converted before the Maturity date, the Company is obliged to repay the outstanding amount in cash.
- The OCAs do not bear any interest. However, in the event of the occurrence of a Default (2), each OCA outstanding will bear interest at the rate of 15% per year from the date of the Default and up to (i) the date on which the Default is resolved, or (ii) the date on which the OCA has been fully converted and/or repaid, if the Default has not yet been resolved.
- The number of new shares issued by the Company for the benefit of each OCA holder when converting one or more OCAs corresponds to the amount of the conversion divided by the applicable Conversion Price. The "Conversion Price" is equal to 92% of the weighted average share price quoted on Euronext (as reported by Bloomberg) (the "Average Prices") on the five (5) consecutive stock exchange sessions up to the trading session immediately before the conversion date.

The Company incurred €103 thousand of expenses directly attributable to the issuance of the debt.

Initial Accounting treatment

The convertible bonds are analyzed as hybrid instruments (the parity for conversion is not fixed and depends on the stock market price) including a non-derivative host (financial debt) and an embedded derivative (conversion option). In accordance with IFRS 9, the debt component is amortized using the effective interest rate method, over the estimated maturity date. If the convertible bond is converted before the estimated maturity date, any difference between the fair value of the subscribed shares and the total value of (the net book value of the financial debt + the fair value of the conversion option) is recorded to the profit and loss.

The conversion option of the convertible bonds was bifurcated and classified in derivative instruments due to the parity not being fixed and measured at fair value on the date of issuance (based on the Monte-Carlo valuation model) with recognition of the changes in fair value in profit or loss in accordance with IFRS 9.

At the date of issue, the value of the derivative liability was €128 thousand or 8% of the total nominal amount of €1,600 thousand.

In the course of 2019, subsequently to the issuance of the 2019 Yorkville OCA, Yorkville converted 80 OCAs for €0.8 million representing 437,966 shares (share price for conversion purposes ranging from €1.785 to €1.810). As of December 31, 2019, the derivative liability was €64 thousand or 8% of the residual nominal amount of €800 thousand.

Conversions in financial year 2020

In financial year 2020, Yorkville converted the 80 remaining 2019 YORKVILLE OCA in accordance with the following terms and conditions:

Conversion date	Number of bonds	Amounts (in €)	Conversion price	Number of shares issued	Issuance premium
01/14/2020	30	€300,000	€1.874	160,085	139,914
01/15/2020	50	€500,000	€1.940	257,731	242,267

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 10: Borrowings and financial liabilities (continued)

Conversion date	Number of bonds	Amounts (in €)	Conversion price	Number of shares issued	Issuance premium
Total converted in 2020	**80**	**€800,000**		**417,816**	**382,181**

As of September 30, 2020, no more 2018 YORKVILLE OCABSAs or 2019 YORKVILLE OCA were outstanding.

The 666,312 BSAs which were issued with the first tranche of the 2018 YORKVILLE OCABSAs (giving the right to subscribe 66,631 shares after taking into account the reverse stock split which took place on March 29, 2019) were still outstanding.

10.3 Lease obligations

The following table shows the changes in lease liabilities:

CHANGES IN FINANCIAL DEBT—LEASE OBLIGATIONS (amounts in thousands of euros)	Financial debt (lease liabilities)
As of January 1, 2019	—
IFRS 16 first application impact	263
(+) Newlease liabilities	—
(-) Repayments (IFRS 16)	(121)
(-) Advance payment	(9)
Exchange rate	6
As of December 31, 2019	**139**
(+) New lease liabilities	171
(-) Repayments (IFRS 16)	(102)
(-) Advance payment	—
Exchange rate	1
As of September 30, 2020	**208**

Note 11: Employment benefit obligations

EMPLOYEE BENEFIT OBLIGATIONS (amounts in thousands of euros)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Swiss employees	1,335	874
French employees	13	86
Employee benefit obligations	**1,348**	**960**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 11: Employment benefit obligations (continued)

11.1 Swiss employees

The defined benefit obligation related to the 2nd pillar of the Swiss pension system is assessed using the following assumptions:

ACTUARIAL ASSUMPTIONS	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Age at retirement	Voluntary retirement 64 years of age for women/ 65 years of age for men	
Discount rate	0.20%	0.20%
Mortality table	LPP 2015 generation	LPP 2015 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%

Mortality rate

Assumptions regarding future mortality are based on advice, statistics publications and experience. The weighted average duration of the retirement obligation is as follows:

	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
The weighted average duration of the retirement obligation	26.00	25.90

Changes to the retirement obligation and the fair value of retirement benefit plan assets are as follows:

(amounts in thousands of euros)	Defined benefit plan obligation	Fair value of plan assets	Employee benefit obligations
January 1, 2019	**2,228**	**(1,237)**	**991**
Service costs	328	—	328
Interest expense	19	(11)	8
Employee contribution	—	(109)	(109)
Subtotal included in the statement of consolidated operations	**347**	**(120)**	**227**
Amounts paid/received	**(22)**	**22**	—
Return on assets (excluding interest expenses)	—	(2)	(2)
Actuarial gains and losses related to changes in demographic assumptions	—	—	—
Actuarial gains and losses related to changes in financial assumptions	172	—	172
Other actuarial gains (losses)	11	—	11
Experience effect	—	—	—
Subtotal included in other items of comprehensive income	**182**	**(2)**	**180**
Employer contributions	—	**(109)**	**(109)**
Currency translation effect	**98**	**(52)**	**45**
December 31, 2019	**2,833**	**(1,498)**	**1,335**

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 11: Employment benefit obligations (continued)

(amounts in thousands of euros)	Defined benefit plan obligation	Fair value of plan assets	Employee benefit obligations
Service costs	257	—	257
Interest expense	4	(2)	2
Curtailment	(1,114)	564	(550)
Employee contribution	—	(66)	(66)
Subtotal included in the statement of the consolidated operations	**(852)**	**496**	**(357)**
Amounts paid/received	**(46)**	**46**	—
Return on assets (excluding interest expenses)	—	(9)	(9)
Actuarial gains and losses related to changes in demographic assumptions	—	—	—
Actuarial gains and losses related to changes in financial assumptions	—	—	—
Other actuarial gains (losses)	(41)	—	(41)
Experience effect	—	—	—
Subtotal included in other items of comprehensive income	**(41)**	**(9)**	**(50)**
Employer contributions	—	**(66)**	**(66)**
Currency translation effect	**24**	**(12)**	**12**
September 30, 2020	**1,918**	**(1,044)**	**874**

The retirement obligation as of September 30, 2020 decreased from December 31, 2019 due to an employee leave and the transfer of an employee toward the French entity of the Group.

Sensitivity analysis as of September 30, 2020

(Amounts in € thousands)		Salary revaluation rate	
Sensitivity analysis	0.50%	**Assumptions: 1.00%**	1.50%
Retirement obligation	1,879	**1,918**	1,958
		Discount rate	
Sensitivity analysis	-0.30%	**Assumptions: 0.20%**	0.70%
Retirement obligation	2,190	**1,918**	1,691
		Pension inflation rate	
Sensitivity analysis	0.00%	**Assumptions: 0.50%**	1.00%
Retirement obligation	1,803	**1,918**	2,045

Asset classes from the retirement plan and their respective allocations are as follows:

Allocation (in € thousands)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Cash and cash equivalent	37	23
Bonds	840	599
Mortgage loans	228	143
Shares	259	34
Real estate	—	155

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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Note 11: Employment benefit obligations (continued)

Allocation (in € thousands)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Other investments	133	90
Total	**1,498**	**1,044**

The full-year Group contributions for the 2020 retirement plan are estimated at €116 thousand.

The following table shows estimated benefit payments for the next years:

2021	€105 thousand
2022	€93 thousand
2023	€82 thousand
2024	€69 thousand
2025–2029	€197 thousand

11.2 French employees

The main actuarial assumptions used to measure retirement indemnities are as follows:

ACTUARIAL ASSUMPTIONS	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Age at retirement	Voluntary retirement age between 65 and 67	
Collective bargaining agreement	Pharmaceutical industry	
Discount rate		
(IBOXX Corporates AA)	0.77%	0.59%
Mortality table	INSEE 2018	INSEE 2018
Salary revaluation rate	2.00%	2.00%
Turnover rate	20 years to 30 years old from 18.3% to 10.90% 31 years old to 40 years old from 10.4% to 6.3% 41 years old to 50 years old from 6% to 4.2% 51 years old to 60 years old from 3.9% to 1% 61 years old to 64 years old 1% Above 65 years nil	
Social security expense ratio		
Managers	47%	45%
Non-managers	47%	45%

The following shows the change in retirement provisions:

(amounts in thousands of euros)	Retirement obligation
As of January 1, 2019	**5**
Service costs	5
Interest expense	0
Actuarial gains and losses	**3**
As of December 31, 2019	**13**
Service costs	73
Interest expense	0

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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Note 11: Employment benefit obligations (continued)

(amounts in thousands of euros)	Retirement obligation
Actuarial gains and losses	(0)
As of September 30, 2020	**86**

Note 12: Provisions

In 2020, a tax control occurred in France over the fiscal years 2016, 2017 and 2018. The French Tax Authorities completed their audit in November 2020 and reassessed the research tax credit. Based on this reassessment the Company booked a provision totaling €258 thousand as of September 30, 2020. The related expense has been recognized in the consolidated income statement as an increase of the "Research and development expenses".

Note 13: Tax and social liabilities

(amounts in thousands of euros)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Bonus (including social security contributions)	17	417
Payroll & related accounts	190	309
Social security expenses	134	61
Other taxes and similar	128	21
Total tax and social liabilities	**469**	**808**

Note 14: Financial assets and liabilities and impacts on statements of consolidated operations

The Company's financial assets and liabilities are measured as follows as of December 31, 2019 and September 30, 2020, respectively:

	AS OF DECEMBER 31, 2019			
			Value–Statement of financial position (IFRS 9)	
(amounts in thousands of euros)	Value–Statement of financial position	Fair value	Fair value through profit or loss	Amortized cost
Non-current financial assets Level 1	29	29	—	29
Other current assets Level 1	1,349	1,349	—	1,349
Prepaid expenses Level 1	151	151		151
Cash and cash equivalents Level 1	2,417	2,417	2,417	—
Total assets	**3,946**	**3,946**	**2,417**	**1,529**
Non-current financial liabilities Level 1	17	17	—	17
Current financial liabilities Level 3 & level 1	912	912	725	186
Accounts payables Level 1	562	562	—	562
Other payables Level 1	512	512	—	512
Total liabilities	**2,002**	**2,002**	**725**	**1,277**

The Company's financial instruments that are recognized at fair value through profit or loss are:

- cash and cash equivalents which are classified as Level 1; and
- derivative instruments in connection with convertible notes (see Note 10.2), which are classified as Level 3.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 14: Financial assets and liabilities and impacts on statements of consolidated operations (continued)

	AS OF SEPTEMBER 30, 2020			
			Value–Statement of financial position (IFRS 9)	
(amounts in thousands of euros)	Value–Statement of financial position	Fair value	Fair value through profit or loss	Amortized cost
Non-current financial assets Level 1	36	36	—	36
Other current assets Level 1	668	668	—	668
Prepaid expenses Level 1	179	179		179
Cash and cash equivalents Level 1	3,590	3,590	3,590	—
Total assets	**4,473**	**4,473**	**3,590**	**883**
Non-current financial liabilities Level 1	63	63	—	63
Current financial liabilities Level 1	146	146	—	146
Accounts payables Level 1	656	656	—	656
Other payables Level 1	862	862	—	862
Total liabilities	**1,727**	**1,727**	**—**	**1,727**

The impact of the Company's financial assets and liabilities on the consolidated income statement are as follows for the twelve-month period ended December 31, 2019 and for the nine-month period ended September 30, 2020:

	AS OF DECEMBER 31, 2019		AS OF SEPTEMBER 30, 2020	
(amounts in thousands of euros)	Interest	Change in fair value	Interest	Change in fair value
Profit or loss impact of assets				
Fair value through income/(loss)	—	—	—	—
Cash and cash equivalents	—	—	—	—
Profit or loss impact of liabilities				
Financial debt at amortized cost (conditional advances)	1	—	—	—
Financial debt at amortized cost (lease liabilities)	5	—	3	—
Convertible bond at amortized cost	156	—	—	75
Derivative liability at fair value through profit or loss	—	(64)	—	(64)
Bonds at fair value through profit or loss	—	—	—	—

Note 15: Revenue

Following the signature of an extension to the license agreement for the Vaxiclase platform with the Serum Institute of India (SIIL) in June 2018, the contract provides for:

- An initial payment of €750 thousand (recognized during the first half of 2018);
- Milestone payments for emerging markets for up to USD 57 million;
- Milestone payments for industrialized countries for up to €100 million.

In accordance with IFRS 15, the Group has reviewed the license agreement with the Serum Institute of India Pvt. Ltd. (SIIL) for the Vaxiclase platform. The Group considers that the license covered by the agreement constitutes a right of use (static license).

The agreement provides for four types of variable compensation:

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 15: Revenue (continued)

- Development milestone payments based on the progress of work undertaken by the customer;
- Commercial milestone payments based on levels of total sales achieved by the customer;
- Milestone payments in the event that the customer grants any sublicenses;
- "Single digit percentage" royalties on sales.

The development milestone payments set out in the contract will be recognized when they become highly probable. Given that the various phases of the project progress at uncertain rates, the revenue associated with these milestone payments is recognized as of the date the customer achieves these development phases.

The other two types of milestone payments are related to sales and are treated as royalties. They will therefore be recognized as income when the sale is made.

As of September 30, 2020, other income of €35 thousand (nil in 2019) was recognized relating to the license contract agreement with SIIL. It mainly involves the re-invoicing of fees for patent maintenance costs.

Note 16: Details of expenses and products by function

16.1 Research and Development expenses

(amounts in thousands of euros)	DECEMBER 31, 2019 12 months	SEPTEMBER 30, 2020 9 months
Raw materials and consumables	(83)	(19)
Research and studies	(3,158)	(1,281)
Personnel expenses	(1,277)	(1,315)
Expenses related to retirement obligations	(84)	147
Licenses and intellectual property costs	(722)	(388)
Depreciation and amortization	(581)	(690)
Share-based payments	(258)	(129)
Miscellaneous	(44)	(22)
Amortization of rights of use	(98)	(71)
Impairment of SIIL contract	—	(5,859)
Research and development expenses	**(6,305)**	**(9,627)**
Research tax credit	899	356
Subsidies	—	—
Research tax credit and subsidies	**899**	**356**
Research and development expenses, net	**(5,406)**	**(9,271)**

Net research and development expenses amounted to €9,271 thousand for the nine-month period ended September 30, 2020, compared with €5,406 thousand for the twelve-month period ended December 31, 2019, i.e., an increase of €3,865 thousand. This decrease can be explained primarily by a reduction in the study and research costs associated with the end of the Phase 2 trial of its GKT831 product offset by the impairment recorded on the SIIL contract (refer to note 3).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 16: Details of expenses and products by function (continued)

16.2 General and administrative expenses

(amounts in thousands of euros)	DECEMBER 31, 2019 12 months	SEPTEMBER 30, 2020 9 months
Travel and incidental expenses	(208)	(56)
Fees	(889)	(874)
Insurance	(35)	(44)
Marketing and sales expenditure	(89)	(130)
Taxes and duties	(29)	(18)
Personnel expenses	(411)	(504)
Expenses related to retirement obligations	(39)	203
Attendance fees	(49)	(60)
Depreciation and amortization	(3)	(1)
Share-based payments	(226)	(142)
Miscellaneous	(150)	(99)
Amortization of rights of use	(33)	(32)
General and administrative expenses	**(2,160)**	**(1,757)**

General and administrative expenses amounted to €1,757 thousand for the nine-month period ended September 30, 2020 compared with €2,160 thousand for the twelve-month period ended December 31, 2019, i.e., a decrease of €404 thousand. This change can be explained primarily by the following:

- A decrease in travel expenses of €152 thousand
- A reduction of €242 thousand in expenses related to retirement obligations in relation to a curtailment gain
- Compensated by an increase of personnel expenses of €93 thousand.

Note 17: Net financial income and expenses

(amounts in thousands of euros)	DECEMBER 31, 2019 12 months	SEPTEMBER 30, 2020 9 months
Convertible bonds effective interest expenses	(156)	(75)
Other financial expenses	(7)	(3)
Currency losses	(27)	(23)
Financial expenses	***(190)***	***(101)***
Currency gains	348	12
Derivative liabilities (change in fair value)	64	64
Total net financial expense	**222**	**(25)**

Gains and losses on currency translation for the twelve-month period ended December 31, 2019 and for the nine-month period ended September 30, 2020 primarily represent the impact of fluctuations in the CHF/EUR exchange rate on the intragroup accounts of Genkyotex Suisse SA with Genkyotex SA.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 18: Income taxes

Genkyotex SA had tax losses in France that can be carried forward indefinitely totaling €93,345 thousand as of September 30, 2020.

The tax rate on applicable income for Genkyotex SA is the rate that is currently applicable in France (28%). This rate will gradually decrease to reach 25% by 2022.

Genkyotex Suisse SA had approximately €66,417 thousand (CHF 70,934 thousand) in tax loss carryforwards as of September 30, 2020, which break down as follows:

- €5,257 thousand (CHF 5,706 thousand) originating in 2019 and expiring in 2027,
- €9,941 thousand (CHF 10,790 thousand) originating in 2018 and expiring in 2026,
- €3,478 thousand (CHF 3,775 thousand) originating in 2017 and expiring in 2025,
- €11,848 thousand (CHF 12,860 thousand) originating in 2015 and expiring in 2023,
- €14,285 thousand (CHF 15,505 thousand) originating in 2014 and expiring in 2022,
- €12,416 thousand (CHF 13,476 thousand) originating in 2013 and expiring in 2021,
- €4,665 thousand (CHF 5,063 thousand) originating in 2012 and expiring in 2020.

The tax rate applicable on income for Genkyotex Suisse SA is the rate that is currently applicable in the Swiss Canton of Geneva (24%).

In accordance with the principles described above, no deferred tax assets have been recognized beyond deferred tax liabilities in the Group's consolidated financial statements as of September 30, 2020 and December 31, 2019.

Genkyotex SA was the subject of a tax audit covering the financial years 2016 to 2018 (refer to note 12).

Reconciliation between the theoretical tax expense and effective tax

TAX PROOF (amounts in thousands of euros)	DECEMBER 31, 2019 12 months	SEPTEMBER 30, 2020 9 months
Net loss	(7,203)	(11,017)
Income taxes	—	—
Loss before taxes	**(7,203)**	**(11,017)**
Current tax rate in Switzerland	24.00%	24.00%
Theoretical income tax (expense) benefit	**1,729**	**2,644**
Non-taxable items	105	(1,696)
Share based payments	(135)	(76)
Unrecognized deferred tax	(1,777)	(1,189)
Effect of tax rate differences	78	316
Group income taxes (expense) benefit	**0**	**0**
Effective tax rate	0.00%	0.00%

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 18: Income taxes (continued)

Nature of deferred tax

(amounts in thousands of euros)	AS OF DECEMBER 31, 2019	AS OF SEPTEMBER 30, 2020
Retirement	297	218
Other	4	5
Total items with a deferred tax asset nature	**301**	**223**
Unrecognized deferred tax assets	(301)	(223)
Deferred taxes, net	—	—

Note 19: Earnings (loss) per share

	DECEMBER 31, 2019 12 months	SEPTEMBER 30, 2020 9 months
Weighted average number of outstanding shares	8,146,178	11,160,072
Net loss (in thousands of euros)	(7,203)	(11,017)
Basic loss per share (€/share)	**(0.88)**	**(0.99)**
Diluted loss per share (€/share)	**(0.88)**	**(0.99)**

Note 20: Related Parties

20.1 Compensation due to executive officers

Executive compensation breaks down as follow:

(amounts in thousands of euros)	DECEMBER 31, 2019 12 months	SEPTEMBER 30, 2020 9 months
Fixed compensation	221	177
Variable compensation	—	150
Benefits in kind	20	10
Employer contributions to the retirement plan	29	17
Share-based payments	232	130
Attendance fees	49	60
Total compensation of executive officers	**551**	**543**

No post-employment benefits were granted to members of the Board of Directors or to executives, with the exception of the mandatory defined benefit plan applicable for Swiss employees under the 2nd pillar of the Swiss social security system.

The variable components of compensation were allocated on the basis of performance criteria.

The methods used to calculate the fair value of share-based payments are explained in Note 9.

Note 21: Off-balance-sheet commitments

21.1 Guarantee

A bank guarantee for €22 thousand (CHF 24 thousand) was provided to the landlord of the Plan-les-Ouates premises.

21.2 Contractual obligations

21.2.1 Licensing agreement with the Institut Pasteur

Genkyotex SA signed a license agreement with the Institut Pasteur that takes effect on January 1, 2018 and replaces the first agreement signed on February 22, 2006.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 21: Off-balance-sheet commitments (continued)

The new agreement provides for:

- royalties on net proceeds by the Company, categorized by human use and by veterinary use (lack of revenue generated by the Company under the agreement);
- a share in the cost of maintaining the patents: the Institut Pasteur is responsible for obtaining the issuance and assuring the continuing validity of patents. However, the Company will reimburse the Institut Pasteur for all of the direct external expenses incurred by the Institut Pasteur to maintain and extend the patents (€22 thousand for 2020 and €22 thousand for 2019);
- a royalty in the case of sublicensing (to date, the Company has not signed this type of agreement).

21.3 Other commitments

The first-time application of IFRS 16 as from January 1, 2019 has removed the distinction between finance leases and operating leases. The standard means that the Company's obligation to pay future lease payments must be recognized as a liability and a right of use as an asset.

As a result of the impact of IFRS 16, the current off-balance sheet commitments in connection with leases as of September 30, 2020 are deemed to be immaterial.

Note 22: Management and assessment of financial risks

Genkyotex SA may find itself exposed to various types of financial risk: market risk, credit risk and liquidity risk. When necessary, Genkyotex SA implements simple measures proportional to its size to minimize the potential adverse effects of those risks on its financial performance.

It is Genkyotex SA's policy not to use financial instruments for speculative purposes.

Market risk

Interest rate risk

Genkyotex SA is not significantly exposed to interest rate risk, to the extent that no variable rate debt has been obtained.

Foreign exchange risk

The main risks related to the impact of foreign exchange rates are considered insignificant, except for the SIIL contract where some milestone revenue and royalties are denominated in US dollars (see Note 2.6).

The Company, at its present stage of development, does not use hedging instruments to protect its activity from exchange rate fluctuations. However, the Company cannot rule out the possibility that a major increase in its activity will increase its exposure to exchange rate risk. In such a case, the Company would consider adopting an appropriate policy to hedge such risks.

As of December 31, 2020, assets and liabilities in foreign currencies are not significant.

Credit risk

Credit risk is associated with deposits with banks and financial institutions. For its cash investments, Genkyotex SA uses top-tier financial institutions and therefore does not carry significant credit risk on its cash.

Liquidity risk

The Company's going concern depends on the support of its controlling shareholder, Calliditas Therapeutics AB. (refer to Note 2.1).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except for share data)

Note 22: Management and assessment of financial risks (continued)

The maturity of the financial liabilities as at September 30, 2020 can be analyzed as follows:

(amounts in thousands of euros)	Value– Statement of financial position	Current < 1 year	Non current	
			1 to 5 years	>5 years
Non-current financial liabilities	63	—	63	—
Current financial liabilities	146	146	—	—
Accounts payables	656	656	—	—
Other payables	862	862	—	—
Total liabilities	**1,727**	**1,664**	**63**	**—**

Note 23: Subsequent events

Setanaxib

Setanaxib (the lead product candidate of the Company or GKT831) has been designated as an orphan drug (ODD—Orphan Drug Designation) for the treatment of primary biliary cholangitis (PBC) by the Food and Drug Administration ("FDA") in October 2020 and by the European Commission in December 2020.

Acquisition by Calliditas Therapeutics

On November 3, 2020, Genkyotex announced the completion of the acquisition by the company Calliditas Therapeutics AB of 62.7% of the shares of Genkyotex in an off-market transaction.

Following the transaction, all members of the Board of Directors resigned, other than Elias Papatheodorou, the Chief Executive Officer of Genkyotex.

M. Elmar Schnee, Chairman of the Board of Directors of Calliditas Therapeutics, Ms. Renée Aguiar-Lucander, Chief Executive Officer of Calliditas Therapeutics and M. Jonathan Schur, Group General Counsel, were co-opted as members of the Board of Directors. M. Elmar Schnee was elected President of the Board of Directors of Genkyotex.

Calliditas Therapeutics filed with the French Financial Market Authority ("Autorité des Marchés Financiers" or the "AMF") a simplified mandatory cash tender offer for the remaining Genkyotex shares at €2.80 per ordinary share plus contingent right payable upon regulatory approvals of setanaxib. Following the tender offer, Calliditas owned 86.24% of the share capital and voting rights of Genkyotex.

Following the closing of the acquisition by Calliditas Therapeutics of a controlling interest of 62.7% in Genkyotex SA in November 2020, the stock option$_{012018}$, stock option$_{092018}$ and stock option$_{032019}$ were waived by current employees. The vesting of the stock option$_{062020}$ has been accelerated and all stock option$_{062020}$ have been exercised. Two former employees agreed to waive their stock options$_{012018}$ and stock option$_{032019}$ in case of a squeeze out subsequent to a tender offer.

4,500,000 Common Shares

(including Common Shares in the Form of American Depositary Shares)

$ per American Depositary Share

SEK per Common Share

PRELIMINARY PROSPECTUS

, 2021

Citigroup	**Jefferies**	**Stifel**
Kempen & Co	**LifeSci Capital**	**Carnegie**

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. Indemnification of Directors and Officers.

Subject to the Swedish Companies Act, members of the registrant's board of directors and its officers (excluding auditors) have the benefit of the following indemnification provisions in the registrant's articles of association:

Current and former members of the registrant's board of directors or officers shall be reimbursed for:

(i) all costs, charges, losses, expenses and liabilities sustained or incurred in relation to his or her actual or purported execution of his or her duties in relation to the registrant, including any liability incurred in defending any criminal or civil proceedings; and

(ii) expenses incurred or to be incurred in defending any criminal or civil proceedings, in an investigation by a regulatory authority or against a proposed action to be taken by a regulatory authority, or in connection with any application for relief under the statutes of the Sweden and any other statutes that concern and affect the registrant as a company, or collectively the Statutes, arising in relation to the registrant or an associated company, by virtue of the actual or purposed execution of the duties of his or her office or the exercise of his or her powers.

In the case of current or former members of the registrant's board of directors, there shall be no entitlement to reimbursement as referred to above for (i) any liability incurred to the registrant or any associated company, (ii) the payment of a fine imposed in any criminal proceeding or a penalty imposed by a regulatory authority for non-compliance with any requirement of a regulatory nature, (iii) the defense of any criminal proceeding if the member of the registrant's board of directors is convicted, (iv) the defense of any civil proceeding brought by the registrant or an associated company in which judgment is given against the director, and (v) any application for relief under the statutes of the Sweden and any other statutes that concern and affect the registrant as a company in which the court refuses to grant relief to the director.

In addition, members of the registrant's board of directors and its officers who have received payment from the registrant under these indemnification provisions must repay the amount they received in accordance with the statutes or in any other circumstances that the registrant may prescribe or where the registrant has reserved the right to require repayment.

The underwriting agreement the registrant will enter into in connection with the global offering of the common shares and ADSs being registered hereby provides that the underwriters will indemnify, under certain conditions, the registrant's board of directors and its officers against certain liabilities arising in connection with the global offering.

Item 7. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Issuances of Share Capital

- On June 9, 2020, concurrently with our initial public offering on The Nasdaq Global SelectMarket, we issued 924,000 common shares to certain investors pursuant to a private placement forgross proceeds of SEK 829 million.
- On July 3, 2019, we issued 3,505,291 common shares to certain investors pursuant to a private placement for gross proceeds of SEK 210.3 million.
- On June 29, 2018, we issued a total of 16,414,444 common shares in our initial public offering on Nasdaq Stockholm for gross proceeds of SEK 738.7 million.

The sales of securities described above were deemed to be exempt from registration pursuant to either (i) Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving a public offering or

(ii) Regulation S promulgated under the Securities Act in that the offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States.

(b) Grants and Exercises of Warrants and Share Awards under the LTIP Warrants

- In 2017, we issued warrants to purchase up to 1,296,500 common shares pursuant to the 2017 Program to certain of our employees, suppliers, and Board members at an exercise price of SEK 42.36 per share, of which 4,741 warrants to purchase 1,185,250 common shares were exercised in July 2020 and 445 warrants to purchase 111,250 shares were exercised in August 2020;
- In 2018, we issued warrants to purchase up to 856,586 common shares pursuant to the 2018 Program to certain of our employees and consultants at an exercise price of SEK 74.30 per share;
- In 2019, we issued warrants to purchase up to 422,500 common shares pursuant to the 2019 Program to certain of our employees and consultants at an exercise price of SEK 74.50 per share.

Share Awards

- Since May 8, 2019, the date of the adoption of the program, we issued 51,399 common shares in the form of share awards pursuant to the LTIP 2019.
- Since June 25, 2020, the date of the adoption of the program, we issued 31,371 common shares in the form of share awards pursuant to the LTIP 2020.

The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The common shares issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

Item 8. Exhibits and Financial Statement Schedules.

(a) Exhibits

Exhibits Number	Description of Exhibit
1.1	Form of Underwriting Agreement.
2.1	Share Purchase Agreement, dated August 13, 2020, by and between the Registrant and the Block Sellers.
3.1	Articles of Association of the Registrant.
4.1	Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form F-1/A filed by the Registrant with the SEC on June 1, 2020).
4.2	Form of American Depositary Receipt (included in Exhibit 4.1).
5.1	Opinion of Advokatfirman Vinge, Swedish counsel to the Registrant.
10.1†	License Agreement regarding NEFECON, dated June 10, 2019, by and between the Registrant and Everest Medicines II Limited (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.2	English translation of Lease Agreement, dated as of March 20, 2019, by and between Vasaterminalen AB and the Registrant (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.3#	English Translation of Warrants 2018/2022 in Calliditas Therapeutics AB (publ) (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.4#	English Translation of Warrants 2019/2022 in Calliditas Therapeutics AB (publ) (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).

Exhibits Number	Description of Exhibit
10.5#	Board Long Term Incentive Program 2019 (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.6	Board Long Term Incentive Program 2020.
10.7	English Translation of Principles for the 2020 ESOP for the Registrant's management and key personnel (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.8	ESOP 2020 United States Sub-Plan (incorporated by reference to Exhibit 99.1 to the Registration Statement on Form S-8 filed by the Registrant with the SEC on July 27, 2020).
10.9#	Employment Agreement, by and between the Registrant and Renée Aguiar-Lucander, dated May 1, 2017 (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.10#	Employment Agreement, by and between the Registrant and Fredrik Johansson, dated August 1, 2017 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.11#	Employment Agreement, by and between the Registrant and Frank Bringstrup, dated February 1, 2019 (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.12#	Employment Agreement, by and between the Registrant and Andrew B. Udell, dated March 1, 2019 (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
10.13#	Employment Agreement, by and between the Registrant and Katayoun Welin-Berger, dated September 17, 2019.
10.14#	Employment Agreement, by and between the Registrant and Richard Philipson, dated March 26, 2020.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registration Statement on Form F-1 filed by the Registrant with the SEC on May 14, 2020).
23.1	Consent of Ernst & Young AB, independent registered public accounting firm.
23.2	Consent of KPMG S.A., independent auditors.
23.3	Consent of Advokatfirman Vinge, Swedish counsel to the registrant (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page to this registration statement).

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

Indicates a management contract or any compensatory plan, contract or arrangement.

(b) Financial Statement Schedules

None. All schedules have been omitted because the information required to be set forth therein is not applicable or has been included in the audited consolidated financial statements and notes thereto.

Item 9. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions described in Item 6 hereof, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in

the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Stockholm, Sweden, on January 26, 2021.

CALLIDITAS THERAPEUTICS AB

By: /s/ Renée Aguiar-Lucander

Renée Aguiar-Lucander
Chief Executive Officer

POWER OF ATTORNEY

We, the undersigned directors, officers and/or authorized representative in the United States of Calliditas Therapeutics AB, hereby severally constitute and appoint Renée Aguiar-Lucander and Fredrik Johansson, and each of them singly, our true and lawful attorneys-in-fact and agents, with full power to any of them, and to each of them singly, to sign for us and in our names in the capacities indicated below the registration statement on Form S-8 filed herewith, and any and all pre-effective and post-effective amendments to said registration statement, under the Securities Act of 1933, as amended, in connection with the registration under the Securities Act of 1933, as amended, of equity securities of Calliditas Therapeutics AB, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of them might or could do in person, and hereby ratifying and confirming all that said attorneys-in fact and agents, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney. Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following person in the capacities and on the date indicated.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Renée Aguiar-Lucander Renée Aguiar-Lucander	Chief Executive Officer *(Principal Executive Officer)*	January 26, 2021
/s/ Fredrik Johansson Fredrik Johansson	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	January 26, 2021
/s/ Elmar Schnee Elmar Schnee	Chairman of the Board of Directors	January 26, 2021
/s/ Hilde Furberg Hilde Furberg	Director	January 26, 2021
/s/ Lennart Hansson, Ph.D. Lennart Hansson, Ph.D.	Director	January 26, 2021

Signature	Title	Date
/s/ Diane Parks Diane Parks	Director	January 26, 2021
/s/ Molly Henderson Molly Henderson	Director	January 26, 2021

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE OF REGISTRANT

Pursuant to the requirements of the Securities Act of 1933, the undersigned, the duly authorized representative in the United States of the registrant has signed this registration statement, on January 26, 2021.

By: /s/ Renée Aguiar-Lucander — Authorized Representative in the United States

Calliditas Therapeutics Inc.
By: Renée Aguiar-Lucander
Title: President

Exhibit 1.1

CALLIDITAS THERAPEUTICS AB

[●] Common Shares (Quota Value SEK 0.04 Per Share)
(including [●] American Depositary Shares, each Representing Two Common Shares)

Underwriting Agreement

January [●], 2021

Citigroup Global Markets Inc.
Jefferies LLC
Citigroup Global Markets Limited
Jefferies International Limited
Jefferies GmbH
As Representatives of the several Underwriters,

c/o Citigroup Global Markets Inc.
388 Greenwich Street
New York, New York 10013

c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

c/o Citigroup Global Markets Limited
Citigroup Centre
Canada Square
Canary Wharf
London E14 5LB
United Kingdom

c/o Jefferies International Limited
100 Bishopsgate
London EC2N 4JL
United Kingdom

c/o Jefferies GmbH
Bockenheimer Landstrasse 24
60323 Frankfurt am Main
Germany

Ladies and Gentlemen:

Calliditas Therapeutics AB, a Swedish public limited liability company (the "Company"), proposes to issue and sell to the Underwriters (as defined below) an aggregate of (i) [●] common shares, quota value SEK 0.04 per share ("Common Shares"), of the Company to be delivered in the form of [●] American Depositary Shares ("ADSs"), each representing two Common Shares in a public offering in the United States (the "Public Offering") and (ii) [●] Common Shares of the Company in a private placement in Europe and countries outside the United States (the "Private Placement"). The aggregate of [●] ADSs so proposed to be issued and sold in the Public Offering are hereinafter referred to as the "Firm ADSs", the aggregate of [●] Common Shares to be issued and sold in the Private Placement are hereinafter referred to as the "Firm Shares", and the Firm ADSs and Firm Shares are hereinafter collectively referred to as the "Firm Securities". The Company also proposes to grant to the Underwriters an option to purchase up to [●] additional Common Shares, which may be in the form of (i) ADSs (the "Option ADSs") and/or (ii) Common Shares (the "Option Shares" and, together with the Option ADSs, the "Option Securities") in the Private Placement. The Firm Shares and the Option Shares are hereinafter collectively referred to as the "Offered Shares" and the Firm ADSs and the Option ADSs are hereinafter collectively referred to as the "Offered ADSs." The Option Securities and the Firm Securities are hereinafter called the "Offered Securities". The new Common Shares underlying the Offered ADSs are herein called the "Underlying Shares."

The Offered ADSs will be evidenced by American Depositary Receipts ("ADRs") and issued pursuant to that certain Deposit Agreement dated as of June 9, 2020 (the "Deposit Agreement"), by and among the Company, Citibank, N.A. as depositary (the "Depositary") and all holders and beneficial owners of ADSs issued thereunder. The Company shall, following subscription by the Underwriters of the Offered Securities pursuant to this Agreement, deposit, on behalf of the Underwriters, the Underlying Shares being delivered in the form of ADSs with Citibank Europe plc as custodian (the "Custodian") for the Depositary, which shall deliver the Offered ADSs to the Representatives for the account of the several Underwriters for subsequent delivery to the other several Underwriters or the investors, as the case may be.

The term "Representatives" or "you" as used herein shall mean, with respect to the Public Offering and sale of the Offered ADSs, Citigroup Global Markets Inc. and Jefferies LLC, as representatives of the several underwriters named in the first table in Schedule I hereto (the "U.S. Underwriters"), and, with respect to the Private Placement and sale of the Offered Shares, Citigroup Global Markets Limited, Jefferies International Limited and Jefferies GmbH, as representatives of the several underwriters named in the second table in Schedule I hereto (the "EU Underwriters" and, together with the U.S. Underwriters, the "Underwriters"). The division of services between Jefferies International Limited and Jefferies GmbH shall be determined at Jefferies' absolute discretion, whereby regulated services with respect to EU 27 countries and EU 27 investors shall be undertaken by Jefferies GmbH only. References herein to the "Underwriters" shall mean, with respect to the Public Offering and sale of the Offered ADSs, the U.S. Underwriters, and, with respect to the Private Placement and sale the Offered Shares, the EU Underwriters. The Offered Shares offered in the Private Placement will be offered in the context of a private placement to institutional investors including (i) in Sweden and other member states of the European Economic Area (the "EEA") to "qualified investors" within the meaning of article 2(e) of the Prospectus Regulation (as defined below) and (ii) in the United Kingdom to "qualified investors" as defined in Article 2 of the Prospectus Regulation as it forms part of domestic law in the United Kingdom by virtue of the European Union (Withdrawal) Act 2018 who are persons who (a) have professional experience in matters relating to investments falling within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (b) are high net worth bodies corporate, unincorporated associations or partnerships or trustees of high value trusts as described in Article 49(2)(a) to (d) of the Order. To the extent there are no additional Underwriters listed on Schedule I other than you, the term Representatives as used in this Agreement shall mean you, as Underwriters, and the terms Representatives and Underwriters shall mean either the singular or plural as the context requires.

Unless the context otherwise requires, each reference to the Offered Securities or Offered ADSs herein also includes the Underlying Shares and the ADRs evidencing such ADSs. Unless the context otherwise requires, each reference to the Offered Securities, the Offered Shares or the Offered ADSs, as the case may be, refers to the Firm Securities, the Firm Shares or the Firm ADSs, respectively, and, to the extent the Underwriters' option referred to in Section 2(b) of this Agreement is exercised, any Option Securities, Option Shares or Option ADSs, respectively, purchased pursuant to such option. The use of the neuter in this Agreement shall include the feminine and masculine wherever appropriate.

As used in this Agreement, the "Registration Statement" means the registration statement referred to in Section 1(a) hereof, including the exhibits, schedules and financial statements and any prospectus supplement relating to the Offered Securities that is filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b) under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (the "Securities Act") and deemed part of such registration statement pursuant to Rule 430A under the Securities Act ("Rule 430A"), as amended at the date and time that this Agreement is executed and delivered by the parties hereto (the "Execution Time"), and, in the event any post-effective amendment thereto or any registration statement and any amendments thereto filed pursuant to Rule 462(b) under the Securities Act (a "Rule 462(b) Registration Statement") becomes effective prior to the Closing Date (as defined in Section 3 hereof), shall also mean such registration statement as so amended or such Rule 462(b) Registration Statement, as the case may be; the "Effective Date" means each date and time that the Registration Statement and the ADR Registration Statement (as defined below), any post-effective amendment or amendments thereto or any Rule 462(b) Registration Statement became or becomes effective, as applicable; the "Preliminary Prospectus" means any preliminary prospectus with respect to the offering of the Offered Securities included in the Registration Statement at the Effective Date that omits information with respect to the Offered Securities and the offering thereof permitted to be omitted from the Registration Statement when it becomes effective pursuant to Rule 430A ("Rule 430A Information"); and the "Prospectus" means the prospectus relating to the Offered Securities that is first filed pursuant to Rule 424(b) under the Securities Act ("Rule 424(b)") after the Execution Time.

The Public Offering and the Private Placement will be completed on basis of an available prospectus exemption set out in Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC, which, jointly with the Commission Delegated Regulation (EU) 2019/979 of 14 March 2019 and the Commission Delegated Regulation (EU) 2019/980 of 14 March 2019, is referred to as the "Prospectus Regulation", and, accordingly, no offer prospectus or other offering documents will be required to be prepared under the Prospectus Regulation in connection with the Offering Public Offering and the Private Placement.

As used in this Agreement, the "Disclosure Package" shall mean (i) the Preliminary Prospectus, as generally distributed to investors and used to offer the Offered Securities, (ii) any issuer free writing prospectus, as defined in Rule 433 under the Securities Act ("Rule 433" and, any such issuer free writing prospectus, an "Issuer Free Writing Prospectus"), identified in Schedule II hereto, and (iii) any other free writing prospectus, as defined in Rule 405 under the Securities Act ("Rule 405" and, any such free writing prospectus, a "Free Writing Prospectus"), that the parties hereto shall hereafter expressly agree in writing to treat as part of the Disclosure Package.

1. Representations and Warranties.

The Company represents and warrants to, and agrees with, each Underwriter as set forth below in this Section 1.

(a) The Company has prepared and filed with the SEC a registration statement (File No. 333-[●]) on Form F-1, including a related Preliminary Prospectus, for the registration of the offering and sale of the Offered Securities under the Securities Act. Such Registration Statement, including any amendments thereto filed prior to the Execution Time, has become effective. The Company may have filed one or more amendments thereto, including the related Preliminary Prospectus, each of which has previously been furnished to you. The Company will file with the SEC a final Prospectus relating to the Offered Securities in accordance with Rule 424(b) after the Execution Time. As filed, such final Prospectus shall contain all information with respect to the Offered Securities and the offering thereof required by the Securities Act and the rules thereunder and, except to the extent the Representatives shall agree in writing to a modification, shall be in all substantive respects in the form furnished to you prior to the Execution Time or, to the extent not completed at the Execution Time, shall contain only such specific additional information and other changes (beyond that contained in the latest Preliminary Prospectus) as the Company has advised you, prior to the Execution Time, will be included or made therein.

(b) When the Prospectus is first filed in accordance with Rule 424(b), on the Closing Date and on any date on which Option Securities are purchased, if such date is not the Closing Date (a "settlement date"), the Prospectus (and any supplement thereto) will comply in all material respects with the applicable requirements of the Securities Act and the rules thereunder; on the Effective Date, at the Execution Time and on the Closing Date, the Registration Statement complied and will comply in all material respects with the applicable requirements of the Securities Act and the rules thereunder, and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the date of any filing pursuant to Rule 424(b) and on the Closing Date and any settlement date, each Prospectus (together with any supplement thereto) will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that the Company makes no representations or warranties as to the information contained in or omitted from the Registration Statement or the Prospectus (or any supplement thereto) in reliance upon and in conformity with information furnished in writing to the Company by or on behalf of any Underwriter through the Representatives specifically for inclusion in the Registration Statement or the Prospectus (or any supplement thereto), it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof.

(c) The Company has filed with the SEC a registration statement (File No. 333-238726) on Form F-6 for the registration under the Securities Act of the offering and sale of the Offered ADSs (such registration statement, including all exhibits thereto, at the time it became effective, being hereinafter referred to as the "ADR Registration Statement"), and the ADR Registration Statement has become effective under the Securities Act. The Company may have filed one or more amendments thereto, each of which has previously been furnished to you. Such ADR Registration Statement at the time of its effectiveness did comply and on the Closing Date, will comply, in all material respects with the applicable requirements of the Securities Act and the rules thereunder and at the time of its Effective Date and at the Execution Time, did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading.

(d) A registration statement on Form 8-A (File No. 001-39308), and any amendments thereto, in respect of the registration of the Offered Securities under the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC thereunder (collectively, the "Exchange Act") has been filed with the SEC; such registration statement in the form heretofore delivered to the Representatives and, excluding exhibits, to the Representatives for each of the other Underwriters, has been declared effective by the SEC; no other document with respect to such registration statement has heretofore been filed with the SEC; no stop order suspending the effectiveness of such registration statement has been issued and, to the knowledge of the Company, no proceeding for that purpose has been initiated or threatened by the SEC (the various parts of such registration statement, including all exhibits thereto, each as amended at the time such part of the registration statement became effective, being hereinafter called the "Form 8-A Registration Statement"); and the Form 8-A Registration Statement when it became effective complied, and any further amendments thereto will comply, in all material respects with the Exchange Act, and did not, as of the applicable effective date, and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading.

(e) The Public Offering and the Private Placement will be completed on the basis of an available prospectus exemption set out in the Prospectus Regulation and, accordingly, the Company will not be required to prepared any prospectus under the Prospectus Regulation in connection with the Public Offering or the Private Placement.

(f) The issuance of the Offered Shares and the Underlying Shares has been duly authorized and the Offered Shares and the Underlying Shares will, in each case, upon payment, issuance and registration with the Swedish Companies Registration Office (*Bolagsverket*), constitute valid, fully paid and non-assessable shares that are freely transferable, without the need to obtain any approval or authorization in connection therewith, under the Company's Articles of Association and there are vis-à-vis the Company no other restrictions on subsequent transfers of the Offered Securities or on the voting rights of the Offered Securities by the Underwriters; and the issuance of the Offered Securities is not subject to the preemptive or other similar rights of any security holder of the Company. The Offered Shares and the Underlying Shares will, once registered with Swedish Companies Registration Office and upon admission to trading on Nasdaq Stockholm, conform to all statements relating thereto contained in the Registration Statement, the Disclosure Package and the Prospectus and such descriptions conform to the rights set forth in the instruments defining the same. No holder of the Offered Securities will be subject to personal liability by reason of being such a holder. Upon the delivery to the Custodian of the Underlying Shares, the Depositary will, subject to the terms of the Deposit Agreement, acquire good, marketable and valid title to such Underlying Shares, free and clear of all pledges, liens, security interests, charges, claims or encumbrances of any kind.

(g) Except as described in each of the Disclosure Package and the Prospectus, all dividends and other distributions declared and payable on the Common Shares may under current Swedish law and regulations be paid to the Depositary and to the holders of the Offered Securities, as the case may be, in Swedish Krona and may be converted into foreign currency that may be transferred out of the Kingdom of Sweden in accordance with the Deposit Agreement.

(h) The Company is not currently a Passive Foreign Investment Company ("PFIC") within the meaning of Section 1296 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"), and does not expect to become a PFIC in the future.

(i) The Company is not currently a Controlled Foreign Corporation ("CFC") within the meaning of Section 957 of the Code, and does not expect to become a CFC in the future.

(j) The Company is not currently a "foreign personal holding company" within the meaning of the Code.

(k) (i) The Disclosure Package and the price to the public, the number of Firm Securities and the number of Option Securities to be included on the cover page of the Prospectus, when taken together as a whole, (ii) each electronic road show, when taken together as a whole with the Disclosure Package and the price to the public, the number of Firm Securities and the number of Option Securities to be included on the cover page of the Prospectus, and (iii) any individual Written Testing-the-Waters Communication, when taken together as a whole with the Disclosure Package and the price to the public, the number of Firm Securities and the number of Option Securities to be included on the cover page of the Prospectus, does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from the Disclosure Package based upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof.

(l) (i) At the time of filing the Registration Statement and (ii) as of the Execution Time (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an Ineligible Issuer (as defined in Rule 405), without taking account of any determination by the SEC pursuant to Rule 405 that it is not necessary that the Company be considered an Ineligible Issuer.

(m) From the time of initial confidential submission of the Registration Statement to the SEC (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the Execution Time, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "Emerging Growth Company"). "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(n) The Company (i) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than Citigroup Global Markets Inc. and Jefferies LLC to engage in Testing-the-Waters Communications. The Company reconfirms that each of Citigroup Global Markets Inc. and Jefferies LLC have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule III hereto. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405.

(o) Each Issuer Free Writing Prospectus does not include any information that conflicts with the information contained in the Registration Statement. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 8 hereof.

(p) Each of the Company and its subsidiaries has been duly incorporated or organized and is validly existing as a corporation or other organization in good standing under the laws of the jurisdiction in which it is chartered or organized with full corporate power and authority to own or lease, as the case may be, and to operate its properties and conduct its business as described in the Disclosure Package and the Prospectus, and is duly qualified to do business as a foreign corporation and is in good standing under the laws of each jurisdiction which requires such qualification, except when the failure to be qualified or in good standing would not reasonably be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or otherwise), prospects, earnings, business or properties of the Company and its subsidiaries, taken as a whole (a "Material Adverse Effect").

(q) The Company's issued share capital is as set forth in the Disclosure Package and the Prospectus under the heading "Capitalization"; the share capital of the Company conforms to the description thereof contained in the Disclosure Package and the Prospectus; and, except as set forth in the Disclosure Package and the Prospectus, no options, warrants or other rights to purchase, agreements or other obligations to issue, or rights to convert any obligations into or exchange any securities for shares or ownership interests in the Company are outstanding.

(r) All the outstanding share capital of each subsidiary have been duly and validly authorized and issued and are fully paid and non-assessable, and, except as otherwise set forth in the Disclosure Package and the Prospectus, all outstanding share capital of the subsidiaries are owned by the Company either directly or through wholly owned subsidiaries free and clear of any perfected security interest or any other security interests, claims, liens or encumbrances.

(s) There is no franchise, contract or other document of a character required to be described in the Registration Statement, the ADR Registration Statement or the Prospectus, or to be filed as an exhibit thereto, which is not described or filed as required (and the Preliminary Prospectus contains in all material respects the same description of the foregoing matters contained in the Prospectus); and the statements in the Preliminary Prospectus and the Prospectus under the headings "Material Income Tax Considerations," "Risk Factors—Risks Related to Intellectual Property," "Risk Factors—Risks Related to the Discovery, Development and Commercialization of Our Product Candidates," "Business—Intellectual Property," "Business—Government Regulation" and "Description of Share Capital and Articles of Association," insofar as such statements summarize legal matters, agreements, documents or proceedings discussed therein, are accurate and fair summaries of such legal matters, agreements, documents or proceedings.

(t) This Agreement has been duly authorized, executed and delivered by the Company.

(u) The Deposit Agreement has been duly authorized, executed and delivered by the Company. Assuming due authorization, execution and delivery by the Depositary, the Deposit Agreement constitutes a valid and legally binding agreement of the Company enforceable against the Company in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles relating to enforceability. Upon (i) issuance by the Depositary of the Offered ADSs against the deposit of the Underlying Shares in respect thereof and/or (ii) due execution and delivery by the Depositary of ADRs evidencing the Offered ADSs against the deposit of the Underlying Shares in respect thereof, in accordance with the provisions of the Deposit Agreement, such ADSs and/or ADRs will be duly and validly issued and the persons in whose names the ADSs and/or the ADRs are registered will be entitled to the rights specified therein and in the Deposit Agreement; the deposit of the Underlying Shares with the Depositary and the issuance of the Offered ADSs in respect thereof and the ADRs evidencing the same as contemplated by this Agreement and the Deposit Agreement is not subject to the preemptive or other similar rights of any securityholder of the Company; and the Deposit Agreement and the ADSs and ADRs conform to the descriptions thereof contained in the Registration Statement, the Disclosure Package and the Prospectus.

(v) The Company is not and, after giving effect to the offering and sale of the Offered Securities and the application of the proceeds thereof as described in the Disclosure Package and the Prospectus, will not be an "investment company" as defined in the Investment Company Act of 1940, as amended.

(w) No consent, approval, authorization, filing with or order of any court or governmental agency or body is required in connection with the transactions contemplated herein or in the Deposit Agreement, except such as have been obtained under the Securities Act and such as may be required under the listing rules of the Nasdaq Stock Market, applicable rules of the Financial Industry Regulatory Authority, Inc. ("FINRA") and the blue sky laws of any jurisdiction or the Swedish Companies Act (*Aktiebolagslagen (2005:551)*), as amended, in connection with the purchase and distribution of the Offered Securities by the Underwriters in the manner contemplated herein and in the Disclosure Package and the Prospectus. Without limitation, the Company has not, directly or indirectly, without giving effect to activities by the Underwriters, caused the Offered Securities to be, and will not cause them to be, the subject of an offer to the public in the Kingdom of Sweden (or in any other EU Member State) for the purposes of Swedish law (or any laws of any other EU Member State) or in the United Kingdom for the purposes of law in the United Kingdom, and no invitation or inducement to acquire them has been or will be made by the Company, directly or indirectly, without giving effect to activities of the Underwriters, which would be prohibited by Swedish law (or any laws of any other EU Member State) or law in the United Kingdom.

(x) Neither the issue and sale of the Offered Securities nor the consummation of any other of the transactions herein contemplated nor the fulfillment of the terms of this Agreement or of the Deposit Agreement or the execution or delivery of this Agreement or the Deposit Agreement will conflict with, result in a breach or violation of, or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, (i) the articles of association or bylaws of the Company or any of its subsidiaries, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which the Company or any of its subsidiaries is a party or bound or to which its or their property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree applicable to the Company or any of its subsidiaries of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or any of its subsidiaries or any of its or their properties (including, without limitation, the rules and regulations of Nasdaq Stockholm), except in the case of clause (ii) and (iii) for any such breach, violation or imposition as would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Effect and as would not have a material adverse effect on the ability of the Underwriters to execute the transactions contemplated by this agreement.

(y) No holders of securities of the Company have rights to the registration of such securities under the Registration Statement.

(z) The consolidated historical financial statements, together with the related notes and schedules, of the Company and its consolidated subsidiaries included in the Preliminary Prospectus, the Prospectus and the Registration Statement present fairly in all material respects the financial condition, results of operations and cash flows of the Company and its consolidated subsidiaries as of the dates and for the periods indicated, comply as to form in all material respects with the applicable accounting requirements of the Securities Act. Such statements and related notes and schedules have been prepared in accordance with International Financial Reporting Standards, as adopted by the International Accounting Standards Board ("IFRS"), and in compliance with the financial reporting requirements of Swedish law, in each case applied on a consistent basis throughout the periods involved except as may be set forth in the related notes included in the Prospectus. The consolidated historical financial statements, together with the related notes, of Genkyotex S.A. and its consolidated subsidiary included in the Preliminary Prospectus, the Prospectus and the Registration Statement present fairly in all material respects the financial condition, results of operations and cash flows of Genkyotex S.A. and its consolidated subsidiary as of the dates and for the periods indicated, comply as to form in all material respects with the applicable accounting requirements of the Securities Act. Such statements and related notes have been prepared in accordance with IFRS, as adopted by the International Accounting Standards Board, and, with respect to the nine month period ended September 30, 2020, in accordance with IAS 34 "Interim financial reporting", applied on a consistent basis throughout the periods involved except as may be set forth in the related notes included in the Prospectus, except that they do not include comparative financial information as of and for the year ended December 31, 2018 and for the nine-month period ended September 30, 2019 as required by IAS 1 "Presentation of Financial Statements". The financial statements, together with the related notes and schedules, included in the Preliminary Prospectus, the Prospectus and the Registration Statement comply in all material respects with Regulation S-X. No other financial statements or supporting schedules or exhibits are required by Regulation S-X to be described or included in the Preliminary Prospectus, the Prospectus and the Registration Statement. The selected financial data set forth under the caption "Selected Consolidated Financial Data" in the Preliminary Prospectus, the Prospectus and Registration Statement fairly present in all material respects, on the basis stated in the Preliminary Prospectus, the Prospectus and the Registration Statement, the information included therein. The pro forma financial statements included in the Preliminary Prospectus, the Prospectus and the Registration Statement include assumptions that provide a reasonable basis for presenting the significant effects directly attributable to the transactions and events described therein, the related pro forma adjustments give appropriate effect to those assumptions, and the pro forma adjustments reflect the proper application of those adjustments to the historical financial statement amounts in the pro forma financial statements included in the Preliminary Prospectuses, the Prospectuses and the Registration Statement. The pro forma financial statements included in the Preliminary Prospectuses, the Prospectuses and the Registration Statement comply as to form in all material respects with the applicable accounting requirements of Regulation S-X and the pro forma adjustments have been properly applied to the historical amounts in the compilation of those statements

(aa) No action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries or its or their property is pending or, to the knowledge of the Company, threatened that (i) would reasonably be expected to have a material adverse effect on the performance of this Agreement or the consummation of any of the transactions contemplated hereby or (ii) could reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(bb) Each of the Company and each of its subsidiaries owns or leases all such properties as are necessary to the conduct of its operations as presently conducted, and except as would not reasonably be expected to have a Material Adverse Effect.

(cc) Neither the Company nor any subsidiary is in violation or default of: (i) any provision of its articles of association or bylaws, (ii) the terms of any indenture, contract, lease, mortgage, deed of trust, note agreement, loan agreement or other agreement, obligation, condition, covenant or instrument to which it is a party or bound or to which its property is subject, or (iii) any statute, law, rule, regulation, judgment, order or decree of any court, regulatory body, administrative agency, governmental body, arbitrator or other authority having jurisdiction over the Company or such subsidiary or any of its properties, as applicable, except in case of clauses (ii) and (iii), for any such violation or default as would not reasonably expected, individually or in the aggregate, to have a Material Adverse Effect.

(dd) (i) Ernst & Young AB, who have audited the consolidated financial statements of the Company and its consolidated subsidiaries and delivered their report with respect to the audited consolidated financial statements and schedules included in the Disclosure Package and the Prospectus, are independent public accountants with respect to the Company within the meaning of the Securities Act and the applicable published rules and regulations thereunder. (ii) KPMG S.A., who have audited the consolidated financial statements of Genkyotex S.A. and its subsidiary included in the Disclosure Package and the Prospectus and who have delivered their report with respect thereto, are independent certified public accountants with respect to Genkyotex S.A. under Rule 101 of the AICPA Code of Professional Conduct, and its interpretations and rulings, which is accepted by the SEC for audits of acquiree financial statements pursuant to Rule 3-05 of Regulation S-X

(ee) No stamp, documentary, issuance, registration, transfer or other similar taxes or duties are payable by or on behalf of the Underwriters, the Company or any of its subsidiaries in the Kingdom of Sweden, the United States, any state or political subdivision thereof or to any taxing authority thereof or therein in connection with (i) the execution, delivery or consummation of this Agreement, (ii) the creation, allotment and issuance of the Offered Securities by the Company, (iii) the sale and delivery of the Offered Securities by the Company to the Underwriters or purchasers procured by the Underwriters, or (iv) the resale and delivery of the Offered Securities by the Underwriters in the manner contemplated herein.

(ff) The Company and each of its subsidiaries have filed all tax returns that are required to be filed or have requested extensions thereof (except in any case in which the failure to so file would not have a Material Adverse Effect or except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto)) and have paid all taxes required to be paid by it and any other assessment, fine or penalty levied against it, to the extent that any of the foregoing is due and payable, except for any such assessment, fine or penalty that is currently being contested in good faith or as would not have a Material Adverse Effect or except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto). No tax deficiency has been determined adversely to the Company or any of its subsidiaries which has had (nor does the Company nor any of its subsidiaries have any notice or knowledge of any tax deficiency which would reasonably be expected to be determined adversely to the Company or any of its subsidiaries and which would reasonably be expected to have) a Material Adverse Effect on the Company and its subsidiaries, taken as a whole.

(gg) No labor problem or dispute with the employees of the Company or any of its subsidiaries exists or is threatened in writing or, to the Company's knowledge, imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, that would be reasonably expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(hh) The Company and each of its subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as the Company reasonably believes are prudent and customary in the businesses in which they are engaged; all policies of insurance and fidelity or surety bonds insuring the Company or any of its subsidiaries or their respective businesses, assets, employees, officers and directors are in full force and effect; the Company and its subsidiaries are in compliance with the terms of such policies and instruments in all material respects; and there are no material claims by the Company or any of its subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor any such subsidiary has been refused any insurance coverage sought or applied for; and neither the Company nor any such subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect.

(ii) No subsidiary of the Company is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such subsidiary's share capital, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's property or assets to the Company or any other subsidiary of the Company, except as described in or contemplated by the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(jj) The Company and its subsidiaries possess all licenses, certificates, permits and other authorizations issued by all applicable authorities necessary to conduct their respective businesses, except where the failure to possess such license, certificate, permit and other authorization would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; neither the Company nor any such subsidiary has received any notice of proceedings relating to the revocation or modification of any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a Material Adverse Effect, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(kk) The Company and each of its subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with IFRS and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as otherwise set forth in the Prospectus, the Company and its subsidiaries' internal controls over financial reporting are effective and the Company and its subsidiaries are not aware of any material weakness in their internal controls over financial reporting. Neither the Company nor any of its subsidiaries has any material off-balance sheet financing arrangement as defined in accordance with IFRS.

(ll) The Company and its subsidiaries maintain "disclosure controls and procedures" (as such term is defined in Rule 13a-15(e) under the Exchange Act; such disclosure controls and procedures are effective.

(mm) The Company has not taken, directly or indirectly (without giving effect to the activities of the Underwriters), any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Offered Securities.

(nn) The Company and its subsidiaries are (i) in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, the "Environmental Laws"), (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) have not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability would not, individually or in the aggregate, have a Material Adverse Effect. Except as set forth in the Disclosure Package and the Prospectus, neither the Company nor any of the subsidiaries has been named as a "potentially responsible party" under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(oo) None of the following events has occurred or exists, except where the occurrence of any such event would not reasonably be expected to result in a Material Adverse Effect: (i) a failure to fulfill the obligations, if any, under the minimum funding standards of Section 302 of the U.S. Employee Retirement Income Security Act of 1974, as amended ("ERISA"), or any foreign equivalent, and the regulations and published interpretations thereunder with respect to a Plan, determined without regard to any waiver of such obligations or extension of any amortization period; (ii) an audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other federal or state governmental agency or any foreign regulatory agency with respect to the employment or compensation of employees by any of the Company or any of its subsidiaries; (iii) any breach of any contractual obligation, or any violation of law or applicable qualification standards, with respect to the employment or compensation of employees by the Company or any of its subsidiaries . None of the following events has occurred or is reasonably likely to occur, except where the occurrence of any such event would not reasonably be expected to result in a Material Adverse Effect: (i) an increase in the aggregate amount of contributions required to be made to all Plans in the current fiscal year of the Company and its subsidiaries compared to the amount of such contributions made in the most recently completed fiscal year of the Company and its subsidiaries; (ii) an increase in the "accumulated post-retirement benefit obligations" (within the meaning of Statement of Financial Accounting Standards 106) of the Company and its subsidiaries compared to the amount of such obligations in the most recently completed fiscal year of the Company and its subsidiaries; (iii) any event or condition giving rise to a liability under Title IV of ERISA (or any foreign equivalent); or (iv) the filing of a claim by one or more employees or former employees of the Company or any of its subsidiaries related to their employment. For purposes of this paragraph, the term "Plan" means a plan (within the meaning of Section 3(3) of ERISA) subject to Title IV of ERISA with respect to which the Company or any of its subsidiaries may have any liability.

(pp) There is and has been no failure on the part of the Company and any of the Company's directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated in connection thereunder (the "Sarbanes-Oxley Act"), that are in effect and with which the Company is required to comply as of the effectiveness of the Registration Statement, including Section 402 relating to loans.

(qq) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has (i) taken any action, directly or indirectly, that could result in a violation or a sanction for violation by such persons of the U.S. Foreign Corrupt Practices Act of 1977 or the U.K. Bribery Act 2010, each as may be amended, or any similar law of any other relevant jurisdiction, or the rules or regulations thereunder (collectively, "Anti-Corruption Laws"); (ii) promised, offered, provided, attempted to provide, or authorized the provision of money or anything of value, directly or indirectly, to any person for the purpose of obtaining or retaining business, influencing any act or decision of the recipient, or securing any improper advantage; or (iii) made, offered, agreed, or requested any unlawful bribe or unlawful benefit including, without limitation, any rebate, payoff, influence payment, kickback, or other unlawful or improper payment or benefit. The Company and its subsidiaries have instituted and maintain policies and procedures to ensure compliance with Anti-Corruption Laws. No part of the proceeds of the offering will be used, directly or indirectly, in violation of Anti-Corruption Laws.

(rr) The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements and the money laundering statutes and the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(ss) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate or other person acting on behalf of the Company or any of its subsidiaries (i) is, or is controlled or 50% or more owned in the aggregate by or is acting on behalf of, one or more individuals or entities that are currently the subject of any sanctions administered or enforced by the United States (including any administered or enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury, the U.S. Department of State or the Bureau of Industry and Security of the U.S. Department of Commerce), the United Nations Security Council, the European Union, a member state of the European Union (including sanctions administered or enforced by Her Majesty's Treasury of the United Kingdom) or other relevant sanctions authority (collectively, "Sanctions" and such persons, "Sanctioned Persons" and each such person, a "Sanctioned Person"), (ii) is located, organized or resident in a country or territory that is, or whose government is, the subject of Sanctions that broadly prohibit dealings with that country or territory (collectively, "Sanctioned Countries" and each, a "Sanctioned Country") or (iii) will, directly or indirectly, use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other individual or entity in any manner that would result in a violation of any Sanctions by, or could result in the imposition of Sanctions against, any individual or entity (including any individual or entity participating in the offering, whether as underwriter, advisor, investor or otherwise).

(tt) Neither the Company nor any of its subsidiaries has engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country, in the preceding three years, nor does the Company or any of its subsidiaries have any plans to engage in dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country.

(uu) The subsidiaries listed on Exhibit 21.1 to the Registration Statement are the only "significant subsidiaries" of the Company as defined by Rule 1-02 of Regulation S-X.

(vv) The Company and its subsidiaries own, possess, license or have other rights to use, on reasonable terms, all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, know-how and other intellectual property (collectively, the "Intellectual Property") necessary for the conduct of the Company's business as now conducted or as proposed in the Disclosure Package and Prospectus to be conducted. Except as set forth in the Disclosure Package and the Prospectus under the caption "Business—Intellectual Property," (a) there are no rights of third parties to any such Intellectual Property; (b) to the knowledge of the Company, there is no material infringement by third parties of any such Intellectual Property; (c) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the Company's rights in or to any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (d) the Intellectual Property has not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, (e) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such claim; (f) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company infringes, misappropriates or otherwise violates any patent, trademark, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any other fact which would form a reasonable basis for any such claim; and (g) there is no prior art of which the Company is aware that may render any patent held by the Company invalid or any patent application held by the Company un-patentable which has not been disclosed to the U.S. Patent and Trademark Office.

(ww) Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of any of the Underwriters; and (ii) does not intend to use any of the proceeds from the sale of the Offered Securities hereunder to repay any outstanding debt owed to any affiliate of any of the Underwriters**.**

(xx) The Company (i) is, and at all relevant times has been, in compliance with all applicable Health Care Laws (as defined below) related to the regulation of the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by or for the Company, except where the failure to comply would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. For the purposes of this Agreement, Health Care Laws means: (1) Federal Food, Drug and Cosmetic Act (21 U.S.C. §301 et seq.); (2) all applicable federal, state, local and all foreign civil and criminal laws relating to health care fraud and abuse, including but not limited to the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), criminal false statements (42 U.S.C. §1320a-7b(a)), the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. §§ 1320d et seq.), the exclusions law (42 U.S.C. § 1320a-7), the U.S. Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), and the civil monetary penalties law (42 U.S.C. §1320a-7a); (3) Medicare (Title XVIII of the Social Security Act); (4) Medicaid (Title XIX of the Social Security Act); (5) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (42 U.S.C. §§ 17921 et seq.); (6) the Patient Protection and Affordable Care Act (Pub. Law 111-148), as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (Pub. Law 111-152), the regulations promulgated pursuant to such laws, and any successor government programs and comparable state laws; (7) regulations relating to Good Clinical Practices and Good Laboratory Practices; and (8) all other local, state, federal, national and foreign health care laws applicable to the regulation of the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by or for the Company; (ii) has not received any written notice from any court or arbitrator or governmental or regulatory authority or third party alleging or asserting noncompliance with any Health Care Laws or any licenses, exemptions, certificates, approvals, clearances, authorizations, permits, registrations and supplements or amendments thereto required by any such Health Care Laws ("Authorizations"); (iii) possesses all necessary Authorizations and such Authorizations are valid and in full force and effect and are not in violation of any term of any such Authorizations; (iv) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Health Care Laws or Authorizations nor, to the knowledge of the Company, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened; (v) has not received any written notice that any court or arbitrator or governmental or regulatory authority has taken, is taking or intends to take, action to materially limit, suspend, materially modify or revoke any Authorizations nor, to the knowledge of the Company, is any such limitation, suspension, modification or revocation threatened; (vi) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws or Authorizations and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and accurate on the date filed (or were corrected or supplemented by a subsequent submission); and (vii) has not, nor have any of its officers or directors, nor, to the knowledge of the Company, have any of its employees, been excluded, suspended or debarred from participation in any U.S. state or federal health care program or human clinical research or subject to a governmental inquiry, investigation, proceeding, or other any other Action that could reasonably be expected to result in debarment, suspension, or exclusion; and (viii) is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority.

(yy) The clinical trials and pre-clinical studies conducted by or on behalf of or sponsored by the Company, or in which the Company has participated, that are described in the Registration Statement, the Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Disclosure Package and the Prospectus, as applicable, and are intended to be submitted to Regulatory Authorities as a basis for product approval, were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures and all applicable statutes, rules and regulations of the U.S. Food and Drug Administration (the "FDA") and comparable drug regulatory agencies outside of the United States to which they are subject including but not limited to the European Medicines Agency (collectively, the "Regulatory Authorities") and current Good Clinical Practices and Good Laboratory Practices, as applicable; the descriptions in the Registration Statement, the Disclosure Package or the Prospectus of the results of such studies and trials are accurate and complete in all material respects and fairly present the data derived from such studies and trials; the Company has no knowledge of any other studies or trials the results of which are inconsistent with or otherwise call into question the results described or referred to in the Registration Statement, the Disclosure Package and the Prospectus; the Company is in compliance in all material respects with all applicable statutes, rules and regulations of the Regulatory Authorities and has not received any written notices, correspondence or other communication from the Regulatory Authorities or any other governmental agency which could lead to the termination or suspension of any clinical trials or pre-clinical studies that are described in the Registration Statement, the Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, Disclosure Package or the Prospectus, and, to the Company's knowledge, there are no reasonable grounds for same.

(zz) The Company (i) possesses all licenses, certificates, permits and other authorizations (collectively, "Permits") issued by, and has made all declarations and filings with, the applicable federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of its properties or the conduct of its businesses as described in the Registration Statement, the Disclosure Package and the Prospectus, or to permit all clinical trials and nonclinical studies conducted by or on behalf of the Company, including, without limitation, all necessary FDA and applicable foreign regulatory agency approvals; (ii) the Company is not in violation of, or in default under, any such Permit; and (iii) the Company has not received notice of any revocation, suspension or modification of any such Permit in each case, except where failure to do so would reasonably be expected to result in a Material Adverse Effect. The Company (i) is, and at all times has been, in material compliance with all such Permits; and (ii) has not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or regulatory authority alleging or asserting non-compliance with (A) any Health Care Laws or (B) any Permits required by any such Health Care Laws.

(aaa) To the knowledge of the Company, the manufacturing facilities and operations of its suppliers are operated in compliance in all material respects with all applicable statutes, rules, regulations and policies of the Regulatory Authorities.

(bbb) None of the Company's product candidates have received marketing approval from any Regulatory Authority.

(ccc) The Company is a "foreign private issuer" within the meaning of Rule 405.

(ddd) Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(eee) The statistical and market-related data included in the Registration Statement, the Disclosure Package and the Prospectus are based on or derived from sources which the Company reasonably and in good faith believes are reliable and accurate in all material respects.

(fff) Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement, the Disclosure Package or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement.

(ggg) Neither the Company nor any of its subsidiaries nor any of its or their properties or assets has any immunity from the jurisdiction of any court or from any legal process (whether through service or notice, attachment prior to judgment, attachment in aid of execution or otherwise), including under the laws of the Kingdom of Sweden and the European Union. The irrevocable and unconditional waiver and agreement of the Company contained in Section 14 of this Agreement not to plead or claim any such immunity in any legal action, suit or proceeding based on this Agreement is valid and binding under the laws of the Kingdom of Sweden.

(hhh) Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, neither the Company nor any of its subsidiaries have been notified of, or have any knowledge of (i)(x) a security breach or incident, unauthorized access or disclosure, violations, outages or other compromise of or relating to any of the Company's or any of its subsidiaries' information technology and computer systems, networks, hardware, software, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them and all Personal Data (defined below), sensitive, confidential or regulated data), equipment or technology (collectively, "IT Systems and Data") or (y) of any event or condition that would reasonably be expected to result in, any security breach or incident, unauthorized access or disclosure or other compromise to its IT Systems and Data, except as would not, in the case of this clause (i), individually or in the aggregate, be reasonably expected to have a Material Adverse Effect; (ii) the Company and each of its subsidiaries have at all times been in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, in the case of this clause (ii), individually or in the aggregate, be reasonably expected to have a Material Adverse Effect; and (iii) the Company and its subsidiaries have implemented information system backup and disaster recovery procedures.

(iii) The outstanding Common Shares of the Company have been duly listed and are freely tradable on Nasdaq Stockholm; the Company is in compliance with all listing and admission requirements and continuing obligations pursuant to applicable laws and the rules of Nasdaq Stockholm.

(jjj) The sale or issuance of the Offered Securities by the Company will not violate the rules and regulations of Nasdaq Stockholm, the Swedish Penalties for Market Abuse in Financial Instruments Trading Act (SFS 2016:1307) (*Lag (2016:1307) om straff för marknadsmissbruk på värdepappersmarknaden)*, as amended or the Market Abuse Regulation (EU) No 596/2014.

(kkk) The Company has no debt securities that has been rated by any "nationally recognized statistical rating organization" (as defined for purposes of Rule 3(a)(62) under the Exchange Act).

Any certificate signed by any officer of the Company and delivered to the Representatives or counsel for the Underwriters in connection with the offering of the Offered Securities shall be deemed a representation and warranty by the Company, as to matters covered thereby, to each Underwriter.

2. Purchase and Sale.

(a) Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, (i) the Company agrees to issue to each U.S. Underwriter, and each U.S. Underwriter agrees, severally and not jointly, to subscribe for from the Company, the respective numbers of Firm ADSs set forth opposite such Underwriter's name in the first table in Schedule I hereto and (ii) the Company agrees to issue to each EU Underwriter, and each EU Underwriter agrees, severally and not jointly, to subscribe for from the Company, the respective numbers of Firm Shares set forth opposite such Underwriter's name in the second table in Schedule I hereto. The Firm Shares (and, as the case may be, the Option Shares) and the Firm ADSs (and, as the case may be, the Option ADSs) are being offered as part of a single capital increase at an identical purchase price of $[●] per ADS (the "ADS Purchase Price"), corresponding to SEK [●] per Common Share (the "Share Purchase Price" and, together with the ADS Purchase Price, the "Purchase Price").

(b) Subject to the terms and conditions and in reliance upon the representations and warranties herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to [●] Option Securities, which may be in the form of (i) Option ADSs, less an amount per ADS equal to any dividends or distributions declared by the Company and payable on the Firm ADSs or the Firm ADSs' Underlying Shares but not payable on the Option ADSs or the Option ADSs' Underlying Shares; and/or (ii) Option Shares, less an amount per Common Share equal to any dividends or distributions declared by the Company and payable on the Firm Shares but not payable on the Option Shares. The number of Option Shares and Option ADSs, respectively, may be reallocated provided that the total number of Common Shares, including Common Shares represented by ADSs, issued as Option Securities shall not exceed 15% of the total number of Common Shares, including Common Shares represented by ADSs, issued as Firm Securities. Said option may be exercised in whole or in part at any time on or before the 30th day after the date of the Prospectus upon written, electronic or telegraphic notice by the Representatives to the Company setting forth the number of shares of the Option Securities as to which the several Underwriters are exercising the option and the settlement date. The number of Option ADSs or Option Shares, as the case may be, to be purchased by each Underwriter shall be the same percentage of the total number of shares of the Option ADSs or Option Shares, as the case may be, to be purchased by the several Underwriters as such Underwriter is purchasing of the Firm ADSs or Firm Shares, as the case may be, subject to such adjustments as you in your absolute discretion shall make to eliminate any fractional shares.

3. Delivery and Payment. Timing of payment and delivery of the Offered Securities shall be made in accordance with Schedule IV hereto. Delivery of and payment for (i) the Firm ADSs and the Option ADSs and (ii) the Firm Shares and the Option Shares (in each case if the option provided for in Section 2(b) hereof shall have been exercised on or before the second Business Day immediately preceding the Closing Date) shall be made at 10:00 AM, New York City time, on [●], 2021, or at such time on such later date not more than two Business Days after the foregoing date as the Representatives shall designate, which date and time may be postponed by agreement among the Representatives and the Company or as provided in Section 9 hereof (such date and time of delivery and payment for the Offered Securities being called in this Agreement the "Closing Date"). As used herein, "Business Day" shall mean any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions or trust companies are authorized or obligated by law to close in New York City. Delivery of the Offered ADSs shall be made to the U.S. Representatives for the designated accounts of the several U.S. Underwriters against payment by the several U.S. Underwriters through the U.S. Representatives of the ADS Purchase Price to or upon the order of the Company by wire transfer payable in same-day funds to an account specified by the Company. Delivery of the Offered ADSs shall be made through the facilities of The Depository Trust Company unless the U.S. Representatives shall otherwise instruct. Delivery of the Offered Shares shall be made to the EU Representatives for the designated accounts of the several EU Underwriters against payment by the several EU Underwriters through the EU Representatives of the Share Purchase Price to or upon the order of the Company by wire transfer payable in same-day funds to an account specified by the Company. Delivery of the Offered Shares shall be made through the facilities of Euroclear Sweden AB unless the EU Representatives shall otherwise instruct.

If the option provided for in Section 2(b) hereof is exercised with respect to the Option ADSs or Option Shares after the second Business Day immediately preceding the Closing Date, the Company will deliver the Option ADSs or Option Shares (at the expense of the Company), as the case may be, to the Representatives on the date specified by the Representatives (which shall be within two Business Days after exercise of said option) for the designated accounts of the several Underwriters, against payment by the several Underwriters through the Representatives of the ADS Purchase Price or the Share Purchase Price, as the case may be, to or upon the order of the Company by wire transfer payable in same-day funds to an account specified by the Company. If settlement for the Option ADSs or Option Shares occurs after the Closing Date, the Company will deliver to the Representatives on the settlement date for the Option ADSs or Option Shares, as the case may be, and the obligation of the Underwriters to purchase the Option ADSs or Option Shares, as the case may be, shall be conditioned upon receipt of, supplemental opinions, certificates and letters confirming as of such date the opinions, certificates and letters delivered on the Closing Date pursuant to Section 6 hereof.

The ADR certificates, if any, evidencing the Firm ADSs and Option ADSs shall be registered in such names and in such denominations as the Representatives may request not less than one full Business Day prior to the Closing Date or the settlement date for the Option Securities, as the case may be.

4. Offering by Underwriters. It is understood that the several Underwriters propose to offer the Offered Securities for sale to the public as set forth in the Prospectus.

5. Agreements. The Company agrees with the several Underwriters that:

(a) Prior to the termination of the offering of the Offered Securities, the Company will not file any amendment of the Registration Statement or the ADR Registration Statement or supplement to the Prospectus or any Rule 462(b) Registration Statement unless the Company has furnished you a copy for your review prior to filing and will not file any such proposed amendment or supplement to which you reasonably object. The Company will cause the Prospectus, properly completed, and any supplement thereto to be filed in a form approved by the Representatives with the SEC pursuant to the applicable paragraph of Rule 424(b) within the time period prescribed and will provide evidence satisfactory to the Representatives of such timely filing. The Company will promptly advise the Representatives (i) when the Prospectus, and any supplement thereto, shall have been filed (if required) with the SEC pursuant to Rule 424(b) or when any Rule 462(b) Registration Statement or the ADR Registration Statement shall have been filed with the SEC, (ii) when, prior to termination of the offering of the Offered Securities, any amendment to the Registration Statement or the ADR Registration Statement shall have been filed or become effective, (iii) of any request by the SEC or its staff for any amendment of the Registration Statement, the ADR Registration Statement or any Rule 462(b) Registration Statement, or for any supplement to the Prospectus or for any additional information, (iv) of the issuance by the SEC of any stop order suspending the effectiveness of the Registration Statement or the ADR Registration Statement or of any notice objecting to their use or the institution or threatening of any proceeding for that purpose and (v) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Offered Securities for sale in any jurisdiction or the institution or threatening of any proceeding for such purpose. The Company will use its best efforts to prevent the issuance of any such stop order or the occurrence of any such suspension or objection to the use of the Registration Statement or the ADR Registration Statement and, upon such issuance, occurrence or notice of objection, to obtain as soon as possible the withdrawal of such stop order or relief from such occurrence or objection, including, if necessary, by filing an amendment to the Registration Statement or the ADR Registration Statement or a new registration statement and using its best efforts to have such amendment or new registration statement declared effective as soon as practicable.

(b) If, at any time prior to the filing of the Prospectus pursuant to Rule 424(b) , any event occurs as a result of which the Disclosure Package would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Representatives so that any use of the Disclosure Package may cease until it is amended or supplemented; (ii) amend or supplement the Disclosure Package to correct such statement or omission; and (iii) supply any amendment or supplement to you in such quantities as you may reasonably request.

(c) If, at any time when a prospectus relating to the Offered Securities is required to be delivered under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act ("Rule 172")), any event occurs as a result of which the Prospectus as then supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, or if it shall be necessary to amend the Registration Statement or supplement the Prospectus to comply with the Securities Act or the rules thereunder, the Company promptly will (i) notify the Representatives of any such event; (ii) prepare and file with the SEC, subject to the second sentence of paragraph (a) of this Section 5, an amendment or supplement which will correct such statement or omission or effect such compliance; and (iii) supply any supplemented Prospectus to you in such quantities as you may reasonably request.

(d) As soon as practicable, the Company will make generally available to its security holders and to the Representatives an earnings statement or statements of the Company and its subsidiaries which will satisfy the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act.

(e) Upon request, the Company will furnish to the Representatives and counsel for the Underwriters, without charge, signed copies of the Registration Statement and the ADR Registration Statement (including exhibits thereto) and to each other Underwriter a copy of the Registration Statement and the ADR Registration Statement (without exhibits thereto) and, so long as delivery of a prospectus by an Underwriter or dealer may be required (including in circumstances where such requirement may be satisfied pursuant to Rule 172) by the Securities Act, as many copies of each Preliminary Prospectus, the Prospectus and each Issuer Free Writing Prospectus and any supplement thereto as the Representatives may reasonably request. The Company will pay the expenses of printing or other production of all documents relating to the offering.

(f) The Company will arrange, if necessary, for the qualification of the Offered Securities for sale under the laws of such jurisdictions as the Representatives may designate and will maintain such qualifications in effect so long as required for the distribution of the Offered Securities; provided that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action that would subject it to service of process in suits, other than those arising out of the offering or sale of the Offered Securities, in any jurisdiction where it is not now so subject.

(g) The Company will not, without the prior written consent of Citigroup Global Markets, Inc. and Jefferies LLC, offer, sell, contract to sell, pledge, or otherwise dispose of, (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the Company or any affiliate of the Company or any person in privity with the Company or any affiliate of the Company) directly or indirectly, including the filing (or participation in the filing) of a registration statement with the SEC in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Exchange Act, any Common Shares or ADSs or any other securities convertible into, or exercisable, or exchangeable for, Common Shares or ADSs; or publicly announce an intention to effect any such transaction, for a period of 90 days after the date of this Agreement; provided, however, that the Company may: (i) effect the transactions contemplated hereby; (ii) issue and sell Common Shares pursuant to any employee stock option plan, incentive plan, employee stock purchase plan, stock bonus plan, stock option ownership plan, dividend reinvestment plan or warrant program of the Company in effect at the Execution Time or adopted in connection with the offering contemplated by this Agreement and described in the Disclosure Package, and the Company may issue Common Shares issuable upon the conversion of securities or the exercise of warrants outstanding at the Execution Time; (iii) file one or more registration statements on Form S-8 relating to stock options or employee benefit plans of the Company described in the Disclosure Package and Prospectus; (iv) offer, issue and sell Common Shares in connection with any merger, acquisition or strategic investment (including any joint venture, strategic alliance, partnership, the acquisition or license of the business, property, technology or other assets of another individual or entity, or the assumption of an employee benefit plan in connection with such a merger or acquisition); (v) offer, issue and sell Common Shares, on an arm's length basis to, to any unaffiliated collaborators, manufacturers, distributors, or any other similar parties pursuant to a collaboration, licensing agreement, strategic alliance, manufacturing or distribution agreement or similar transaction; or (vi) offer, issue and sell Common Shares, on an arm's length basis to, to unaffiliated financial institutions or lessors pursuant to a commercial agreement, equipment financing transaction or commercial property lease transaction, provided, however, that the aggregate number of Common Shares that the Company may issue or agree to issue pursuant to clauses (iv), (v) and (vi) shall not exceed 5 % of the number of Common Shares outstanding immediately after the issuance and sale of securities, and provided, further, that each recipient of such securities agrees to restrictions on the resale of securities that are consistent with the provisions set forth in the lock-up letter described in Section 6(r) hereof .

(h) If Citigroup Global Markets, Inc. and Jefferies LLC, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up letter described in Section 6(r) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver substantially in the form of Exhibit B-1 at least three Business Days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B-2 hereto through a major news service at least two Business Days before the effective date of the release or waiver.

(i) The Company will use the net proceeds received by it from the sale of the Offered Securities in all material respects in the manner specified in the Disclosure Package under the heading "Use of Proceeds."

(j) The Company will use its reasonable best efforts to maintain the listing for both the ADSs listed by the Company on the Nasdaq Global Select Market and the Common Shares listed by the Company on Nasdaq Stockholm.

(k) The Company will file with the SEC such reports as may be required by Rule 463 under the Securities Act.

(l) The Company will not take, directly or indirectly, without giving effect to activities by the Underwriters, any action designed to or that would constitute or that might reasonably be expected to cause or result in, under the Exchange Act or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Offered Securities.

(m) The Company agrees to pay the costs and expenses relating to the following matters: (i) the preparation, printing or reproduction and filing with the SEC of the Registration Statement (including financial statements and exhibits thereto), each Preliminary Prospectus, the Prospectus, each Issuer Free Writing Prospectus, the ADR Registration Statement, and each amendment or supplement to any of them; (ii) the preparation of the Deposit Agreement, the deposit of the Underlying Shares under the Deposit Agreement, the issuance thereunder of ADSs representing such deposited Underlying Shares, the issuance of ADRs evidencing such ADSs and the fees of the Depositary; (iii) the printing (or reproduction) and delivery (including postage, air freight charges and charges for counting and packaging) of such copies of the Registration Statement, each Preliminary Prospectus, the Prospectus, the ADR Registration Statement, and each Issuer Free Writing Prospectus, and all amendments or supplements to any of them, as may, in each case, be reasonably requested for use in connection with the offering and sale of the Offered Securities; (iv) the preparation, printing, authentication, issuance and delivery of certificates for the Offered Securities, including any stamp or transfer taxes in connection with the issuance and sale of the Offered Securities; (v) the printing (or reproduction) and delivery of this Agreement, any blue sky memorandum and all other agreements or documents printed (or reproduced) and delivered in connection with the offering of the Offered Securities; (vi) the registration of the Offered Securities under the Exchange Act and the listing of the Offered Securities on the Nasdaq Global Select Market; (vii) the listing of each of the Offered Shares and the Underlying Shares on Nasdaq Stockholm; (viii) any registration or qualification of the Offered Securities for offer and sale under the securities or blue sky laws of the several states (including filing fees and the reasonable fees and expenses of counsel for the Underwriters relating to such registration and qualification); (ix) any filings required to be made with FINRA (including filing fees and the reasonable fees and expenses of counsel for the Underwriters relating to such filings, with such fees and expenses of counsel contained in clauses (viii) and (ix) not to exceed $35,000 in the aggregate); (x) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Offered Securities, provided, however, that if the Representatives and the Company mutually agree that an aircraft shall be chartered in connection with any road show, the Company shall be responsible for 50% of the cost and expenses of such chartered aircraft and the Underwriters shall be responsible for the remaining 50% of such costs and expenses; (xi) the fees and expenses of the Company's accountants and the fees and expenses of counsel (including local and special counsel) for the Company; and (xii) all other costs and expenses incident to the performance by the Company of its obligations hereunder.

(n) The Company agrees that, unless it has or shall have obtained the prior written consent of the Representatives, and each Underwriter, severally and not jointly, agrees with the Company that, unless it has or shall have obtained, as the case may be, the prior written consent of the Company, it has not made and will not make any offer relating to the Offered Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus" (as defined in Rule 405) required to be filed by the Company with the SEC or retained by the Company under Rule 433; provided that the prior written consent of the parties hereto shall be deemed to have been given in respect of the Free Writing Prospectuses included in Schedule II hereto and any electronic road show. Any such free writing prospectus consented to by the Representatives or the Company is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company agrees that (x) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus and (y) it has complied and will comply, as the case may be, with the requirements of Rule 164 under the Securities Act ("Rule 164") and Rule 433 applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the SEC, legending and record keeping.

(o) The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) completion of the distribution of the Offered Securities within the meaning of the Securities Act and (b) completion of the 90-day restricted period referred to in Section 5(g) hereof.

(p) If at any time following the distribution of any Written Testing-the-Waters Communication, any event occurs as a result of which such Written Testing-the-Waters Communication would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein in the light of the circumstances under which they were made or the circumstances then prevailing not misleading, the Company will (i) notify promptly the Representatives so that use of the Written Testing-the-Waters Communication may cease until it is amended or supplemented; (ii) amend or supplement the Written Testing-the-Waters Communication to correct such statement or omission; and (iii) supply any amendment or supplement to the Representatives in such quantities as may be reasonably requested.

(q) The Company agrees, at or prior to the Closing Date, to facilitate the issue of the Underlying Shares to the Custodian in accordance with the provisions of the Deposit Agreement and otherwise to comply with the Deposit Agreement so that the Offered ADSs will be issued by the Depositary against receipt of such Underlying Shares and delivered to the Underwriters on the Closing Date.

(r) The Company will make the appropriate filings with the Swedish Companies Registration Office in relation to allotment of each of the Offered Shares and the Underlying Shares.

6. Conditions to the Obligations of the Underwriters. The obligations of the Underwriters to subscribe for the Firm Securities and the Option Securities, as the case may be, shall be subject to the accuracy of the representations and warranties on the part of the Company contained in this Agreement as of the Execution Time, the Closing Date and any settlement date pursuant to Section 3 hereof, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations under this Agreement and to the following additional conditions:

(a) The Prospectus, and any supplement thereto, have been filed in the manner and within the time period required by Rule 424(b); any material required to be filed by the Company pursuant to Rule 433(d) shall have been filed with the SEC within the applicable time periods prescribed for such filings by Rule 433; and no stop order suspending the effectiveness of the Registration Statement or the ADR Registration Statement or any notice objecting to their use shall have been issued and no proceedings for that purpose shall have been instituted or threatened.

(b) The Company shall have requested and caused Goodwin Procter LLP, U.S. counsel for the Company, to have furnished to the Representatives their opinion and negative assurance letter, dated the Closing Date and addressed to the Representatives, in form and substance as previously agreed to with the Representatives.

(c) The Company shall have requested and caused Advokatfirman Vinge KB, Swedish counsel for the Company, to have furnished to the Representatives their opinion, dated the Closing Date and addressed to the Representatives, in form and substance as previously agreed to with the Representatives.

(d) The Company shall have requested and caused each of Potter Clarkson LLP and Panitch Schwarze Belisario & Nadel, LLP, special counsel for the Company with respect to certain intellectual property matters, to have furnished to the Representatives their opinions, in form and substance as previously agreed to with the Representatives.

(e) The Depositary shall have requested and caused Patterson Belknap Webb & Tyler LLP, counsel for the Depositary, to have furnished to the Representatives their opinion dated the Closing Date and addressed to the Representatives, in form and substance as previously agreed to with the Representatives.

(f) The Representatives shall have received from Cooley LLP, U.S. counsel for the Underwriters, their opinion, dated the Closing Date and addressed to the Representatives, in form and substance as the Representatives may reasonably require, and the Company shall have furnished to such counsel such documents as they request for the purpose of enabling them to pass upon such matters.

(g) The Representatives shall have received from Baker & McKenzie Advokatbyrå KB, Swedish counsel for the Underwriters, such opinions, dated the Closing Date and addressed to the Representatives, in form and substance as the Representatives may reasonably require, and the Company shall have furnished to such counsel such documents as they request for the purpose of enabling them to pass upon such matters.

(h) The Company shall have furnished to the Representatives a certificate of the Company, signed by the Chief Executive Officer and the principal financial or accounting officer of the Company, dated the Closing Date, to the effect that the signers of such certificate have carefully examined the Registration Statement, the ADR Registration Statement, the Disclosure Package, the Prospectus and any amendment or supplement thereto, as well as each electronic road show used in connection with the offering of the Offered Securities, and this Agreement and that:

(i) the representations and warranties of the Company in this Agreement are true and correct on and as of the Closing Date with the same effect as if made on the Closing Date and the Company has complied with all the agreements and satisfied all the conditions on its part to be performed or satisfied at or prior to the Closing Date;

(ii) no stop order suspending the effectiveness of the Registration Statement or the ADR Registration Statement, or any notice objecting to their use, has been issued and no proceedings for that purpose have been instituted or, to the Company's knowledge, threatened; and

(iii) since the date of the most recent financial statements included in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto), there has been no material adverse change in the condition (financial or otherwise), prospects, earnings, business or properties of the Company and its subsidiaries, taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(i) The Company shall have requested and caused Ernst & Young AB to have furnished to the Representatives, at the Execution Time and at the Closing Date, letters, dated respectively as of the Execution Time and as of the Closing Date, in form and substance satisfactory to the Representatives, confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the applicable rules and regulations adopted by the SEC thereunder and by the Public Company Accounting Oversight Board and under applicable Swedish law, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Disclosure Package and the Prospectus (including, for the avoidance of doubt, as to compliance with Article 11 of Regulation S-X). The Company shall have requested and caused KPMG S.A. to have furnished to the Representatives, at the Execution Time and at the Closing Date, letters, dated respectively as of the Execution Time and as of the Closing Date, in form and substance satisfactory to the Representatives, confirming that they are independent certified public accountants with respect to Genkyotex S.A. under Rule 101 of the AICPA Code of Professional Conduct, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Disclosure Package and the Prospectus.

(j) Subsequent to the Execution Time or, if earlier, the dates as of which information is given in the Registration Statement (exclusive of any amendment or supplement thereto) and the Prospectus (exclusive of any amendment or supplement thereto), there shall not have been (i) any change or decrease specified in the letter or letters referred to in paragraph (i) of this Section 6 or (ii) any change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), earnings, business or properties of the Company and its subsidiaries taken as a whole, whether or not arising from transactions in the ordinary course of business, except as set forth in or contemplated in the Disclosure Package and the Prospectus the effect of which, in any case referred to in clause (i) or (ii) above, is, in the sole judgment of the Representatives, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Offered Securities as contemplated by the Registration Statement (exclusive of any amendment or supplement thereto), the Disclosure Package and the Prospectus (exclusive of any amendment or supplement thereto).

(k) The Deposit Agreement is and remains in full force and effect; the Company and the Depositary shall have taken all action necessary to permit the deposit of the Underlying Shares and the issuance of the Offered ADSs in accordance with the Deposit Agreement.

(l) The Depositary shall have furnished or caused to be furnished to the Representatives a certificate of one of its authorized officers, satisfactory to the Representatives, evidencing the deposit with the Custodian of the Underlying Shares against the issuance of the Offered ADSs to be delivered by the Company on the Closing Date, the execution, issuance, countersignature (if applicable) and delivery of the Offered ADSs pursuant to the Deposit Agreement and such other matters related thereto as the Representatives reasonably request.

(m) At or prior to the Closing Date, the Company shall have furnished to the Representatives such further information, certificates and documents as the Representatives may reasonably request.

(n) The Offered ADSs shall have been listed and admitted and authorized for trading on the Nasdaq Global Select Market, and satisfactory evidence of such actions shall have been provided to the Representatives.

(o) Each of the Offered Shares and the Underlying Shares have been registered by the Swedish Companies Registration Office.

(p) Each of the Offered Shares and the Underlying Shares shall have been listed and admitted and authorized for trading on Nasdaq Stockholm, and satisfactory evidence of such actions shall have been provided to the Representatives.

(q) At or before the Execution Time, the Company shall have furnished to the Representatives a lock-up letter substantially in the form of Exhibit A hereto from each officer and director of the Company listed on Annex A, addressed to the Representatives.

(r) At the Execution Time and as of each Closing Date, the Representatives shall have received from the principal financial officer of the Company a certificate, in form and substance satisfactory to the Representatives.

If any of the conditions specified in this Section 6 shall not have been fulfilled when and as provided in this Agreement, or if any of the opinions and certificates mentioned above or elsewhere in this Agreement shall not be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters, this Agreement and all obligations of the Underwriters hereunder may be canceled at, or at any time prior to, the Closing Date by the Representatives. Notice of such cancellation shall be given to the Company in writing or by telephone or facsimile confirmed in writing.

The documents required to be delivered by this Section 6 shall be delivered at the office of Cooley LLP, counsel for the Underwriters, at 55 Hudson Yards, New York, New York 10001, on the Closing Date.

7. Reimbursement of Underwriters' Expenses. If the sale of the Offered Securities provided for in this Agreement is not consummated because any condition to the obligations of the Underwriters set forth in Section 6 hereof is not satisfied, because of any termination pursuant to Section 10 hereof or because of any refusal, inability or failure on the part of the Company to perform any agreement herein or comply with any provision hereof other than by reason of a default by any of the Underwriters, the Company will reimburse the Underwriters severally through Citigroup Global Markets Inc. on demand for all documented expenses (including reasonable fees and disbursements of counsel) that shall have been reasonably incurred by them in connection with the proposed purchase and sale of the Offered Securities.

8. Indemnification and Contribution.

(a) The Company agrees to indemnify and hold harmless each Underwriter, the directors, officers, employees, affiliates and agents of each Underwriter and each person who controls any Underwriter within the meaning of either the Securities Act or the Exchange Act against any and all losses, claims, damages or liabilities, joint or several, to which they or any of them may become subject under the Securities Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement for the registration of the Offered Securities as originally filed or in any amendment thereof, or in the ADR Registration Statement as originally filed or in any amendment thereof, or in any Preliminary Prospectus, or in the Prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication or in any amendment thereof or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and agrees to reimburse each such indemnified party, as incurred, for any legal or other expenses reasonably incurred by them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon any such untrue statement or alleged untrue statement or omission or alleged omission made therein in reliance upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representatives specifically for inclusion therein. This indemnity agreement will be in addition to any liability which the Company may otherwise have.

(b) Each Underwriter severally and not jointly agrees to indemnify and hold harmless the Company, each of its directors, each of its officers who signs the Registration Statement or the ADR Registration Statement, and each person who controls the Company within the meaning of either the Securities Act or the Exchange Act, to the same extent as the foregoing indemnity from the Company to each Underwriter, but only with reference to written information relating to such Underwriter furnished to the Company by or on behalf of such Underwriter through the Representatives specifically for inclusion in the documents referred to in the foregoing indemnity. This indemnity agreement will be in addition to any liability which any Underwriter may otherwise have. The Company acknowledges that the only information furnished in writing by or on behalf of the several Underwriters for inclusion in the Preliminary Prospectus, the Prospectus or any Issuer Free Writing Prospectus consists of the following statements set forth in the Preliminary Prospectus and the Prospectus: [the third sentence of the fifth paragraph, the second and third sentences of the sixth paragraph, the first sentence of the thirteenth paragraph, the third and fourth sentences of the fourteenth paragraph and the sixteenth paragraph] under the heading "Underwriting."

(c) Promptly after receipt by an indemnified party under this Section 8 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against the indemnifying party under this Section 8, notify the indemnifying party in writing of the commencement thereof; but the failure so to notify the indemnifying party (i) will not relieve it from liability under paragraph (a) or (b) above unless and to the extent it did not otherwise learn of such action and such failure results in the forfeiture by the indemnifying party of substantial rights and defenses and (ii) will not, in any event, relieve the indemnifying party from any obligations to any indemnified party other than the indemnification obligation provided in paragraph (a) or (b) above. The indemnifying party shall be entitled to appoint counsel of the indemnifying party's choice at the indemnifying party's expense to represent the indemnified party in any action for which indemnification is sought (in which case the indemnifying party shall not thereafter be responsible for the fees and expenses of any separate counsel retained by the indemnified party or parties except as set forth below); provided, however, that such counsel shall be reasonably satisfactory to the indemnified party. Notwithstanding the indemnifying party's election to appoint counsel to represent the indemnified party in an action, the indemnified party shall have the right to employ separate counsel (including local counsel), and the indemnifying party shall bear the reasonable fees, costs and expenses of such separate counsel if (i) the use of counsel chosen by the indemnifying party to represent the indemnified party would present such counsel with a conflict of interest, (ii) the actual or potential defendants in, or targets of, any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, (iii) the indemnifying party shall not have employed counsel reasonably satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of the institution of such action or (iv) the indemnifying party shall authorize the indemnified party to employ separate counsel at the expense of the indemnifying party. An indemnifying party will not, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any indemnified party.

(d) In the event that the indemnity provided in paragraph (a), (b) or (c) of this Section 8 is unavailable to or insufficient to hold harmless an indemnified party for any reason, the Company and the Underwriters severally agree to contribute to the aggregate losses, claims, damages and liabilities (including legal or other expenses reasonably incurred in connection with investigating or defending the same) (collectively, "Losses") to which the Company and one or more of the Underwriters may be subject in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and by the Underwriters on the other from the offering of the Offered Securities. If the allocation provided by the immediately preceding sentence is unavailable for any reason, the Company and the Underwriters severally shall contribute in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and of the Underwriters on the other in connection with the statements or omissions which resulted in such Losses as well as any other relevant equitable considerations. Benefits received by the Company shall be deemed to be equal to the total net proceeds from the offering (before deducting expenses) received by it, and benefits received by the Underwriters shall be deemed to be equal to the total underwriting discounts and commissions, in each case as set forth on the cover page of the Prospectus. Relative fault shall be determined by reference to, among other things, whether any untrue or any alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information provided by the Company on the one hand or the Underwriters on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contribution were determined by pro rata allocation or any other method of allocation which does not take account of the equitable considerations referred to above. Notwithstanding the provisions of this paragraph (d), in no event shall any Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Offered Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this paragraph (d), no person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 8, each person who controls an Underwriter within the meaning of either the Securities Act or the Exchange Act and each director, officer, employee, affiliate and agent of an Underwriter shall have the same rights to contribution as such Underwriter, and each person who controls the Company within the meaning of either the Securities Act or the Exchange Act, each officer of the Company who shall have signed the Registration Statement and the ADR Registration Statement and each director of the Company shall have the same rights to contribution as the Company, subject in each case to the applicable terms and conditions of this paragraph (d).

9. Default by an Underwriter. If any one or more Underwriters shall fail to purchase and pay for any of the Offered Securities agreed to be purchased by such Underwriter or Underwriters under this Agreement and such failure to purchase shall constitute a default in the performance of its or their obligations under this Agreement, the remaining Underwriters shall be obligated severally to take up and pay for (in the respective proportions which the amount of Offered Securities set forth opposite their names in Schedule I hereto bears to the aggregate amount of Firm Securities set forth opposite the names of all the remaining Underwriters) the Offered Securities which the defaulting Underwriter or Underwriters agreed but failed to purchase; provided, however, that in the event that the aggregate amount of Offered Securities which the defaulting Underwriter or Underwriters agreed but failed to purchase shall exceed 10% of the aggregate amount of Firm Securities set forth in Schedule I hereto, the remaining Underwriters shall have the right to purchase all, but shall not be under any obligation to purchase any, of the Offered Securities, and if such nondefaulting Underwriters do not purchase all the Offered Securities, this Agreement will terminate without liability to any nondefaulting Underwriter or the Company. In the event of a default by any Underwriter as set forth in this Section 9, the Closing Date shall be postponed for such period, not exceeding five Business Days, as the Representatives shall determine in order that the required changes in the Registration Statement, the ADR Registration Statement and the Prospectus or in any other documents or arrangements may be effected. Nothing contained in this Agreement shall relieve any defaulting Underwriter of its liability, if any, to the Company and any nondefaulting Underwriter for damages occasioned by its default under this Agreement.

10. Termination. This Agreement shall be subject to termination in the absolute discretion of the Representatives, by notice given to the Company prior to delivery of and payment for the Offered Securities, if at any time prior to such delivery and payment (i) trading in the Company's Common Shares or ADSs shall have been suspended by the SEC, Nasdaq Stockholm or the Nasdaq Global Select Market or trading in securities generally on the New York Stock Exchange, the Nasdaq Stock Market or Nasdaq Stockholm shall have been suspended or limited or minimum prices shall have been established on any of such exchanges, (ii) a banking moratorium shall have been declared by U.S. Federal, New York State authorities or authorities in the Kingdom of Sweden, the United Kingdom or the European Union, (iii) there shall have occurred a material disruption in commercial banking or securities settlement or clearance services or (iv) there shall have occurred any outbreak or escalation of hostilities, declaration by the United States or the Kingdom of Sweden of a national emergency or war, or other calamity or crisis the effect of which on financial markets is such as to make it, in the sole judgment of the Representatives, impractical or inadvisable to proceed with the offering or delivery of the Offered Securities as contemplated by the Preliminary Prospectus and the Prospectus (exclusive of any amendment or supplement thereto).

11. Representations and Indemnities to Survive. The respective agreements, representations, warranties, indemnities and other statements of the Company or its officers or directors and of the Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of the officers, directors, employees, agents, affiliates or controlling persons referred to in Section 8 hereof, and will survive delivery of and payment for the Offered Securities. The provisions of Sections 7 and 8 hereof shall survive the termination or cancellation of this Agreement.

12. Notices. All communications hereunder will be in writing and effective only on receipt, and, if sent to the Representatives, will be mailed, delivered or telefaxed to (i) Citigroup Global Markets Inc., at 388 Greenwich Street, New York, New York 10013, Attention: General Counsel, facsimile number: +1 (646) 291-1469; (ii) Citigroup Global Markets Limited, at Citigroup Centre, Canada Square, Canary Wharf, London E14 5LB, United Kingdom, Attention: General Counsel; and (iii) Jefferies LLC, Jefferies International Limited and Jefferies GmbH, at 520 Madison Avenue, New York, New York 10022, Attention: General Counsel, facsimile number: +1 646 619 4437 with a copy (which shall not constitute notice) to Cooley LLP, 55 Hudson Yards, New York, New York 10001, Attention: Joshua A. Kaufman and Divakar Gupta; or, if sent to the Company, will be mailed, delivered or telefaxed to Calliditas Therapeutics AB at Kungsbron 1, C8, SE-111 22 Stockholm, Sweden, 46-0-8-611-3303., Attention: Chief Financial Officer, with a copy (which shall not constitute notice) to Goodwin Procter LLP, 620 Eighth Avenue, New York, New York 10018, Attention: Kristopher Brown and James Xu.

13. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers, directors, employees, agents and controlling persons referred to in Section 8 hereof, and no other person will have any right or obligation hereunder.

14. Jurisdiction. The Company agrees that any suit, action or proceeding against the Company brought by any Underwriter, the directors, officers, employees, affiliates and agents of any Underwriter, or by any person who controls any Underwriter, arising out of or based upon this Agreement or the transactions contemplated hereby may be instituted in any State or U.S. federal court in The City of New York and County of New York, and waives any objection which it may now or hereafter have to the laying of venue of any such proceeding, and irrevocably submits to the non-exclusive jurisdiction of such courts in any suit, action or proceeding. The Company has appointed Calliditas Therapeutics Inc. as its authorized agent (the "Authorized Agent") upon whom process may be served in any suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated herein that may be instituted in any State or U.S. federal court in The City of New York and County of New York, by any Underwriter, the directors, officers, employees, affiliates and agents of any Underwriter, or by any person who controls any Underwriter, and expressly accepts the non-exclusive jurisdiction of any such court in respect of any such suit, action or proceeding. The Company hereby represents and warrants that the Authorized Agent has accepted such appointment and has agreed to act as said agent for service of process, and the Company agrees to take any and all action, including the filing of any and all documents that may be necessary to continue such appointment in full force and effect as aforesaid. Service of process upon the Authorized Agent shall be deemed, in every respect, effective service of process upon the Company. Notwithstanding the foregoing, any action arising out of or based upon this Agreement may be instituted by any Underwriter, the directors, officers, employees and agents of any Underwriter, or by any person who controls any Underwriter, in any court of competent jurisdiction in the Kingdom of Sweden.

15. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 15, "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k); "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b), (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b) or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b); "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable; and "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

16. No Fiduciary Duty. The Company hereby acknowledges that (a) the purchase and sale of the Offered Securities pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriters and any affiliate through which it may be acting, on the other, (b) the Underwriters are acting as principal and not as an agent or fiduciary of the Company and (c) the Company's engagement of the Underwriters in connection with the offering and the process leading up to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether any of the Underwriters has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Underwriters have rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

17. Integration. This Agreement supersedes all prior agreements and understandings (whether written or oral) between the Company and the Underwriters, or any of them, with respect to the subject matter hereof.

18. Applicable Law. This Agreement will be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and to be performed within the State of New York.

19. Currency. Each reference in this Agreement to U.S. Dollars (the "relevant currency") is of the essence. To the fullest extent permitted by law, the obligations of each of the Company in respect of any amount due under this Agreement will, notwithstanding any payment in any other currency (whether pursuant to a judgment or otherwise), be discharged only to the extent of the amount in the relevant currency that the party entitled to receive such payment may, in accordance with its normal procedures, purchase with the sum paid in such other currency (after any premium and costs of exchange) on the Business Day immediately following the day on which such party receives such payment. If the amount in the relevant currency that may be so purchased for any reason falls short of the amount originally due, the Company making such payment will pay such additional amounts, in the relevant currency, as may be necessary to compensate for the shortfall. Any obligation of any of the Company not discharged by such payment will, to the fullest extent permitted by applicable law, be due as a separate and independent obligation and, until discharged as provided herein, will continue in full force and effect.

20. EEA Product Governance. Solely for the purposes of Article 9(8) of the Commission Delegated Directive 2017/593 (the "Delegated Directive") regarding the responsibilities of "manufacturers" under the Product Governance requirements contained within: (a) Directive 2014/65/EU on markets in financial instruments, as amended ("MIFID II"); (b) Articles 9 and 10 of the Delegated Directive; and (c) local implementing measures (the "EU MIFID II Product Governance Requirements"), each Underwriter, to whom such rules apply, acknowledges to each other Underwriter that it understands the responsibilities conferred upon it under the EU MIFID II Product Governance Requirements relating to: (i) the target market for the Private Placement; (ii) the eligible distribution channels for dissemination of the Offered Shares; and (iii) the requirement to carry out a product approval process.

21. UK Product Governance. Solely for the purposes of PROD 3.2.7 of the FCA Handbook Product Intervention and Product Governance Sourcebook ("PROD") regarding the responsibilities of "manufacturers" under the Product Governance requirements contained within PROD (the "UK MiFIR Product Governance Rules"), each Underwriter, to whom such rules apply, acknowledges to each other Underwriter that it understands the responsibilities conferred upon it under the UK MiFIR Product Governance Rules relating to: (i) the target market for the Private Placement; (ii) the eligible distribution channels for dissemination of the Offered Shares; and (iii) the requirement to carry out a product approval process.

22. Taxes. All payments to be made by the Company to the Underwriters under this Agreement shall be made gross, without withholding or deduction for or on account of any present or future Swedish taxes, duties or governmental shares whatsoever unless the Company is compelled by law to deduct or withhold such taxes, duties or charges. In that event, except for any net income, capital gains, dividends or franchise taxes imposed on the Underwriters by the Kingdom of Sweden or the United States or the United Kingdom or any political subdivision or any taxing authority thereof or therein as a result of any present or former connection (other than any connection resulting from the transactions contemplated by this Agreement) between the Underwriters and the jurisdiction imposing such withholding or deductions, the Company shall pay such additional amounts as may be necessary in order to ensure that the net amounts received after such withholding or deductions shall equal the amounts that would have been received if no withholding or deduction has been made.

23. Waiver of Immunity. To the extent that the Company has or hereafter may acquire any immunity (sovereign or otherwise) from any legal action, suit or proceeding, from jurisdiction of any court or from set-off or any legal process (whether service or notice, attachment in aid or otherwise) with respect to itself or any of its property, the Company hereby irrevocably waives and agrees not to plead or claim such immunity in respect of its obligations under this Agreement

24. Waiver of Jury Trial. The Company hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

25. Counterparts. This Agreement may be signed in one or more counterparts, each of which shall constitute an original and all of which together shall constitute one and the same agreement. This Agreement may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, including www.docusign.com or www.echosign.com) or other transmission method of any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

26. Headings. The section headings used herein are for convenience only and shall not affect the construction hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to us the enclosed duplicate hereof, whereupon this letter and your acceptance shall represent a binding agreement among the Company and the several Underwriters.

Very truly yours,

CALLIDITAS THERAPEUTICS AB

By: _____
Name:
Title:

[*Signature Page to Underwriting Agreement*]

The foregoing Agreement is hereby
confirmed and accepted as of the date
first above written.
Citigroup Global Markets Inc.
Jefferies LLC
Citigroup Global Markets Limited
Jefferies International Limited
Jefferies GmbH

By: CITIGROUP GLOBAL MARKETS INC.

By: _____
Name:
Title:

By: JEFFERIES LLC

By: _____
Name:
Title:

By: CITIGROUP GLOBAL MARKETS LIMITED

By: _____
Name:
Title:

By: JEFFERIES INTERNATIONAL LIMITED

By: _____
Name:
Title:

By: JEFFERIES GMBH

By: _____
Name:
Title:

By: _____
Name:
Title:

For themselves and the other several
Underwriters named in Schedule I to
the foregoing Agreement.

SCHEDULE I

Underwriters	Number of Firm ADSs to be Purchased
Citigroup Global Markets Inc.	[●]
Jefferies LLC	[●]
Stifel, Nicolaus & Company, Incorporated	[●]
Kempen & Co U.S.A., Inc.	[●]
LifeSci Capital, LLC	[●]
Total	[●]

Underwriters	Number of Firm Shares to be Purchased
Citigroup Global Markets Limited	[●]
Jefferies International Limited/Jefferies GmbH[(1)]	[●]
Stifel, Nicolaus & Company, Incorporated	[●]
Kempen & Co U.S.A., Inc.	[●]
LifeSci Capital, LLC	[●]
Carnegie Investment Bank AB (publ)	[●]
Total	[●]

(1) The division of services between Jefferies International Limited and Jefferies GmbH shall be determined at Jefferies' absolute discretion, whereby regulated services with respect to EU 27 countries and EU 27 investors shall be undertaken by Jefferies GmbH only.

SCHEDULE II

Schedule of Free Writing Prospectuses included in the Disclosure Package

[None]

SCHEDULE III

Schedule of Written Testing-the-Waters Communications

[Testing-the-Waters Presentation dated January 2020]

[Form of Lock Up Agreement] **EXHIBIT A**

Lock-Up Agreement

Calliditas Therapeutics AB
Public Offering of Securities

_____, 2021

Citigroup Global Markets Inc.
Jefferies LLC
As Representatives of the several Underwriters,

c/o Citigroup Global Markets Inc.
388 Greenwich Street
New York, New York 10013

c/o Jefferies LLC
520 Madison Avenue
New York, New York 10022

Ladies and Gentlemen:

This letter agreement (this "Agreement") is being delivered to you in connection with the proposed Underwriting Agreement (the "Underwriting Agreement"), between Calliditas Therapeutics AB, a Swedish public limited liability company (the "Company"), and each of you as representatives (the "Representatives") of a group of underwriters named therein (the "Underwriters"), relating to an underwritten public offering of ordinary shares (the "Offering"), quotient value SEK 0.04 per share (the "Ordinary Shares"), and/or American Depository Shares representing a certain number of Ordinary Shares to be determined (the "ADSs" and, together with the Ordinary Shares, the "Securities"), of the Company (the "Offering").

In order to induce you and the other Underwriters to enter into the Underwriting Agreement, the undersigned will not, without the prior written consent of the Representatives, offer, sell, contract to sell, pledge or otherwise dispose of, (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise) by the undersigned or any affiliate of the undersigned or any person in privity with the undersigned or any affiliate of the undersigned), directly or indirectly, including the filing (or participation in the filing) of a registration statement with the Securities and Exchange Commission in respect of, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations of the Securities and Exchange Commission promulgated thereunder with respect to, any Securities or any other securities convertible into, or exercisable or exchangeable for Securities, or publicly announce an intention to effect any such transaction, for a period from the date hereof until 90 days after the date of the Underwriting Agreement (the "Lock-Up Period"). If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing restrictions shall be equally applicable to any issuer-directed Securities the undersigned may purchase in the Offering.

The foregoing restrictions shall not apply to:

(i) sales of Securities by the undersigned to the underwriters pursuant to the Underwriting Agreement;

(ii) transactions relating to Securities or any other security acquired in the Offering (other than any issuer-directed Securities purchased in the Offering by an officer or director of the Company) or in open market transactions after the completion of the Offering;

(iii) transfers of shares of Securities or any security convertible into Securities as a bona fide gift or charitable contribution;

(iv) exercises of share options or warrants to purchase Securities or the vesting of awards of Securities and any related transfer of Securities to the Company in connection therewith (x) deemed to occur upon the "cashless" or "net" exercise of such options or warrants or (y) for the purpose of paying the exercise price, or debt obtained to pay the exercise price, of such options or warrants or for paying taxes due as a result of the exercise of such options or warrants, the vesting of such options, warrants or awards, or as a result of the vesting of such shares of Securities, it being understood that all shares of Securities received upon such exercise, vesting or transfer will remain subject to the restrictions of this agreement during the Lock-Up Period;

(v) transfers of Securities or any security convertible into or exercisable or exchangeable for Securities to the Company in connection with the termination of the undersigned's employment with the Company or pursuant to contractual arrangements under which the Company has the option to repurchase such shares;

(vi) transfers to the spouse, domestic partner, parent, child or grandchild or first cousin of the undersigned (each, an "Immediate Family Member") or to a trust formed for the direct or indirect benefit of the undersigned or an Immediate Family Member;

(vii) transfers by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary, trustee or Immediate Family Member of the undersigned;

(viii) transfers pursuant to a divorce settlement agreement or decree or a qualified domestic relations order;

(ix) transfers of Securities or any security convertible into or exchangeable for Securities to any affiliate (as such term is defined in Rule 405 of the Securities Act of 1933, as amended), limited partners, general partners, limited liability company members or stockholders of the undersigned, or if the undersigned is a corporation to any wholly owned subsidiary of such corporation;

(x) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Securities or any security convertible into or exchangeable for Securities, *provided* that such plan does not provide for the transfer of shares of Securities during the Lock- Up Period and no filing under the Exchange Act or other public announcement shall be required or voluntarily made during the Lock-Up Period;

(xi) transfers of Securities to a bona fide third party pursuant to a merger, consolidation, tender offer or other similar transaction made to all holders of Securities and involving a "Change of Control" of the Company after the Public Offering and approved by the Company's Board of Directors (with "Change of Control" meaning the transfer of the Company's voting securities in one transaction or a series of related transactions to any "person" (as defined in Section 13(d)(3) of the Exchange Act) or group of affiliated persons if, after such transfer, such person or group of affiliated persons would hold more than 75% of the outstanding voting securities of the Company (or the surviving entity)), *provided* that in the event that such transaction is not completed, the Securities held by the undersigned shall remain subject to the restrictions contained in this Agreement, and *provided further* that in the event any Securities not transferred in the Change of Control shall remain subject to the restrictions contained in this Agreement; or

(xii) transfers of Securities to a capital insurance (Sw. *kapitalförsäkring*) or to an Investment Savings Account (Sw. *investeringssparkonton*), *provided* that no transactions in any such Securities shall be permitted during the Lock-Up Period;

provided, that, in the case of clauses (ii), (iv), (v) and (xii), (a) no filing under the Exchange Act or other public announcement reporting a reduction in beneficial ownership of Securities shall be required or voluntarily made during the Lock-Up Period, other than a filing required by Schedule 13F; *provided further*, that, in the case of any transfer or distribution pursuant to clauses (iii), (vi), (vii), (viii) and (ix), (a) the recipient agrees to be bound in writing by the same restrictions set forth herein for the duration of the Lock-Up Period and (b) no filing under the Exchange Act reporting a reduction in beneficial ownership of Securities shall be required or voluntarily made during the Lock-Up Period, other than a filing required by Schedule 13F, which shall state the nature of such transfer or distribution and (c) any such transfer shall not involve a disposition for value.

This lock-up agreement shall automatically terminate, and the undersigned shall be released from its obligations hereunder, upon the earliest to occur, if any, of (1) the execution of the Underwriting Agreement in connection with the Offering shall not have occurred on or before March 31, 2021 (provided that the Company may by written notice to the undersigned prior to March 31, 2021 extend such date for a period of up to three additional months), (2) the Company files an application to withdraw the registration statement relating to the Offering, (3) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Securities to be sold thereunder or (4) the Representatives, on behalf of the underwriters, advise the Company, or the Company advises the Representatives, in writing, prior to the execution of the Underwriting Agreement, that they have determined not to proceed with the Offering.

If the undersigned is an officer or director of the Company, (i) the Representatives agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of Securities, the Representatives will notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this letter to the extent and for the duration that such terms remain in effect at the time of the transfer.

This lock-up agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

Yours very truly,

By: _____
Name:
Title:

EXHIBIT B-1

[Form of Waiver of Lock-up]

Calliditas Therapeutics AB
Public Offering of Securities

, 2021

[*name and address of officer or director requesting waiver***]**

Dear Mr./Ms. **[**Name**]**:

This letter is being delivered to you in connection with the offering by Calliditas Therapeutics AB (the "Company") of (i) common shares, quota value SEK 0.04 per share (the "Common Shares"), and (ii) Common Shares to be delivered in the form of American Depositary Shares ("ADSs"), of the Company, and the lock-up letter dated _____, 2021 (the "Lock-up Letter"), executed by you in connection with such offering, and your request for a [waiver] [release] dated **[***insert date***]**, 2021, with respect to [__ Common Shares (the "Lock-Up Shares")] [__ ADSs (the "Lock-Up ADSs")].

Citigroup Global Markets Inc. and Jefferies LLC hereby agree to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the [Lock-Up Shares][Lock-Up ADSs], effective _____, 2021; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Yours very truly,

Citigroup Global Markets Inc.

By: _____
Name:
Title:

Jefferies LLC

By: _____
Name:
Title:

cc: Calliditas Therapeutics AB

EXHIBIT B-2

[Form of Press Release]

Calliditas Therapeutics AB
[Date**]**

Calliditas Therapeutics AB (the "Company") announced today that Citigroup Global Markets Inc. and Jefferies LLC, the joint book-running managers in the Company's recent public sale of [●] common shares ("Common Shares"), including [●] common shares to be delivered in the form of [●] American Depositary Shares ("ADSs"), are [waiving] [releasing] a lock-up restriction with respect to _____ [Common Shares][ADSs] of the Company held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on _____, 2021, and the [Common Shares][ADSs] may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

ANNEX A

Lock-up Securityholders

Executive Officers:

- Renée Aguiar-Lucander
- Fredrik Johansson
- Richard Philipson, M.D.
- Andrew Udell
- Frank Bringstrup, M.D.
- Katayoum Welin-Berger, Ph.D.

Directors:

- Elmar Schnee
- Hilde Furberg
- Lennart Hansson, Ph.D.
- Diane Parks
- Molly Henderson

SHARE PURCHASE AGREEMENT

BIODISCOVERY 2

BIODISCOVERY 3

ECLOSION2 & CIE SCPC

VESALIUS BIOCAPITAL II SA, SICAR

NEOMED INNOVATION V L.P.

N5 INVESTMENTS AS

WELLINGTON PARTNERS NOMINEE LTD

MR. ELIAS PAPATHEODOROU

MR. PHILIPPE WIESEL

MR. ALEXANDRE GRASSIN

as Sellers

and

CALLIDITAS THERAPEUTICS AB (PUBL)

as Buyer

13 August 2020

TABLE OF CONTENTS

THIS AGREEMENT is made on 13 August 2020

AMONG

(1) **BioDiscovery 2**, a *Fonds Professionnel de Capital Investissement* organized under the laws of France, represented by Andera Partners, a *Société en commandite par actions* whose registered office is at whose registered office is at 374 rue Saint Honoré, 75001 Paris, registered with the Trade and Companies Register of Paris under number 444 071 989;

(2) **BioDiscovery 3**, a *Fonds Professionnel de Capital Investissement* organized under the laws of France, represented by Andera Partners, a *Société en commandite par actions* whose registered office is at whose registered office is at 374 rue Saint Honoré, 75001 Paris, registered with the Trade and Companies Register of Paris under number 444 071 989;

(3) **Eclosion2 & Cie SCPC**, a partnership for collective investments (*société en commandite de placements collectifs*) organized under the laws of Switzerland, whose registered office is at rue du Nant 8, c/o Duchosal Berney SA, 1207 Geneva, Switzerland and registered under number CHE-116.231.008, represented by Eclosion2 SA, whose registered office is at rue du Nant 8, c/o Duchosal Berney SA, 1207 Geneva, Switzerland and registered under number CHE-116.043.501;

(4) **Vesalius Biocapital II SA, SICAR**, a *Société anonyme Société d'investissement en capital à risque* organized under the laws of Luxemburg, whose registered office is at 8, rue Lou Hemmer, L-1748 Senningerberg, Luxembourg, registered with the Trade and Companies Register of Luxemburg under number B-158, represented by SGV MANAGEMENT SERVICES BVBA, a *société de personnes à responsabilité limitée* organized under the laws of Belgium, whose registered office is at 1B, Liskenstraat, B-3080 Tervuren, Belgium, registered with the Banque-Carrefour des Entreprises under number BE 0472.774.139, represented by Stephane Verdood and ORRIX MANAGEMENT BVBA, a *société de personnes à responsabilité limitée* organized under the laws of Belgium, whose registered office is at 27, Hoevestraat, B-1640 Sint-Genesius-Rode, Belgium, registered with the Banque-Carrefour des Entreprises under number BE 0476 019 184;

(5) **Neomed Innovation V L.P.**, a Limited Partnership organized under the laws of Jersey, whose registered office is at IFC 5 ST Helier Jersey, JE1 1ST, Jersey, represented by its General Partner Neomed Innovation V Limited;

(6) **N5 Investments AS**, a company organized under the laws of Norway, whose registered office is at Parkveien 55, N-0256 Oslo, Norway, registered under number 998406730;

(7) **Wellington Partners Nominee Ltd**, a limited company organized under the laws of Jersey, whose registered office is at 11-15 Seaton Place, St. Helier, Jersey JE4 0QH, British Channel Islands, registered with the Jersey Financial Services Commission under number RC112326;

(8) **Mr. Elias Papatheodorou**, a Greek citizen, born on 30 May 1969 at Athens (Greece) and residing at Engelfriedshalde 27, 72076 Tubingen, Germany;

(9) **Mr. Philippe Wiesel**, a Swiss citizen, born on 7 November 1966 in Uccle (Belgium) and residing at 11 Rue Juliette Lamber, 75017 Paris, France;

(10) **Mr. Alexandre Grassin**, a French and Swiss citizen, born on 3 February 1978 at Reims, France and residing at rue Micheli-du-Crest 20, 1205 Geneva, Switzerland;

(individually a "**Seller**" and collectively, the "**Sellers**")

(11) **Calliditas Therapeutics AB (publ)**, a public limited liability company (*aktiebolag*) organized under the laws of Sweden, whose registered office is at Kungsbron 1, C8, SE-111 22, Stockholm, Sweden, registered under the corporate registration number 556659-9766 and which common shares are admitted to trading on Nasdaq Stockholm under ISIN code SE0010441584 and, in the form of American depositary shares on the Nasdaq Global Select Market under ISIN code US13124Q1067;

(the "**Buyer**")

The Sellers and the Buyer are hereinafter referred to individually as a "**Party**" and collectively as the "**Parties**".

PREAMBLE

(a) **GENKYOTEX** is a limited liability company (*société anonyme*) organized under the laws of France with a share capital of €11,548,562, whose registered office is at 218 avenue Marie Curie – Forum 2 Archamps Technopole, 74166 Saint-Julien-en-Genevois Cedex, France and registered with the Commerce and Companies Registry under number 439 489 022 RCS Thonon-les-Bains (the "**Company**"). As of the date hereof, the Company has issued 11,548,562 ordinary shares with a nominal value of €1.00 which are admitted to trading on Euronext Paris and Euronext Brussels under ISIN code FR0013399474 (the "**Company Shares**") including 9,243 ordinary shares held in treasury.

(b) The Sellers own 7,236,515 Company Shares (the "**Transferred Shares**") representing, as of the date hereof, 62,66% of the issued share capital and of 62,71% the theoretical voting rights of the Company. The details of the Transferred Shares are set out in Schedule 1.

(c) The Buyer is seeking to acquire all the Transferred Shares and, as soon as reasonably practicable after the completion of such acquisition and in compliance with French and Belgian securities laws, the Buyer intends to file with the French Financial Market Authority (*Autorité des Marchés Financiers* – the "**AMF**") a mandatory cash simplified tender offer (*offre publique obligatoire d'achat simplifiée*) on the remaining Company Shares (the "**Tender Offer**") on the terms and subject to the conditions set forth in the Tender Offer Agreement.

(d) In connection with the foregoing, the Buyer is prepared to acquire the Transferred Shares from the Sellers and the Sellers are prepared to sell the Transferred Shares to the Buyer under the terms and conditions of this agreement (the "**Transaction**").

THE PARTIES HEREBY AGREE AS FOLLOWS:

1. DEFINITIONS

1.1 DEFINITIONS

For the purpose of this agreement, the following capitalized terms shall have the following meanings, which shall be equally applicable to the singular and plural forms of such terms:

"**Affiliate**" means, in relation to any Person, any other Person who/which, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such first Person. The term "control" as used in this definition (including its correlative meanings "controlled by" and "under common control with") shall have the meaning ascribed to it in Article L. 233-3 of the French Commercial Code, it being agreed that the managing company or the general partner of an investment fund shall be deemed to have control over such investment fund.

"**Agreement**" means this share purchase agreement and each of its schedules.

"**AMF**" has the meaning given to such term in the Preamble hereof.

"**Andera Sellers**" means the persons listed in paragraphs (1) and (2) of the Parties hereto.

"**Board Represented Sellers**" means the Andera Sellers, Eclosion2 & Cie SCPC, Vesalius Biocapital II SA, SICAR and Neomed Innovation V L.P.

"**Business Day**" means any day other than (i) a Saturday or Sunday, (ii) a day that is not a trading day (*jour de négociation*) on the Euronext Paris and Euronext Bruxelles stock exchanges or (iii) a day on which banks in Belgium, France or Sweden are closed.

"**Buyer**" means the person described in paragraph (1) of the Parties hereto or the Substituted Subsidiary, as the case may be.

"**Closing**" means the consummation of the Transaction by delivery of the documents and completion of the transactions referred to in Clause 6.2 and in particular the payment of the Purchase Price.

"**Closing Date**" means the date referred to in Clause 6.1 on which the Closing shall occur.

"**Company**" has the meaning given to such term in the Preamble hereof.

"**Company Shares**" has the meaning given to such term in the Preamble hereof.

"**Conditions Precedent**" has the meaning given to such term in Clause 4.

"**Contingent Consideration 1**" has the meaning given to such term in Clause 3.2.

"**Contingent Consideration 2**" has the meaning given to such term in Clause 3.2.

"**Contingent Consideration 3**" has the meaning given to such term in Clause 3.2.

"**Contingent Considerations**" has the meaning given to such term in Clause 3.2.

"**Contingent Consideration Portion**" has the meaning given to such term in Clause 3.2.

"**Encumbrance**" means any security interest, mortgage, charge, pledge, lien, assignment or *fiducie* by way of security, hypothecation, title retention, easement, burden, or other restriction or limitation of any kind to the rights of disposal, ownership or assignment of an asset (including any right to acquire, call option, tag along, drag along, preference or pre-emption right) whether created by applicable Laws, by contract or otherwise.

"**FDA**" shall mean the U.S. Food and Drug Administration, and any successor agency thereto.

"**Foreign Investment Authority**" means the French Ministry of Economy and Finance or any other competent French Governmental Authority for the purposes of authorizing the Transaction pursuant to articles L. 151-3, R. 151-1 *et seq.* of the French Monetary and Financial Code.

"**Foreign Investment Clearance**" means (i) a decision from the Foreign Investment Authority which, pursuant to articles L. 151-3, R. 151-1 *et seq*. of the French Monetary and Financial Code, authorizes in accordance with the relevant applicable Laws and regulations or does not prevent the acquisition of the Company by the Buyer or (ii) a written confirmation from the Foreign Investment Authority that the Transaction does not fall within the scope of articles L. 151-3, R. 151-1 *et seq.* of the French Monetary and Financial Code.

"**Governmental Authority**" means any international, European, national, state, regional, departmental, municipal or local body with executive, legislative, judicial, regulatory, or administrative authority including any ministry, department, agency, office, organization or other subdivision thereof and any Person having received delegated authority from any of the above, as well as any judicial authority of competent jurisdiction.

"**Group**" means the Company and its Subsidiary taken as a whole.

"**Investment Services Provider**" means Bryan, Garnier & Co, appointed to act as investment services provider (*prestataire de services d'investissement*) in connection with the Transaction.

"**Law**" means, in respect of any person, any mandatory law or regulation of any Governmental Authority, which is in force and binding upon such person and capable of enforcement, from time to time.

"**Longstop Date**" means 1 November 2020 at 23:59 pm CET.

"**Manager Sellers**" means Mr. Elias Papatheodorou, Mr. Philippe Wiesel and Mr. Alexandre Grassin.

"**Material Company IP Rights**" means intellectual property, patent, patent application, documentation or know-how, and any rights thereto, held by the Group, relating to setanaxib.

"**Milestones**" means the setanaxib Milestone 1, setanaxib Milestone 2 and the setanaxib Milestone 3.

"**Parties**" means either the Buyer or any of the Sellers and together, the Buyer and the Sellers.

"**Permitted Transfer**" means a transfer or disposal of one or more Contingent Considerations

(i) in the case of a Seller who is an individual, upon death or by gift (donation);

(ii) made pursuant to a court order of a court of competent jurisdiction (such as in connection with divorce, bankruptcy or liquidation),

(iii) made by operation of law (including a consolidation or merger) or without consideration in connection with the dissolution, liquidation or termination of any corporation, limited liability company, partnership or other entity;

(iv) if the Contingent Consideration holder is a partnership, a distribution from the transferring partnership to its partners or former partners in accordance with their partnership interests; or

(v) by a venture capital company or fund, private equity company or fund or other similarly-situated type of institutional investor to any Affiliate of such entity; provided, that

(1) such transfer can be effected without subjecting the Contingent Considerations to registration or filing requirements under applicable European, French, Belgian, Swedish or U.S. securities rules and regulations and

(2) to the extent any items above result in the portion of the Contingent Considerations offered in the context of the Tender Offer being subject to registration or filing requirements under applicable European, French, Belgian, Swedish or U.S. securities rules and regulations, such items shall be deemed removed from this definition of Permitted Transfers.

"**Person**" means any present or future individual or any corporation, association, partnership, joint venture, limited liability, joint stock or other company, business trust, trust, organization, business or government or any governmental agency or political subdivision thereof.

"**Purchase Price**" means the total purchase price for the Transferred Shares, to be paid on the Closing Date, as set forth in Clause 3.

"**Rules**" has the meaning given to such term in Clause 17(b).

"**Schedule(s)**" means the Schedule(s) attached hereto and any attachment(s) thereto.

"**Sellers**" means the persons listed in paragraphs (1) to (10) of the Parties hereto.

"**Sellers' Agent**" has the meaning given to such term in Clause 11.

"**setanaxib**" means a NADPH Oxidase 1 (NOX1) and NADPH Oxidase 4 (NOX4) inhibitor, as used in the currently pending clinical trial sponsored by the Company, or an Affiliate or licensee thereof.

"**setanaxib Milestone 1**" means the first approval by the FDA of a new drug application (NDA) that grants the Company or any of its Affiliates (or their respective successors and assigns) the right to commercially manufacture, market and sell setanaxib in the United States in accordance with applicable Laws.

"**setanaxib Milestone 2**" means a marketing authorization by the European Commission that grants the Company or any of its Affiliates (or their respective successors and assigns) the right to commercially manufacture, market and sell setanaxib in the European Union in accordance with applicable Laws.

"**setanaxib Milestone 3**" means the first approval by the FDA of a new drug application (NDA) or a marketing authorization by the European Commission that grants the Company or any of its Affiliates (or their respective successors and assigns) the right to commercially manufacture, market and sell setanaxib in the United States or in the European Union respectively in accordance with applicable Laws for the treatment of Idiopathic Pulmonary Fibrosis (IPF) or Type 1 Diabetes.

"**Stifel**" means Stifel, Nicolaus & Company, Incorporated.

"**Stifel Engagement Letter**" means the engagement letter entered into between Stifel and the Company on 17 June 2019, as amended from time to time.

"**Subsidiary**" means Genkyotex Suisse SA, a limited liability company (*société anonyme*) organized under the Laws of Switzerland, whose registered office is at Chemin des Aulx 16, 1228 Plan-les-Ouates, Switzerland and registered number CHE-112.747.508.

"**Substituted Subsidiary**" has the meaning given to such term in Clause 13.

"**Tender Offer**" has the meaning given to such term in the Preamble hereof.

"**Tender Offer Agreement**" means the tender offer agreement entered into on the date hereof between the Buyer and the Company, a copy of which the Sellers have been provided with.

"**Tender Offer Closing Date**" means the date of closing (*clôture de l'offre*) of the Tender Offer.

"**Transaction**" has the meaning given to such term in the Preamble hereof.

"**Transferred Shares**" has the meaning given to such term in the Preamble hereof.

"**Universal Registration Document**" means the universal registration document, including the annual financial report, filed by the Company with the AMF on 30 April 2020 for the financial year ending on 31 December 2019.

"**Yorkville Warrants**" means the 666,312 share subscription warrants (*bons de souscription d'action*) subscribed on 20 August 2018 by YA II PN, Ltd. allowing for the subscription of 66,845 Company Shares at a price of €18.70 per Company Share and expiring on 20 August 2023.

1.2 INTERPRETATION

(a) In the Agreement, unless the context otherwise requires:

(i) except if otherwise specified, references to clauses and schedules are references to Clauses of and Schedules to the Agreement, references to paragraphs are references to paragraphs of the Clause and the Schedule in which the reference appears and references to the Agreement include the Schedules;

(ii) references to the singular shall include the plural and vice versa and references to one gender include any other gender;

(iii) references to "EUR", "euros", or "€" are references to the lawful currency from time to time of France and references to "dollars", or "$" are references to the lawful currency from time to time of the United States of America;

(iv) any amount to be converted from one currency into another currency for the purposes of this Agreement, if it shall be converted into an equivalent amount, shall be at the Conversion Rate prevailing at the Relevant Date. For the purpose of the foregoing: "**Conversion Rate**" means the close spot mid-trade composite (London) rate for a transaction between the two currencies in question as quoted on Bloomberg on the date immediately preceding the Relevant Date or, if no such rate is quoted on that date, on the preceding date on which such rates are quoted; and "**Relevant Date**" means the date on which a payment or an assessment is to be made;

(v) references to times of the day are to Paris time unless otherwise stated; and

(vi) general words shall not be given a restrictive meaning because they are followed by words which are particular examples of the acts, matters or things covered by the general words and the words "includes" and "including" shall be construed without limitation.

(b) The headings and sub-headings in the Agreement are inserted for convenience only and shall have no legal effect.

(c) Each of the schedules to the Agreement shall form part of the Agreement.

(d) References to the Agreement include the Agreement as amended or varied in accordance with its terms.

(e) Any French term in this Agreement shall supersede its English translation.

(f) The provisions of Articles 640 to 642 of the French Code of Civil Procedure shall be applied to calculate any period of time under the Agreement, provided that the references in Article 642 to "*un jour férié ou chômé*" and "*premier jour ouvrable*" shall be interpreted by reference to the definition of "Business Day" provided herein.

2. SALE AND PURCHASE OF THE TRANSFERRED SHARES

(a) Upon the terms and subject to the conditions of this Agreement, the Buyer shall purchase from each of the Sellers, and each Seller shall sell to the Buyer, on the Closing Date, all of its Transferred Shares as listed in Schedule 1 and representing in the aggregate 7,236,515 Company Shares, free and clear of any Encumbrance, for the Purchase Price specified in Clause 3.

(b) The Transaction shall be completed on the Closing Date by the Investment Services Provider, acting pursuant to the joint instructions of the Sellers and the Buyer.

(c) The transfer of ownership of the Transferred Shares to the Buyer shall occur on the Closing Date by means of off-market block trades (*cessions de bloc hors marché*) and in accordance with the relevant Euroclear procedure.

(d) As of the Closing Date, the Buyer shall have the full ownership of the Transferred Shares together with all the rights attached thereto, including the right to all dividends declared and paid on and after the Closing Date, with respect to the Transferred Shares.

(e) The Buyer shall not be required to purchase the Transferred Shares unless all the Transferred Shares are transferred simultaneously on the Closing Date to an account opened by the Buyer with the Investment Services Provider, free of any Encumbrance. Under any other circumstances, the Buyer shall have the right to terminate this Agreement without incurring any liability *vis à vis* the Sellers in connection with such termination.

(f) The Buyer undertakes (i) unless otherwise agreed with the Sellers' Agent, not to acquire any Company Shares until the filing of the Tender Offer except for the transactions provided in this Agreement and (ii) between the filing of the Tender Offer and the settlement and delivery (*règlement-livraison*) of the Tender Offer, not to acquire any Company Shares at a price higher than the price of the Tender Offer.

3. PURCHASE PRICE

3.1 CONSIDERATION TO BE PAID AT CLOSING

(a) The consideration for the Transferred Shares (the "**Purchase Price**") shall be a total amount of €20,262,242 (as reduced, as the case may be, pursuant to Clause 3.1(c)), representing a price per Transferred Share of €2.8.

(b) The allocation of the Purchase Price among the Sellers is set forth in Schedule 1.

(c) The Purchase Price to be paid on Closing by the Buyer as indicated in Clause 6.2 shall be reduced by any amount (including taxes if any) in excess of (and in excess only) US$400,000 paid or payable by any entity of the Group to Stifel (or any of its Affiliates) pursuant to the Stifel Engagement Letter.

(d) The Purchase Price (as reduced, as the case may be, pursuant to Clause 3.1(c)) shall be paid by the Buyer to the Sellers, on the Closing Date, as indicated in Clause 6.2.

3.2 CONTINGENT CONSIDERATIONS

(a) As an additional consideration for the Transferred Shares and subject to the satisfaction of the conditions set forth below, the Buyer agrees to pay to the Sellers after the Tender Offer Closing Date, additional amounts to the Purchase Price based on the following sums expressed in relation to 100% of the Company Shares on a fully diluted basis on the day preceding the settlement and delivery (*règlement-livraison*) of the Tender Offer (but excluding dilution resulting from any Yorkville Warrants that have not been waived or exercised by such date) apportioned to the Sellers and other security holders of the Company pursuant to the provisions of Clause 3.2(c):

(i) €30,000,000 in cash if the setanaxib Milestone 1 is achieved at the latest on the date falling ten years as from the Tender Offer Closing Date (the "**Contingent Consideration 1**");

(ii) €15,000,000 in cash if the setanaxib Milestone 2 is achieved at the latest on the date falling ten years as from the Tender Offer Closing Date (the "**Contingent Consideration 2**");

(iii) €10,000,000 in cash if the setanaxib Milestone 3 is achieved at the latest on the date falling ten years as from the Tender Offer Closing Date (the "**Contingent Consideration 3**" and, together with the Contingent Consideration 1 and the Contingent Consideration 2, the "**Contingent Considerations**"), provided, however, that if setanaxib Milestone 1 or setanaxib Milestone 2 is achieved for the treatment of Idiopathic Pulmonary Fibrosis (IPF) or Type 1 Diabetes then the Contingent Consideration 3 shall be equal to 0 for the same indication.

(b) The Sellers hereby acknowledge and agree that:

(i) the Buyer (including as the controlling shareholder of the Company after the Closing Date) shall retain sole discretion and decision making authority over any continued operation of, development or investment in setanaxib after the Closing Date, including any decision to cease developing any drug candidate; and

(ii) the Buyer shall not be required to take or pursue any action to ensure the achievement of the Milestones and shall not have any responsibility with respect to the achievement of the Milestones.

(c) The sums to be paid by the Buyer to each Seller under the Contingent Considerations will be equal to (i) the global sum due under the relevant Contingent Consideration (*i.e.* €30,000,000 for the Contingent Consideration 1, €15,000,000 for the Contingent Consideration 2 or €10,000,000 for the Contingent Consideration 3) multiplied by (ii) a percentage equal to (a) the number of Transferred Shares by the relevant Seller as set forth in Schedule 1 divided by (b) the number of Company Shares on a fully diluted basis on the day preceding the settlement and delivery (*règlement-livraison*) of the Tender Offer (the "**Contingent Consideration Portion**").

(d) The Contingent Consideration Portion to be paid to each Seller by the Buyer as indicated in Clause 3.2(g) shall be reduced by an amount in euros equal to 60% of any amount (including taxes if any) paid or payable by any entity of the Group to Stifel (or any of its Affiliates) as a result of the Contingent Considerations being due, such reduction being allocated to each Seller pro rata the number of Transferred Shares sold by such Seller (as set forth in Schedule 1) divided by the total number of Transferred Shares.

(e) The contractual right of each Seller to be paid a Contingent Consideration Portion may not be transferred or disposed of, in whole or in part, other than in relation to a Permitted Transfer.

(f) The Buyer, upon becoming aware that any of the Milestones has been achieved, shall promptly notify the Sellers of the achievement of such Milestone, such notification including a copy of any document evidencing such achievement.

(g) The payment of the Contingent Consideration Portion will be made by the Buyer to each Seller within 30 Business Days following the relevant notification sent pursuant to Clause 3.2(f), by transferring immediately available funds to the bank accounts of the relevant Seller as shall be notified by each Seller to the Buyer in writing by no later than 20 Business Days following receipt of the notification referred in Clause 3.2(f).

(h) In the event that prior to the tenth anniversary of the Tender Offer Closing Date the Buyer desires to consummate a transaction with a third party relating to the transfer or licensing of part or all of Material Company IP Rights necessary for setanaxib to attain either of the setanaxib Milestone 1, the setanaxib Milestone 2, the setanaxib Milestone 3, while any such milestone has not been attained but remains eligible to be attained, the Buyer will, at its discretion, (i) either retain its obligations in respect of the Contingent Considerations or (ii) cause the person acquiring any such Material Company IP Rights relating to setanaxib to assume the Buyer's obligations in respect of the Contingent Considerations. No later than the consummation of any such transaction, the Buyer shall disclose to the Sellers' Agent information relating to such transaction so that the Sellers are informed that such transaction complies with this Clause 3.2(h).

4. CONDITIONS PRECEDENT

The obligation of the Buyer to consummate the Transaction shall be subject to the satisfaction (or waiver by the Buyer in writing) of the following conditions (the "**Conditions Precedent**"):

(i) the Buyer shall have received the Foreign Invest Clearance as provided for in Section 4.2 below; and

(ii) no material impairment of Material Company IP Rights shall have occurred, as provided for in Section 4.3 below.

If at any time either Party becomes aware of any event, circumstance or condition that would be reasonably likely to prevent any Conditions Precedent being satisfied it shall forthwith inform the other Parties.

4.2 FOREIGN INVESTMENT CLEARANCE

(a) The Buyer agrees, as soon as practicable after the date of this Agreement, to make the compulsory filing with the Foreign Investment Authority in order to obtain the Foreign Investment Clearance.

(b) The Buyer shall keep the Sellers' Agent regularly informed of the status of the Foreign Investment Clearance process and the expected timing of obtaining the Foreign Investment Clearance.

(c) The Buyer shall undertake its reasonable best efforts to obtain the Foreign Investment Clearance without undue delay on or before the Longstop Date provided, for the avoidance of doubt, that nothing in this Agreement shall require the Buyer to (i) offer (and not withdraw) any commitments, undertakings and other remedies that the Foreign Investment Authority may impose as a condition to clearance or (ii) divest, dispose of, or hold separate (or otherwise take or commit to take any action that limits the Buyer's freedom of action with respect to, or its ability to retain, operate or control of) any of its businesses or assets or the businesses or assets of the entities of the Group.

(d) The Sellers shall, and (to the extent of their respective available powers as shareholders, directors and corporate officers of the Company or the Subsidiary), shall cause the Company and its management to promptly co-operate with and provide all such assistance as the Buyer may request in order to obtain the Foreign Investment Clearance and shall provide at the request of the Buyer in a timely fashion all information requested by the Buyer for the preparation of the filings with the Foreign Investment Authority and responses to questions raised by the Foreign Investment Authority.

4.3 NO IMPAIRMENT OF MATERIAL COMPANY IP RIGHTS

An impairment of Material Company IP Rights shall be deemed to have occurred if any of the following is untrue as of the Closing Date:

(a) All of the Material Company IP Rights are validly owned by the Company or the Subsidiary (or, in the case of the assay enabling technology, validly licensed to the Company).

(b) No Material Company IP Rights are challenged or, to the knowledge of the Sellers, threatened to be challenged by third parties.

(c) All necessary fees and taxes have been paid, and all necessary and material documents have been filed, in connection with each Material Company IP Right that needs to be registered. In connection with the registered Material Company IP Right, all registrations are in force and all applications for the same are pending (required fees paid) and without any adverse action or proceedings pending or, to the knowledge of the Sellers, threatened by or before the Governmental Authority in which the registrations or applications are issued or filed.

(d) No facts or circumstances exist that, to the knowledge of the Sellers, could render any of the Material Company IP Rights invalid or unenforceable.

5. SELLERS' COVENANTS

(a) From the date hereof up to the Closing Date, to the extent of their respective and available powers as shareholders, directors and corporate officers of the Company or the Subsidiary, the Sellers shall cause the Group to operate and carry on their activity in the ordinary course of business and in substantially the same manner as previously conducted and take all reasonable steps to preserve and protect their assets and goodwill, including their existing relationships with customers and suppliers and including the timely filing of all documents and the timely payment of fees and taxes required to maintain the Material Company IP Rights.

(b) In particular, from the date hereof, in no event will any Seller propose, encourage, otherwise support or approve in their respective capacities as shareholders and/or members of the board of directors of the Company: (i) any plan of complete or partial liquidation, dissolution, merger, consolidation, business combination, restructuring, recapitalization or other reorganization, (ii) any material acquisition by merger or consolidation with, or by purchase of an equity interest in or portion of the assets of, or by any other manner, any business or any corporation, partnership, joint venture, association or other business organization or division thereof, or (iii) any issuance, repurchase, redemption, cancellation, sale, pledge, disposition of, grant, transfer, encumbrance or authorize the issuance, sale, pledge, disposition, grant, transfer or encumbrance of any share capital or other equity or voting interests of the Company, or securities convertible or exchangeable into or exercisable for any share capital or other equity or voting interests of the Company, or any options, warrants or other rights of any kind to acquire any share capital or other equity or voting interests of the Company or such convertible, exchangeable or exercisable securities and (iv) any distribution of profits, dividends (including interim dividends), reserve or assets of the Company, in all cases above except as expressly permitted by the Tender Offer Agreement, provided that, for avoidance of doubt, this covenant in (b) will not restrict the ability of the Board to decide to modify partially or totally the vesting period or other terms of existing stock options in accordance with the Tender Offer Agreement.

(c) From the date hereof up to the Closing Date, the Sellers shall, and to the extent of their respective powers as shareholders and corporate officers of the Company, shall cause the Company to comply with, the provisions of the Tender Offer Agreement.

(d) The Sellers acknowledge that the Purchase Price offers significant value and premium to the shareholders of the Company, and that the Transaction is in the best interest of the Company, its employees and other stakeholders. Consequently, the Sellers hereby agree to support and recommend the Tender Offer, as the case may be, in their respective capacities as shareholders and/or members of the board of directors of the Company.

6. CLOSING AND POST-CLOSING

6.1 CLOSING DATE

The Closing shall take place at the offices of Latham & Watkins, 45 rue Saint-Dominique, 75007 Paris as soon as practicable and no later than ten Business Days following the satisfaction of the Conditions Precedent or on any other date or location as mutually agreed upon by the Parties.

6.2 ACTIONS TO BE TAKEN FOR CLOSING

6.2.1 Transfer of the Transferred Shares

(a) At the latest three Business Days prior to the Closing Date:

(i) The Sellers' Agent shall notify to the Buyer the amount due or to be paid, on or around the Closing Date or the Tender Offer Closing Date, by any entity of the Group pursuant to the Stifel Engagement Letter and the final amount of the Purchase Price to be paid by the Buyer to the Sellers for the Transferred Shares;

(ii) The Sellers' Agent shall (i) instruct the Investment Services Provider to open securities trading accounts (capable of receiving and holding Company Shares) and bank accounts in its books under the name of each Seller and (ii) notify to the Buyer the relevant details of such accounts;

(iii) Each Seller shall transfer all of its Transferred Shares to the securities trading account opened in its respective name in the books of the Investment Services Provider;

(iv) The Buyer shall (i) instruct the Investment Services Provider to open a securities' trading account (capable of receiving and holding Company Shares) and a bank account in its books under its name and (ii) notify to the Sellers' Agent the relevant details of such accounts; and

(v) The Buyer shall notify to the Sellers' Agent the identity of the individuals or entities to be appointed to the board of directors of the Company on the Closing Date.

(b) On the Closing Date, the following should occur:

(i) The Sellers and the Buyer shall deliver prior to 9:00 a.m. Paris time to the Investment Services Provider a joint transfer instruction, in a form to be provided by the Investment Services Provider, giving it irrevocable instructions to complete the Transaction on the Closing Date consisting in an off-market sale and purchase order for the acquisition by the Buyer from the Sellers of the Transferred Shares (with a trade date corresponding to the settlement date).

(ii) The Investment Services Provider shall complete the transactions set forth in the joint transfer instruction and in particular, it shall:

(A) transfer the Transferred Shares to such securities' trading account opened in its books under the name of the Buyer;

(B) deliver to the Buyer a duly executed certificate of registration of shares (*certificat d'inscription en compte*) registering the Buyer as owner of the Transferred Shares as from the Closing Date; and

(C) pay the Purchase Price attributed to the Transferred Shares in immediately available funds by wire transfer to such bank accounts of the Sellers opened in its books.

(iii) The Sellers shall:

(A) cause Eclosion 2 SA, Andera Partners, Claudio Nessi and, if requested by the Buyer, Elias Papatheodorou, to execute and deliver to the Company written resignation letters from their position as directors of the Company with effect from the Closing Date substantially in the form attached as Schedule 2 and provide copies of such resignation letters to the Buyer;

(B) cause Stéphane Verdood to execute and deliver to the Company a written resignation letter from his position as observer of the board of directors of the Company with effect from the Closing Date substantially in the form attached as Schedule 2 and provide a copy of such resignation letter to the Buyer; and

(C) deliver to the Buyer a certified true copy of the extract of the minutes of the board of the Company held on the Closing Date (i) acknowledging the resignation of Eclosion 2 SA, Andera Partners, Claudio Nessi and Stéphane Verdood and (ii) appointing in replacement (*cooptation*) the individuals or entities designated by the Buyer in accordance with Clause 6.2.1(a)(v).

6.2.2 Other Closing considerations

(a) The Parties shall execute all instruments and documents and otherwise take all actions as shall be necessary or required by Law and this Agreement to consummate the Transaction on the Closing Date.

(b) All matters described in this Clause 6.2 will be deemed to take place simultaneously and all documents and items delivered and payments made in connection with Closing shall be held by the recipient to the order of the person delivering them until such time as Closing takes place. Each of such actions, deliveries and payments shall be deemed to have occurred as at the Closing Date.

(c) All of the actions required for Closing described in this Clause 6.2 are conditional upon the occurrence of all other such actions. Therefore:

(i) in the event that any Seller fails to complete any of the actions and deliveries set forth in this Clause 6.2 on the Closing Date, then the Buyer shall be entitled to refuse to proceed with the Closing with respect to that Seller or all Sellers at its discretion; and

(ii) in the event that the Buyer fails to complete any of the actions and deliveries set forth in this Clause 6.2 on the Closing Date, then each Seller shall be entitled to refuse to proceed with the Closing.

(d) Such right to refuse to proceed with Closing is in addition and without prejudice to all other rights and remedies available to the non-defaulting Parties, including the right to claim damages and/or the right to require the specific performance (*exécution forcée*) of the Transaction in accordance with Articles 1221 and 1222 of the French Civil Code.

7. REPRESENTATIONS AND WARRANTIES OF THE SELLERS

The Sellers represent and warrant to the Buyer that the following representations and warranties are true and accurate as of the date hereof, and shall remain true and accurate up to the Closing Date. The Buyer acknowledges that the representations and warranties contained in this Clause 7 are the only representations and warranties on behalf of the Sellers on which the Buyer may rely, or has relied, in entering into this Agreement.

7.1 EXISTENCE - AUTHORIZATION

(a) Each Seller that is not an individual is duly organized and validly incorporated under the Laws of its jurisdiction, and has all requisite corporate power and authority to own its assets and conduct its business as now being conducted.

(b) Each Seller has all requisite capacity and right to enter into this Agreement, to perform its obligations hereunder and to consummate the Transaction contemplated hereby.

(c) This Agreement has been duly authorized by all relevant corporate bodies of each Seller that is not an individual (and, to the extent required, of Affiliates of each Seller), and duly executed and delivered by each Seller and constitutes the legal, valid and binding obligation of such Seller, enforceable against such Seller in accordance with its terms.

(d) Except as otherwise specifically mentioned in this Agreement, no authorization is required to be obtained by any Seller or any of its Affiliates in connection with the signing of this Agreement or the consummation of any of the transactions contemplated by this Agreement.

(e) The execution of the Agreement by each Seller and the performance of its obligations thereunder do not conflict with, or constitute a breach of any Laws, agreement or other obligation to which such Seller is subject.

(f) Each Seller represents that it is not insolvent (*en état de cessation de paiements*). Such Seller is not subject to any safeguard, bankruptcy or insolvency proceedings under any applicable Laws, nor to any other proceedings with regard to the prevention or resolution of business difficulties.

7.2 TITLE TO THE TRANSFERRED SHARES

(a) Each Seller represents that it is the sole holder of all of the Transferred Shares that are mentioned in front of its name in Schedule 1.

(b) The Transferred Shares owned by such Seller are free and clear of any Encumbrance.

(c) The Sellers do not own any Company Shares, securities giving deferred access to Company Shares or rights to acquire Company Shares other than (i) the Transferred Shares and (ii) stock options in the case of the Manager Sellers as further detailed in the Tender Offer Agreement.

(d) No Seller is a party to any option, warrant, purchase right or other contract or commitment that requires such Seller to sell, transfer or otherwise dispose of any capital stock of the Company, except as indicated in this Agreement or as provided for in the Tender Offer Agreement.

(e) To the best of the Sellers' knowledge, (i) all the Company Shares are fully paid up and validly issued and (ii) all the Company Shares have equal voting rights and each such Company Share entitles its holder to dividends in proportion to the percentage of share capital it represents.

(f) To the best of the Sellers' knowledge, the Company Shares represent all of the issued share capital of the Company.

7.3 ACCURACY OF PUBLICLY AVAILABLE INFORMATION

(a) Elias Papatheodorou, Alexandre Grassin (for the information for which he is responsible in his capacity as employee of the Group) and Philippe Wiesel (for the information for which he is responsible in his capacity as employee of the Group) respectively represents that the information in relation to the Group which was made or is publicly available in accordance with the Company's disclosure obligations (and in particular but not limited to the Universal Registration Document) did not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) Each Manager Seller represents that there are no material fact or circumstance (including any suit, action or proceeding pending or, to the knowledge of each Manager Seller, threatened against the Company or its Subsidiary) that, individually or in aggregate is adversely affecting (or reasonably likely to adversely affect) the affairs of the Group which has not been disclosed publicly and which, if disclosed, might have a noticeable (*sensible*) influence on the traded market price of the Company Shares.

7.4 BROKERS' FEES

Each Manager Seller and each Board Represented Seller represents that none of the entities of the Group has any liability or obligation to pay any fees, costs, charges or commissions to any broker, finder, agent or financial advisor with respect to the Transaction or the Tender Offer other than pursuant to the Stifel Engagement Letter and the engagement letter to be entered into with the independent expert in connection with the Tender Offer.

8. REPRESENTATIONS AND WARRANTIES OF THE BUYER

The Buyer represents and warrants to the Sellers that the following representations and warranties are true and accurate as of the date hereof, and shall remain true and accurate up to the Closing Date. The Sellers acknowledge that the representations and warranties contained in this Clause 8 are the only representations and warranties on behalf of the Buyer on which the Sellers may rely, or have relied, in entering into this Agreement.

(a) The Buyer is duly organized and validly incorporated under the Laws of its jurisdiction, and has all requisite corporate power and authority to own its assets and conduct its business as now being conducted.

(b) The Buyer has all requisite corporate capacity and right to enter into this Agreement, to perform its obligations hereunder and to consummate the Transaction contemplated hereby.

(c) This Agreement has been duly authorized by any and all relevant corporate bodies of the Buyer and duly executed and delivered by the Buyer and constitutes and shall constitute the legal, valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms.

(d) The execution of this Agreement by the Buyer and the performance of its obligations thereunder do not, and will not, conflict with, or constitute a breach of any Laws, agreement or other obligation to which the Buyer is subject.

(e) The Buyer is not insolvent (*en état de cessation de paiements*). The Buyer is not subject to any safeguard, bankruptcy or insolvency proceedings under any applicable Laws, nor to any other proceedings with regard to the prevention or resolution of business difficulties.

(f) As of the date hereof, the Buyer does not own any Company Shares, nor has entered into any agreement relating to the acquisition by the Buyer of any Company Shares other than the Transferred Shares under this Agreement or the Tender Offer Agreement.

9. POST-CLOSING UNDERTAKINGS

(a) The Buyer hereby undertakes to file the Tender Offer as soon as reasonably practicable further to Closing in compliance with applicable Laws.

(b) The Sellers shall cooperate with and provide to, and shall cause (to the extent of their respective powers as shareholders, directors and corporate officers of the Company or the Subsidiary) the Group to cooperate with and provide to, the Buyer all necessary information reasonably required for the drafting of the offer documentation prior to the filing of the Tender Offer in compliance with applicable Laws.

(c) The Sellers undertake not to implement, directly or indirectly, any transaction which may disturb the proper implementation of the Tender Offer and/or squeeze-out regarding the Company Shares and in particular shall not, from the date of announcement of such Tender Offer and/or squeeze-out until its final settlement and delivery, directly or indirectly, acquire, transfer (other than to the Buyer or one of its Affiliates), or take an economic exposure on, Company Shares other than in accordance with the Tender Offer Agreement.

(d) For a period of two (2) year from the Closing Date, the Sellers will not, and procure that their Affiliates do not, approach, solicit or employ directly or indirectly any of the managers, directors or employees that is currently or that will remain in the Group following the Transaction, provided that this restriction will not apply (i) if such Sellers or their Affiliate do not control (with the meaning ascribed in Article L. 233-3 of the French Commercial Code) the entity hiring the person that approaches, solicits or employs directly or indirectly any of the managers, directors or employees that is currently or that will remain in the Group following the Transaction, or (ii) if the employment of such employees is terminated by any Group Companies.

10. COMMUNICATION – PUBLIC STATEMENTS

(a) No publicity, public announcement, press release, or disclosure regarding this Agreement or the transactions contemplated herein shall be made by the Sellers without the prior written consent of the Buyer on the time, form and content of such public announcement, release or disclosure, which consent shall not be unreasonably withheld or delayed. In the event any Seller is required by applicable Law to make any public announcement related to this Agreement or the Transaction, such Seller will give the Buyer a reasonable opportunity to review and comment upon such communication before it is disseminated.

(b) Notwithstanding the foregoing, certain Sellers and the Buyer are required to notify the AMF and the Company of the crossing of share ownership thresholds as a consequence of the Transaction, and they are free to do so to the extent required by applicable Laws or the articles of association of the Company.

11. SELLERS' AGENT

(a) For the purposes of this Agreement, each Seller shall hereby appoint Alexandre Grassin (the "**Sellers' Agent**"), who accepts, as its representative, in its name and on its behalf, under the circumstances provided in this Agreement, to sign and negotiate all documents required for the completion of the Transaction as well as any amendment to this Agreement, to make and receive all notices, to make all communications or declarations and to receive all payments which are to be made pursuant to this Agreement or as a consequence thereof, to, or on behalf of, the Sellers. In view of the mutual interest it represents for the Sellers, such power of attorney is irrevocable.

(b) Any notification to the Sellers' Agent shall thus be deemed to have been made to each of the Sellers.

(c) Should Alexandre Grassin, acting as Sellers' Agent, be unable to perform his duties to act as the Sellers' Agent, for any reason whatsoever, the Sellers' Agent will be appointed among the Sellers by the Sellers. If the Sellers do not reach an agreement within 15 Business Days of the date Alexandre Grassin has ceased to perform his duties as Sellers' Agent, then the Sellers' Agent shall be appointed among the Sellers by the President of the Commercial Court of Paris ruling in summary form (*statuant en référé*), such ruling being unchallengeable in appeal.

12. NOTICES

(a) Any notice or other communication given under the Agreement or in connection with the matters contemplated herein shall, except where otherwise specifically provided, be in writing in the English language, addressed as provided in Clause (b) and served:

(i) by hand delivery in which case it shall be deemed to have been given upon delivery to the recipient (as evidenced by the acknowledgement of receipt);

(ii) by registered letter with acknowledgment of receipt or by an internationally recognized express overnight delivery service in which case it shall be deemed to have been given on the date of first presentation; or

(iii) by e-mail, in which case it shall be deemed to have been given when dispatched subject to confirmation of delivery by a delivery receipt,

provided that any notice dispatched after 6:00 p.m. CET on a Business Day shall be deemed given at the start of the next Business Day.

(b) Notices under the Agreement shall be sent for the attention of the person and to the address, or e-mail address, as set out below:

(i) If to the Buyer, to:

Calliditas Therapeutics AB (publ)
Address: Kungsbron 1, C8, SE-111 22, Stockholm, Sweden
Email: Fredrik.johansson@calliditas.com
Attn: Fredrik Johansson

with a copy to:
Latham & Watkins AARPI
Address: 45, rue Saint-Dominique,75007, Paris, France
Email: alexander.crosthwaite@lw.com
Attn: Alexander Crosthwaite

(ii) If to the Sellers, to:

Alexandre Grassin, acting as Sellers' Agent
Address: 218 avenue Marie Curie – Forum 2 Archamps Technopole, 74166 Saint-Julien-en-Genevois Cedex, France
Email: alexandre.grassin@genkyotex.com
Attn: Alexandre grassin

with a copy to:
Mc Dermott Will & Emery AARPI
Address: 23 rue de l'Université
Email: drevcolevschi@mwe.com
Attn: David Revcolevschi

or to such other addresses as a Party may provide to the other Parties in accordance with this Clause 12.

(c) Any notice to be given to or by all of the Sellers under the Agreement shall be deemed to have been properly given if it is given to or by the Sellers' Agent.

13. ASSIGNMENT

The Buyer shall be authorized, at any time prior to the Closing Date, to substitute for itself, in all the rights and obligations provided herein, one or several of its Affiliates (the "**Substituted Subsidiary**"), subject only to the condition that the Buyer notifies the Sellers' Agent of such substitution at least five Business Days prior to the Closing Date and confirms in such notice that it will remain jointly and severally (*solidairement*) liable, with effect from the substitution date, with the Substituted Subsidiary for the performance by the latter of all the Buyer's obligations under this Agreement. The Buyer may not assign, directly or indirectly, the benefit of any provision of this Agreement to any other Person without the prior written consent of the Sellers' Agent.

14. TAXES - OTHER EXPENSES

(a) Any transfer or stamp duty or similar levies that may become payable as a result of the signing of this Agreement or the transfer of the Transferred Shares to the Buyer shall be borne by the Buyer exclusively.

(b) Whether or not the transactions contemplated by this Agreement are consummated and except as may otherwise be specifically provided herein, each Party shall bear its own costs and expenses, including fees of legal and other counsel, incurred in connection with the negotiation, preparation, execution and implementation of this Agreement and the consummation of the transactions contemplated hereby.

15. TERMINATION

(a) This Agreement may be terminated at any time prior to the Closing Date as follows:

(i) by mutual consent of the Buyer and the Sellers' Agent;

(ii) by the Buyer if the Foreign Investment Authority issues, prior to the Longstop Date, a decision in writing denying the Foreign Investment Clearance;

(iii) by the Buyer or the Sellers' Agent if the Conditions Precedent are not satisfied (or waived by the Buyer) at the latest at the Longstop Date, provided that the Buyer shall be entitled to postpone the Longstop Date (not more than once) by up to 30 Business Days by notice to the Sellers' Agent;

(iv) by the Buyer if the Closing does not occur by the Longstop Date as a result of Clause 6.2.2(c)(i); or

(v) by the Sellers' Agent if the Closing does not occur by the Longstop Date as a result of Clause 6.2.2(c)(ii).

(b) If the Agreement is terminated, whatever the reason, the obligations hereunder shall automatically cease to be binding on the Parties and, except as otherwise specifically agreed in this Agreement, no Party shall have any claim hereunder of any nature whatsoever against the other, provided that the foregoing will be without prejudice to the rights of any Party in the event of a prior breach hereof by another Party.

(c) In case of termination of this Agreement, whatever the reason, the obligations set forth in Clauses 10, 11, 12, 14 and 17 shall survive such termination.

16. MISCELLANEOUS

16.1 AMENDMENT – WAIVER

(a) No terms of this Agreement may be altered, modified, amended or supplemented or terminated except by an instrument in writing duly signed by all Parties.

(b) A waiver of any term, provision or condition of, or consent granted under this Agreement shall be effective only if given in writing and signed by the waiving or consenting Party, and then only in the instance and for the purpose for which it is given.

(c) No failure or delay on the part of any Party in exercising any right under this Agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right except as specifically set forth herein.

(d) No breach by any Party of any provision of this Agreement shall be waived or discharged except with the express written consent of the other Parties.

16.2 INVALIDITY – ENTIRE AGREEMENT

(a) If any term or provision herein is held to be void, unenforceable, invalid, illegal or inapplicable, the legality, enforceability, validity and applicability of the other provisions of this Agreement shall not be affected or impaired thereby. In such case the Parties shall negotiate in good faith a lawful substitute provision to replace the void, unenforceability, invalid, illegal or inapplicable provision or term that shall be consistent with the intent and object of the original provision.

(b) This Agreement (including the Schedules hereto and the documents referred to herein) constitutes the entire agreement among the Parties and supersedes all prior understandings, agreements or representations by or among the Parties, written or oral, to the extent they have related in any way to the subject matter hereof.

17. GOVERNING LAW - DISPUTES

(a) This Agreement and any contractual or non-contractual obligation arising out of or in connection with this Agreement shall be governed by, and construed in accordance with, French law.

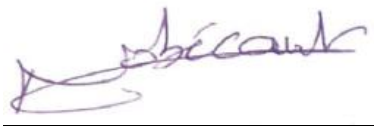
(b) Any dispute, controversy, or claim arising out of or in relation to this Agreement, including in relation to the validity, invalidity, breach, enforcement or termination of this Agreement shall be finally settled in accordance with the Rules of Arbitration of the International Chamber of Commerce (the "**Rules**") in force on the date when the notice of arbitration is submitted. The tribunal shall be composed of three arbitrators appointed as set forth below. Any such arbitration shall be held in Paris. The language in such arbitration proceedings shall be English. The decision and award of the arbitral tribunal shall be final and binding without being subject to further judicial review. The Parties shall jointly appoint two arbitrators and the third arbitrator shall be appointed by the two arbitrators jointly appointed by the Parties. Failing such appointment or in case of disagreement between the Parties on the appointment of the arbitrators, the arbitrators shall be appointed by the Court of the International Chamber of Commerce in accordance with the Rules.

Signed on below on the date specified above, in 11 originals.

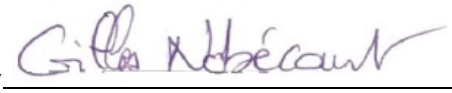
[*Signature pages to follow*]

The Sellers

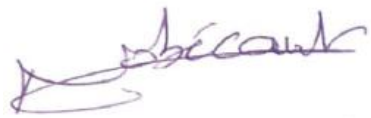
BioDiscovery 2



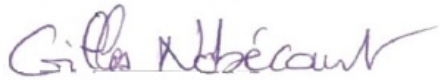
By: Andera Partners SCA

Represented by 

BioDiscovery 3



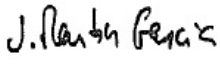
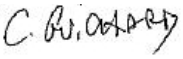
By: Andera Partners SCA

Represented by 

[*Share Purchase Agreement – Signature page – 12 August 2020]*

Eclosion2 & Cie SCPC

By: Eclosion2 SA

Represented by  

[Share Purchase Agreement – Signature page – 12 August 2020]

Vesalius Biocapital II SA, SICAR

By: Stijhan Verbaal Gaston Matthyssens

Represented by Vesalius BioCapital Partners II S.à R.L.

[*Share Purchase Agreement – Signature page – 12 August 2020*]

Neomed Innovation V L.P.

By: Neomed Innovation V Limited

Represented by Ashley Vardon & Christina Kembery

[*Share Purchase Agreement – Signature page – 12 August 2020*]

N5 Investments AS

Pål R. Jensen

By: N5 Investments AS

Represented by PÅL R. JENSEN (CEO)

[*Share Purchase Agreement – Signature page – 12 August 2020*]

Wellington Partners Nominee Ltd

By: ERNST MANNHEIMER

ITS DIRECTOR

[*Share Purchase Agreemenl – Signature page – 12 August 2020*]

Mr. Elias Papatheodorou

[*Share Purchase Agreement – Signature page – 13 August 2020*]

Mr. Philippe Wiesel

[*Share Purchase Agreement – Signature page – 12 August 2020*]

Mr. Alexandre Grassin

[Share Purchase Agreement – Signature page – 12 August 2020]

The Buyer

Calliditas Therapeutics AB (publ)

By: Calliditas Therapeutics AB

Represented by Elmar Schnee and Lennart Hansson

SCHEDULE 1

ALLOCATION OF THE TRANSFERRED SHARES AND PURCHASE PRICE AMONG THE SELLERS

Seller	Number of Transferred Shares	Percentage of Company Shares (based on total shares on the date hereof)	Percentage of allocation of the Purchase Price	Estimated Contingent Consideration Portion (1) (in % of Contingent Consideration)
BioDiscovery 2	209 752	1.82%	2.90%	1.79%
BioDiscovery 3	2 717 174	23.53%	37.55%	23.15%
Eclosion2 & Cie SCPC	1 393 285	12.06%	19.25%	11.87%
Vesalius Biocapital II SA, SICAR	1 087 568	9.42%	15.03%	9.27%
Neomed Innovation V L.P.	940 589	8.14%	13.00%	8.01%
N5 Investments AS	67 633	0.59%	0.93%	0.58%
Wellington Partners Nominee Ltd	482 967	4.18%	6.67%	4.12%
Mr. Philippe Wiesel	115 231	1.00%	1.59%	0.98%
Mr. Elias Papatheodorou	148 689	1.29%	2.05%	1.27%
Mr. Alexandre Grassin	73 627	0.64%	1.02%	0.63%
TOTAL	**7 236 515**	**62.66%**	**100.00%**	**61.66%**

(1) Assuming that the total number of Company Shares on a fully diluted basis on the day preceding the settlement and delivery of the Tender Offer is equal to 11,736,174 (i.e. expected situation if all dilutive instruments other than the 2020 stock options have been waived or have lapsed)

SCHEDULE 2

FORM OF RESIGNATION LETTER

Genkyotex

218 avenue Marie Curie – Forum 2 Archamps Technopole
74166 Saint-Julien-en-Genevois Cedex, France

To: The Board of Directors

Paris, on [•],

Dear Sirs and Madams,

I do hereby resign as a [chairman of the Board of Directors/director/observer] of Genkyotex, a limited liability company (*société anonyme*) organized under the laws of France with a share capital of €11,548,562, whose registered office is at 218 avenue Marie Curie – Forum 2 Archamps Technopole, 74166 Saint-Julien-en-Genevois Cedex, France and registered with the Commerce and Companies Registry under number 439 489 022 RCS Thonon-les-Bains.

This resignation will be effective as of [•] [following the meeting of the Board of Directors of Genkyotex acknowledging my resignation and appointing my successor].

Please proceed with the appropriate formalities required in connection with my resignation.

I hereby confirm that my decision to resign has been made freely. I also confirm that I have, and will have, no claim against Genkyotex or any of its subsidiaries of whatsoever nature (whether statutory, contractual or otherwise) in connection with the exercise or termination of my office as [chairman of the Board of Directors/director/observer] and that Genkyotex or any of its subsidiaries does not owe me any compensation or any other sum in connection therewith or for any reason whatsoever (other than any compensation that may be due under separate existing employment agreements or arrangements with Genkyotex).

Yours sincerely,

***[Director/Observer]**

_____

Exhibit 3.1

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

Adopted at the annual general meeting held on 25 June 2020.

1 § Name of company

The 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.

5 § 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.

6 § Auditors

The company shall have one or two (1–2) auditors and not more than two (2) alternate auditors or a registered accounting firm.

7 § 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.

8 § 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) that relates to the conditions prevailing five workdays prior to the meeting 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.

9 § 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.

10 § Financial year

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

11 § 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).

12 § 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 5.1

Stockholm, 25 January 2021

Calliditas Therapeutics AB (publ), Company Reg. No. (CVR) 556659-9766 – F-1 registration

We, Swedish law firm Advokatfirman Vinge KB, have acted as Swedish law legal advisers to Calliditas Therapeutics AB (publ) (the "**Company**") with respect to certain matters of Swedish law in connection with, *inter alia*, the registration statement on Form F-1 (File No.) initially filed with the United States Securities and Exchange Commission (the "**SEC**") on 25 January 2021 as amended, (the "**Registration Statement**"), for the registration of up to 5,175,000 new ordinary shares in the capital of the Company each with a quota value of SEK 0.04 (the "**New Shares**"), under the United States Securities Act of 1933, as amended, and the issue of the American Depositary Shares (the "**ADSs**"), each representing two New Shares, on Nasdaq Global Select Market, and the concurrent placement of New Shares to certain investors outside of the United States (together the "**Transaction**"). The ordinary shares with quota value of SEK 0.04 each in the capital of the Company shall hereinafter be defined as the "**Ordinary Shares***"*. This legal opinion is delivered to you pursuant to the Company's request.

Basis of the Opinion.—For the purpose of this Opinion we have examined the following documents:

(i) a copy of the Registration Statement;

(ii) the articles of association (Sw. *bolagsordning*) of the Company, adopted on 25 June 2020 (the "**Articles of Association**");

(iii) the certificate of incorporation (Sw. *registreringsbevis*) for the Company, issued by the Swedish Companies Registration Office (Sw. *Bolagsverket*) (the "**SCRO**"), on [7:32] p.m. CEST on [25] January 2021, showing relevant entries in the Swedish Company Registry (Sw. *bolagsregistret*) as per such date;

(iv) the minutes of the annual general meeting of the Company held on 25 June 2020; and

(v) the minutes of the meetings of the board of directors of the Company, held on [●], *inter alia,* approving the Registration Statements and the registration hereof with the SEC.

The documents mentioned in Sections (i) – (v) above are referred to as the "**Corporate Documents**" and individually a "**Corporate Document**".

Reliance.—With respect to various questions of fact, we have relied upon certificates of public officials and upon certificates issued by the SCRO. For the purposes of this opinion, we have examined such other agreements, documents and records as we have deemed necessary or appropriate for the purpose of rendering this opinion.

Assumptions.—This opinion is subject to the following nature of opinion and observations:

a) the accuracy and completeness of: the facts set out in any other documents reviewed by us; and any other information set out in public registers, e.g. certificates from the SCRO, or that has otherwise been supplied or disclosed to us; and as we have not made any independent investigation thereof you are advised to seek verification of such matters or information from other parties or seek comfort in respect thereof in other ways;

b) that the Company and its board of directors have acted in accordance with the general clause (Sw. *generalklausulen*) in the Swedish Companies Act and provisions regarding good market practice (including recommendations issued by the Swedish Corporate Governance Board) in connection with resolving to issue the New Shares;

c) that all signatures on all documents supplied to us as originals or as copies of originals are genuine and that all documents submitted to us are true, authentic and complete;

d) that all documents, authorizations, powers and authorities produced to us remain in full force and effect and have not been amended or affected by any subsequent action not disclosed to us;

e) that where a document has been examined by us in draft form, it will be or has been executed in the form of that draft, and where a number of drafts of a document have been examined by us all changes to them have been marked or otherwise drawn to our attention;

f) all documents retrieved by us or supplied to us electronically (whether in portable document format (PDF) or as scanned copies), as photocopies, facsimile copies or e-mail conformed copies are in conformity with the originals;

g) that there has been no mutual or relevant unilateral mistake of fact and that there exists no fraud or duress; and

h) at or prior to the time of the delivery of the New Shares, the payment for such New Shares will have been received by the Company.

Opinions.—Based upon and subject to the foregoing and subject to the qualifications set out below, we are of the opinion that:

a) The Company is a public limited liability company (Sw. *publikt aktiebolag*) registered and validly existing under the laws of the Kingdom of Sweden;

b) The existing Ordinary Shares have been validly authorized and constitute valid and fully paid shares;

c) Each New Share has been duly authorized, and will, upon registration with the SCRO, be validly issued and fully paid and will be non-assessable.

Qualifications.—The qualifications to which this opinion is subject are as follows:

1) we express no opinion as to the exact interpretation of any particular wording in the Corporate Documents by any court;

2) provisions in the Corporate Documents providing that certain facts, determinations or calculations will be conclusive and binding (or prima facie evidence) may not be effective if they are incorrect and such provisions will not necessarily prevent judicial inquiry into the merits of such facts, determinations or calculations;

3) this Opinion is given only with respect to the laws of the Kingdom of Sweden as in force today and as such laws are currently applied by Swedish courts and we express no opinion with respect to the laws of any other jurisdiction nor have we made any investigations as to any law other than the laws of the Kingdom of Sweden;

4) in rendering this Opinion we have relied on certain matters of information obtained from the Company and other sources reasonably believed by us to be credible;

5) the underwriting agreement, to be entered into between the Company and the underwriters of the Transaction, and this opinion are expressed in the English language whilst addressing and explaining institutions and concepts of the laws of the Kingdom of Sweden; and such institutions and concepts may be reflected in or described by the English language only imperfectly; and we express no opinion on how the courts of the Kingdom of Sweden would construe contractual language expressed in English where the contract would be subject to the laws of the Kingdom of Sweden. However, we believe that such courts may pay attention to the meaning and import of such expressions in the laws of any pertinent jurisdiction in which the English language is normally or habitually employed, in construing, for the purposes of the laws of the Kingdom of Sweden, what the parties intended to put in writing.

Governing Law.—This opinion is given in the Kingdom of Sweden and shall be governed by and construed in accordance with the laws of the Kingdom of Sweden.

Benefit of opinion.—

This Opinion is strictly limited to the matters stated herein and is not to be read as extending by implication to any other matter.

We are not assuming any obligation to notify you of any changes to this Opinion as a result of any facts or circumstances that may come to our attention in the future or as a result of any change in the laws of the Kingdom of Sweden which may hereafter occur.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and the references to this firm in the sections of the Registration Statement entitled “Legal Matters”. This consent is not to be construed as an admission that we are a party whose consent is required to be filed as part of the Registration Statement under the provisions of the Securities Act.

This opinion is addressed to you solely for your benefit in connection with the Registration Statement.

Yours faithfully,

/s/ Advokatfirman Vinge KB
Advokatfirman Vinge KB

Exhibit 10.6

Board LTIP 2020 in Calliditas Therapeutics AB (publ)

GRANT NOTICE & AGREEMENT

On 25 June 2020, the annual general meeting in Calliditas Therapeutics AB (publ) (the "**Company**") resolved to introduce a long-term performance-based incentive program for certain members of the Board of Directors ("**Board LTIP 2020**").

In summary, the resolution entails that the main owner independent 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, _____ 2020, you have, under Board LTIP 2020, 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 2020 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 2023 or (ii) 1 July 2023 (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 2020 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 2020 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 _____ 2020.

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 2020, 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 2020 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 2020 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 2020 IN CALLIDITAS THERAPEUTICS AB (PUBL)

1. Background and scope of Board LTIP 2020

At the annual general meeting in Calliditas Therapeutics AB (publ), Reg. No 556659-9766 (the ”Company” or “Calliditas”), held on 25 June 2020 (the “Annual General Meeting”), it was resolved to introduce a performance-based, long-term incentive program for certain board members in the Company (“Board LTIP 2020”). As part of Board LTIP 2020, the Company will therefore grant share awards subject to performance vesting (“Share Awards”) that entitle to not more than 40,000 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 2020 shall be awarded in accordance with the following:

- [●] Share Awards to the chairman of the board of directors; and
- [●] Share Awards to each of Diane Parks, Hilde Furberg, Lennart Hansson and Molly Henderson.

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 following 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 2023 or (ii) 1 July 2023 (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 2021)) 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 following 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.

ANSTÄLLNINGSAVTAL

Mellan Calliditas Therapeutics AB, 556659-9766, ("Bolaget"), Kungsgatan 1, 111 22 Stockholm och Katayoun Welin-Berger (Welin-Berger), personnummer 19680321-0803, Nybergagatan 18, 152 43 Södertälje, har träffat följande anställningsavtal.

1. Arbetsuppgifter, anställningsform m.m.

1.1 Welin-Berger anställs som VP Operations. Welin-Berger skall arbeta heltid i Bolaget och rapporterar till VD. Normal arbetstid är 40 timmar per vecka.

1.2 Anställningen gäller från och med den 13 januari, 2020 eller tidigare om överenskommits mellan parterna.

1.3 Welin-Berger skall utföra alla delar av sitt arbete med den skicklighet, snabbhet och omsorg som Bolaget har anledning att förvänta sig av en välrenommerad VP Operations. Arbetet skall utföras på bolagets kontor i Stockholm.

2. Lön, övertid m.m.

2.1 Welin-Berger erhåller en lön om 105 000 kr per månad. Lönen utbetalas den 25:e i intjänandemånaden. Infaller den 25:e på en helgdag utbetalas lönen närmast efterföljande vardag.

Förutom lön erhåller Welin-Berger 16,3% av månadslönen per månad i pensions och försäkringsförmån, utöver lagstiftad pension och försäkringar.

Arbetet kan medföra såväl övertid som resor i tjänsten. Welin-Berger har inte rätt till övertids- eller restidsersättning vilket skall anses ingå och vara fullt betalda genom ordinarie lön.

Sjuklön betalas i enlighet med gällande lagstiftning.

2.2 Översyn och eventuell justering av lön sker årligen per den 1 maj.

2.3 Rätt till bonus för Welin-Berger avtalas i förekommande fall i separat skriftligt avtal mellan parterna och utgör inte en del av anställningsavtalet.

3. Semester

Welin-Berger har rätt till 30 dagars betald semester per år. Betald semester intjänas på sedvanligt vis och skall uttas i överenskommelse med bolagets VD.

4. Arbetsverktyg m.m.

4.1 För utförande av Welin-Bergers arbetsuppgifter tillhandahåller Bolaget sådan utrustning som är väsentlig för arbetets utförande. För närvarande innebär detta bärbar dator och mobiltelefon.

4.2 Welin-Berger har rätt till ersättning för skäliga kostnader för representation efter godkännande av VD.

4.3 Welin-Berger skall följa Bolagets policy vad gäller utlägg och skall redovisa samtliga kvitton senast månaden efter att utläggen gjordes. Welin-Berger har inte rätt till ersättning för utlägg om inte Welin-Berger kan redovisa kvitto för utlägget.

5. Lojalitet m.m.

Welin-Berger har att vid alla tillfällen noga bevaka och tillvarata Bolagets intressen. Welin-Berger har inte rätt att utföra arbete eller, direkt eller indirekt, bedriva eller ha ekonomiskt intresse i verksamhet som konkurrerar med den verksamhet som Bolaget bedriver från tid till annan. Vidare skall Welin-Berger inte åta sig något uppdrag som till sin omfattning eller natur negativt kan påverka anställningens utövande.

6. Sekretess

Welin-Berger förbinder sig utan begränsning i tiden att inte för utomstående yppa eller för egen del utnyttja konfidentiell information rörande Bolaget, dess verksamhet, kunder eller samarbetspartner. Med "konfidentiell information" förstås i detta avtal varje uppgift - teknisk, kommersiell eller av annan art - oavsett om uppgiften dokumenterats eller inte, med undantag för uppgifter som är eller blir allmänt kända eller som kommit eller kommer till allmän kännedom på annat sätt än genom Welin-Bergers brott mot denna bestämmelse.

7. Konkurrensförbud

7.1 Parterna är överens om att Welin-Berger genom sin ställning i Bolaget kommer att ta del av företagshemligheter som inte kan skyddas genom patent eller liknande registreringsförfarande, och vars användning i konkurrerande verksamhet skulle medföra påtagligt men för Bolaget. Parterna är också överens om att det är en förutsättning för att Bolaget i förtroende ska kunna överlämna sådana uppgifter till Welin-Berger att Bolaget kan försäkra sig om att Welin-Berger inte använder de kunskaper och de kontakter som erhållits genom anställningen till att bygga upp eller verka i verksamhet som konkurrerar med Bolaget eller dess närstående bolag. Det åligger därför Welin-Berger att under Anställningsavtalets giltighetstid och under nio (9) månader från anställningens upphörande vare sig själv eller i egenskap av ägare, delägare, styrelseledamot, rådgivare eller anställd i annat bolag, vare sig direkt eller indirekt bedriva med Bolaget, eller med dess närstående bolag, konkurrerande verksamhet.

7.2 Bolaget ska – utom i de fall som nämns nedan – som ersättning för den olägenhet som gällande konkurrensförbud innebär för Welin-Berger efter anställningens upphörande, till Welin-Berger per månad i efterskott utbetala skillnaden mellan Welin-Bergers genomsnittliga månatliga ersättning från Bolaget (innefattande såväl fast lön som rörlig ersättning) under de sista 12 månaderna innan anställningens upphörande och den (lägre) inkomst, som Welin-Berger därefter intjänar, eller rimligen kunde ha intjänat i ny anställning eller annan förvärvsverksamhet. Ersättningen från Bolaget ska dock per månad aldrig överstiga sextio (60) procent av Welin-Bergers genomsnittliga månatliga ersättning enligt ovan under den period då konkurrensförbudet gäller. För det fall Welin-Berger trots skäliga åtgärder för att begränsa sin inkomstförlust inte erhåller ny anställning eller bedriver annan förvärvsverksamhet efter anställningens upphörande, utgår kompensation per månad med sextio (60) procent av Welin-Bergers genomsnittliga månatliga ersättning enligt ovan under den period då konkurrensförbudet gäller. Rätt till ersättningen från Bolaget enligt denna punkt förutsätter att det föreligger ett orsakssamband mellan Welin-Bergers åtagande om konkurrensförbud och den inkomstförlust som uppstår till följd av dess tillämpning. Ersättning utgår inte om Welin-Berger bryter mot konkurrensförbudet.

7.3 Welin-Berger ska efter anställningens upphörande fortlöpande hålla Bolaget underrättat om storleken av sina inkomster från ny arbetsgivare eller annan förvärvsverksamhet. Sådan underrättelse ska lämnas skriftligen till Bolaget senast den 15:e i varje månad. Om så inte sker förutsätts att Welin-Berger inte har drabbats av någon inkomstförlust för den månaden, utan att konkurrensbegränsningen enligt punkten 7.1 för den skull bortfaller.

7.4 Ersättning enligt denna punkt ska inte utgå för period under vilken Welin-Berger kan komma att erhålla avgångsvederlag från Bolaget eller om anställningen upphör på grund av: (i) Welin-Bergers pensionering eller (ii) hävning av Anställningsavtalet eller att Bolaget har avskedat Welin-Berger.

7.5 Såväl under anställningen som efter endera partens uppsägning av anställningen och så länge konkurrensförbudet är gällande kan Bolaget ensidigt genom meddelande till Welin-Berger begränsa tillämpningsområdet för konkurrensförbudet alternativt helt befria Welin-Berger från skyldigheten att iaktta konkurrensförbudet. För det fall Bolaget helt befriar Welin-Berger från skyldigheten att iaktta konkurrensförbudet upphör Bolagets ersättningsskyldighet enligt punkten 7.2 ovan upphör att gälla. Bolagets eventuella befrielse från konkurrensförbudet ska ges med en månads uppsägningstid

8. Anställnings- och kundförbud

8.1 Parterna är överens om, att Welin-Berger under Anställningsavtalets giltighetstid och under tolv (12) månader från anställningens upphörande inte får, vare sig personligen eller genom någon annan, ha affärsmässiga kontakter med någon person eller något bolag, som under de sista tolv månaderna före anställningens upphörande har varit kund till eller som aktivt bearbetats av Bolaget eller dess närstående bolag, i syfte att förmå sådan kund/potentiell kund att förändra, upphöra eller inte inleda en kommersiell

relation med Bolaget eller dess närstående bolag. Efter förfrågan från Welin-Berger kan dock Bolaget genom skriftlig bekräftelse i enskilda fall befria Welin-Berger från detta åtagande.

8.2 Parterna är vidare överens om, att Welin-Berger under Anställningsavtalets giltighetstid och under tolv (12) månader från anställningens upphörande inte får, vare sig personligen eller genom någon annan, anställa eller försöka anställa någon som är anställd av Bolaget eller dess närstående bolag eller utnyttja deras tjänster på annat sätt än genom Bolaget. Efter förfrågan från Welin-Berger kan dock Bolaget genom skriftlig bekräftelse i enskilda fall befria Welin-Berger från detta åtagande.

9. Tidrapportering m. fl. policies

Welin-Berger förbinder sig att följa Bolagets vid var tid gällande policy för tidredovisning, IT-säkerhet, användning av e-post och internet, resor m.m.

10. Resultat

Allt resultat, inklusive all information, data, know-how, uppfinningar eller motsvarande och samtliga därtill hörande immateriella rättigheter som ligger inom Bolagets verksamhetsområden och som uppkommer genom Welin-Bergers försorg eller medverkan under anställningstiden ("Resultat") skall omgående tillhöra Bolaget med full och oinskränkt äganderätt utan annan ersättning till Welin-Berger än ordinarie lön enligt detta Avtal. På Bolagets begäran skall Welin-Berger bekräfta överlåtelse av Resultat i separat skriftlig handling där så är lämpligt eller behövligt för tex sökande av immaterialrättsligt skydd eller genomförande av transaktion.

11. Personuppgifter

I syfte att administrera detta anställningsavtal och för att kunna utöva arbetsledning och bedriva verksamheten på ett ändamålsenligt sätt kommer Bolaget att behandla Welin-Bergers personuppgifter med hjälp av bl.a. datorer. Personuppgifterna utgörs av Welin-Berger, personnummer, telefonnummer, hemadress, övriga kontaktdetaljer, uppgifter om bankkonto, m.m. Bolaget kan även komma att publicera Welin-Bergers namn, befattning, telefonnummer, e-postadress samt ett foto på Welin-Berger på Bolagets hemsida.

Welin-Berger lämnar härmed sitt godkännande till Bolagets behandling av Welin-Bergers personuppgifter enligt ovan.

12. Uppsägning

12.1 Ömsesidig uppsägningstid om 3 månader tillämpas.

12.2 Vid anställningens upphörande skall Welin-Berger till Bolaget överlämna allt Bolaget tillhörigt material och egendom som Welin-Berger har i sin besittning eller annars ansvarar för. Detta gäller bland annat nycklar, handlingar och dokument (såväl i pappersform som digitala), dator, mobiltelefon, mjukvara etc.

13. Vite

Skulle Welin-Berger bryta mot bestämmelserna i artikel 5, 6, 8 och 10 skall bolaget utöver skadestånd för faktisk skada även vara berättigat att för varje överträdelse erhålla vite om minst tre månadslöner.

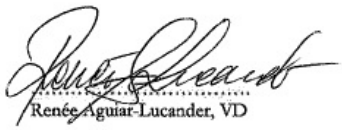
14. Lag

Svensk lag skall tillämpas på detta avtal.

Detta avtal har upprättats i två likalydande exemplar, av vilka parterna tagit var sitt.

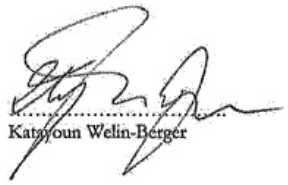
Stockholm den 17/9 2019

Calliditas Therapeutics AB



Renée Aguiar-Lucander, VD

Stockholm den 17/9 2019



Katayoun Welin-Berger

Exhibit 10.14

CONTRACT OF EMPLOYMENT

PRIVATE AND CONFIDENTIAL

CHIEF MEDICAL OFFICER

To: Richard Philipson ("**the Employee**")

Of: 18 Ridley Avenue, London W13 9XW

D.O.B: 6th January 1964

N.I No: NB 78 09 63 A

From: Calliditas Therapeutics AB, 556659-9766 ("**the Company**")

Of: Kungsborn 1, C8

SE-111 22 Stockholm

Date: March 26, 2020

Welcome to Calliditas Therapeutics AB.

This contract sets out your main terms and conditions of employment with the Company unless otherwise agreed in writing. This contract supersedes any previous agreements (including any custom and practice) and shall prevail in the event of any inconsistency of terms.

In respect of new employees, employment is conditional upon the receipt of written references satisfactory to the Company and, if considered appropriate after appointment, a medical assessment satisfactory to the Company. It may also be subject to the provision of proof of academic and/or professional qualifications, work status and identity.

Given the nature and seniority of your position, you will be expected to strictly comply with your express and implied terms and conditions of employment. In particular, you must ensure that you do not breach the implied duties of trust and confidence, fidelity, transparency and integrity or conduct yourself in a manner which is inconsistent or prejudicial to the interests of the Company. This is a condition of your employment.

By signing this Contract of Employment, or in the alternative continuing to work after these terms and conditions have been issued to you, (under protest or otherwise) you agree to the terms and conditions stated below and shall be bound by these terms.

Your terms and conditions of employment include the following:

1. COMMENCEMENT OF EMPLOYMENT

1.1. This employment contract shall commence on September 20, 2020, or earlier if mutually agreed upon, and shall continue until it is terminated in accordance with clause 12 of this contract.

1.2. Your continuous employment began on September 20, 2020, or earlier if mutually agreed upon, and it is agreed that there is no period of previous continuous employment with the Company.

2. JOB TITLE AND DUTIES

2.1. Your job title is Chief Medical Officer and you report to the Company's CEO.

2.2. Your normal duties will be outlined by the CEO and confirmed in a job description which will be provided to you. Flexibility is a condition of your employment. Accordingly, in addition to your normal duties, you may be expected to carry out additional or alternative duties for the Company as the Company may from time to time reasonably require. Your job content and duties may change from time to time according to the requirements of the Company, our business and the sectors in which the Company operates. The Company, therefore, reserves the right, upon giving as much notice as is reasonably practicable to require you to undertake alternative duties upon either a temporary or a permanent basis which, in the Company's reasonable opinion, fall within your capabilities.

2.3. You shall during your employment devote during your working hours the whole of your time, attention, ability and skills to your duties of employment and at all times comply with the reasonable directions and requests of the Company.

2.4. It is a condition of your employment that, apart from your work within the Company, you do not engage in any other employment or engage in any profession, trade or business, directly or indirectly (including any preparatory activity), without the Company's prior consent.

3. PLACE OF WORK

3.1. Your principal place of employment shall be your home address, 18 Ridley Avenue, London W13 9XW.

3.2. You will be required to travel to the Company's headquarters in Sweden on a regular basis.

3.3. You agree to travel upon the Company's business as may be required for the proper performance of your duties.

4. NORMAL HOURS OF WORK

4.1. Your normal hours of work are 40 hours per week, working Monday — Friday.

4.2. It is expected that you will be able to perform your duties in your normal working hours, however you will be required to work any additional hours to ensure the proper performance of your duties.

4.3. If you are unable to work, you must inform the CEO prior to commencing work and make up the time during the day. If you fail to follow this procedure, you may be subject to disciplinary action, and the Company reserves the right to make deductions from your pay.

4.4. The Company may temporarily or permanently alter the above working hours to take account of business needs and service requirements. You agree to vary your hours and/or working pattern in response to the operational needs of the business and accept that this requirement is a condition of your employment. No variation to working hours will be made without prior consultation and wherever possible consideration of individual circumstances.

4.5. By your signature to this statement, you:

4.5.1. acknowledge that you may be required to work in excess of an average of 48 hours per week in any one period of 17 calendar weeks and consent to do so if so requested by the Company or otherwise necessary for the fulfilment of your duties. You may withdraw such consent by giving no less than 3 months prior notice in writing to the Company of such withdrawal; and

4.5.2. confirm that you do not undertake any other work for any other Company and undertake to seek the consent of the Company before undertaking work for any other Company.

5. SALARY

5.1. Your basic rate of pay will be £240,000 per annum payable by monthly payments in arrears by bank transfer on 25th of each month. If the 25th falls on a weekend or a bank holiday, you will be paid on the following week day. Salary shall be deemed to accrue from day to day.

5.2. You shall receive a net salary after deduction of National Insurance Contributions and Income Tax. Any deductions will be notified to you.

5.3. Your salary shall be reviewed from time to time, usually annually on 1 May, however there is no obligation to award an increase. Where an increase is awarded, this will be entirely at the Company's discretion.

5.4. There will be no review of salary after notice has been given by either party to terminate the employment.

5.5. The Company reserves the right to alter its pay frequency, or the date when payment is made, or the method of payment upon giving reasonable notice.

5.6. In exceptional circumstances it may be necessary to make deductions from your salary or other benefits due to you. By your signature to this contract, you authorise the Company to make deductions from any salary or other payment due to you, (including any payment upon termination of your employment) in respect of any sums the Company considers due from you to the Company, including repayment of any loans, advances, repayable expenses, excess holiday pay, course fees, overpayment of salary, unauthorised expenditure (including Company credit or fuel cards), expenses or other benefits due to you or any direct loss caused to the Company or the Company's clients' property or vehicles which in the Company's reasonable opinion is malicious, intentional, negligent or reckless, breach of authority or Company operating rules. The Company will generally not make deductions without notifying you in writing as to the amounts deducted and reasons for deduction.

6. EXPENSES

6.1. The Company shall reimburse (or procure the reimbursement of) all reasonable expenses wholly, properly and necessarily incurred by you in the course of your appointment, subject to production of receipts or other appropriate evidence of payment.

6.2. Expenses such as international travel, conference attendance and significant expenses must be authorised by the CEO, in advance of these being incurred.

6.3. You shall abide by the Company's policies on expenses as contained within the Personnel Handbook or communicated to you by general staff notice.

7. BENEFITS

7.1. Bonus

7.1.1. The Company may, in its absolute discretion, pay the Employee a bonus of such amount, at such intervals and subject to such conditions as the Company may in its absolute discretion determine from time to time. Any bonus will be agreed in a separate written agreement between the parties.

7.1.2. Any bonus payment to the Employee shall be entirely discretionary and shall not form part of the Employee's contractual remuneration under this contract. If the Company makes a bonus payment to the Employee it shall not be obliged to make subsequent bonus payments and shall not constitute a custom or practice.

7.1.3. Notwithstanding clause 7.1, the Employee shall in any event have no right to a bonus or a time-apportioned bonus if their employment terminates for any reason or the Employee is under notice of termination (whether given by the Employee or the Company) at or prior to the date when a bonus might otherwise have been payable.

7.1.4. Any bonus payment shall not be pensionable.

7.2. Mobile Telephone

7.2.1. You may be provided with a mobile telephone to assist you to perform your duties. The Company will pay the line rental and the costs of business telephone calls.

7.2.2. You are permitted reasonable use of the mobile telephone for personal purposes. Where the Company reasonably considers the level of personal calls to be unreasonable, you will be notified of this and you will be responsible for paying the excess costs, normally by deduction from your pay unless you agree an alternative method with the CEO.

7.3. Laptop

7.3.1. You may be provided with a laptop to assist you to perform your duties only. This remains the property of the Company at all times and upon termination of this contract for whatsoever reason it must be returned. immediately.

7.4. Professional Registrations & Subscriptions

7.4.1. The Company will pay the costs for the following:

7.4.1.1. General Medical Council Annual Registration

7.4.1.2. Medical Defence Union Annual Subscription

7.4.1.3. Annual Appraisal for Revalidation Fee

7.4.1.4. Faculty of Pharmaceutical Medicine Fellowship

7.4.1.5. Royal College of Physicians Membership

8. HOLIDAY ENTITLEMENT

8.1. The Company's holiday year runs from January — December ("the Holiday Year"). The Company adheres to the Working Time Regulations in respect of annual leave.

8.2. Full-time employees are entitled to 25 days holiday per year calculated at the rate of 1/52nd of the annual entitlement for each complete week of service ("Basic Leave").

8.3. In addition to Basic Leave full time employees are also entitled to eight public holidays each year, and will be advised of the relevant dates as early as possible. The public holidays that are recognised are as follows:

New Years Day	Good Friday	Easter Monday
May Day	Spring Bank Holiday Monday	Late Summer Bank Holiday
Christmas Day	Boxing Day	

8.4. Where you are expected to work a public holiday, you will be permitted to take that day's annual leave at another point within the current holiday year.

8.5. Where a recognised public holiday falls on a Saturday or a Sunday, alternative dates will be substituted for these. Employees will be advised of these as early as possible.

8.6. All holiday pay will be calculated at your basic rate of pay only and will be subject to normal deductions. Any variations in your basic rate of pay will also be inclusive in calculating your holiday pay including bonus payments.

8.7. Any holiday not taken during the Holiday Year cannot be carried forward to the following Holiday Year and no payment in lieu of untaken holiday or increase in your holiday entitlement in any subsequent year will be made except at the absolute discretion of the Company.

8.8. If, on termination of employment, you have taken more annual holiday entitlement than you have accrued in that holiday year, an appropriate deduction will be made from your final payment.

8.9. Where several employees require the same holiday period, which if granted would impair Company efficiency, the Company will grant holidays upon a 'first come first served' basis.

8.10. During periods of incapacity, you will continue to accrue holiday leave at the normal rate. If there is not enough time left in the current holiday year to make it practicable to take your holiday entitlement which you have been prevented from taking due to sickness, you can carry over up to four weeks' unused holiday entitlement to the following leave year to be used within three months of your return to work. Any annual leave not taken within 18 months of the end of the holiday year in which it accrues (whether or not you have returned to work) will be lost.

8.11. If you fall ill either before or during a period of pre-booked annual leave, you may reschedule that period of holiday for a later date within the current holiday year. If you wish to rearrange a period of annual leave due to sickness or incapacity, you should notify the CEO as soon as possible but no later than one week after the first day of sickness absence.

8.12. Further rules relating to the Company holiday rules can be found in the Personnel Handbook. You are advised to familiarise yourself with these before making an annual leave request.

9. SICKNESS AND SICKPAY

9.1. If you are going to be absent from work due to incapacity or illness, you should ensure that you have notified the CEO no later than 10am UK time. You should inform the CEO of details of the nature of your illness or injury, the expected length of your absence from work, any contact details and any outstanding or urgent work that requires attention.

9.2. For sickness absence of up to seven calendar days, you must telephone the CEO each day to keep them updated. You must complete a self-certification form and return this.

9.3. Failure to report your absence and provide the requisite evidence as set out above, will be considered unauthorised absence and will be unpaid. In addition, unauthorised absence is a disciplinary offence warranting disciplinary action up to and including dismissal without notice.

9.4. For sickness absence of more than a week you must obtain a certificate from your doctor stating that you are not fit for work and the reasons why. This should be forwarded on to the CEO as soon as possible. If your absence continues, further medical certificates must be provided to cover the whole period of absence.

9.5. During authorised absence due to sickness or injury, you will be entitled to receive Statutory Sick Pay (SSP) from the Company. Rules relating to SSP are outlined in the Company Sickness Absence Policy within the Personnel Handbook.

9.6. In addition to SSP, you are entitled to receive the following enhancement of sick pay:

1 month full pay

1 month 50% of pay

9.7. Any payment made in excess of Statutory Sick Pay will be inclusive of the current SSP rate.

9.8. If the incapacity is or appears to be occasioned by actionable negligence, nuisance or breach of any statutory duty on the part of a third party in respect of which damages are or may be recoverable, the Employee shall immediately notify the Company of that fact and of any claim, compromise, settlement or judgment made or awarded in connection with it. The Employee shall, if required, refund to the Company that part of any damages or compensation recovered by him/her relating to the loss of earnings for the period of the incapacity, less any costs borne by him/her in connection with the recovery of such damages or compensation, provided that the amount to be refunded shall not exceed the total amount paid to the Employee by the Company in respect of the period of Incapacity.

9.9. Further rules relating to sickness, sick pay and the Company absence policies and procedures can be found in the Personnel Handbook.

10. PENSION

10.1. The Company will comply with the employer pension duties in respect of the Employee in accordance with Part 1 of the Pensions Act 2008.

10.2. You will become an active member of our occupational pension scheme **(Scheme)** (or such other registered pension scheme as we may establish to replace the Scheme) subject to the rules of the Scheme and the tax reliefs and exemptions available from HM Revenue & Customs, in both cases as amended from time to time. The Company will contribute £10,000 per year to this Scheme.

11. RETIREMENT

11.1. There is no fixed retirement age associated with your position. Your retirement age shall solely be determined by you at any point during your employment. If you wish to retire, you should advise the CEO as soon as possible, providing the minimum notice as required by this contract.

12. TERMINATION OF EMPLOYMENT

12.1. Both parties are required to give 6 months written notice of termination.

12.2. The Company reserves the right to make payment in lieu of notice. Any payment In lieu of notice shall be limited to your basic rate of pay only.

12.3. Should you leave without notice or during the notice period without the Company's consent, the Company reserves the right to deduct pay for time not worked during the notice period. This clause is taken to be authority given by you that the Company shall have such contractual right to deduct such sums from your final payment of salary.

13. GARDEN LEAVE

13.1. After you have given or received notice to terminate your employment:

13.1.1. The Company will be under no obligation to give you any powers or duties, or provide work for you. The Company may, in its discretion vary, or suspend you from, the performance of your duties, exclude from its premises, or require you to perform your duties at home for a period not exceeding 6 months, in which case all other provisions of this contract shall continue in force.

13.1.2. The Company may require you to return all Company property in your possession or control including any Company vehicle (without compensation) and to resign from any positions held by you as part of your duties.

13.1.3. The Company may require you to not, either directly or indirectly, contact the Company's clients, customers, suppliers or employees until your employment ends.

14. COLLECTIVE AGREEMENTS

14.1. There are no collective agreements which affect your terms and conditions of employment

15. RESTRICTIVE COVENANTS

15.1. The parties agree that through your position in the Company, you may disclose corporate secrets that cannot be protected by patents or similar registration procedures, and whose use in competing activities would result in significant loss for the Company. The parties also agree that it is a prerequisite for the Company, in confidence, to submit such information to you in order that the Company can ensure that you do not use the knowledge and contacts obtained through the employment to build or operate in operations that compete with the Company or its affiliates. It is therefore incumbent upon you to, during the term of the Employment Agreement and for nine (9) months from termination of employment, either yourself or as owner, partner, board member, adviser or employee of another company, either directly or indirectly with the Company, or with its affiliates, in competing operations.

15.2. Except in the cases mentioned below, the Company shall pay you a monthly payment in arrears, as compensation for the inconvenience of the competitive prohibition on competition. The compensation shall be calculated as the difference of the income that you subsequently earn, or could reasonably have eamt in a new employment or other employment, and the average compensation received (including both fixed salary and variable remuneration) in the last 12 months before termination of employment. However, the remuneration from the Company shall never exceed sixty (60) percent per month of your average monthly remuneration per month during the period when the prohibition on competition applies. In the event that you, despite reasonable measures to limit its loss of income, do not receive new employment or engage in other employment activities after termination of employment, compensation is paid monthly by sixty (60) percent of your average monthly compensation as set out above during the period of the competitive ban. The right to compensation from the Company in accordance with this paragraph assumes that there is a causal link between your commitment to prohibit competition and the loss of income arising from its application. Compensation is not paid if you violate the prohibition on competition.

15.3. After the termination of employment, you shall keep the Company informed of the size of its income from new employers or other business activities. Such notification shall be made in writing to the Company no later than the 15th of each month. If this does not happen, it is assumed that you have not suffered any loss of income for that month, without the restriction of competition according to point 15.1, for that reason.

15.4. Compensation under this paragraph shall not be paid for the period during which you may receive severance pay from the Company or if the employment terminates due to: (i) your retirement or (ii) cancellation of the Employment Agreement or the Company has terminated you.

15.5. Both during the employment and after either party's termination of employment and as long as the prohibition on competition is in force, the Company can unilaterally, through notification to you, limit the scope of the prohibition on competition or completely free you from the obligation to comply with the prohibition on competition. In the event that the Company completely exempts you from the obligation to comply with the prohibition on competition, the Company's liability under paragraph 15.2 above shall cease to apply. The company's possible exemption from the competition ban must be given with one month's notice period.

15.6. The parties agree that during the term of employment of the Employment Agreement and for twelve (12) months from termination of employment, you must not have, in person or through any other, business contacts with any person or company, which during the last twelve months prior to the employment cessation has been a customer of, or actively processed by, the Company or its affiliated companies, with the aim of causing such customer / potential customer to change, terminate or not enter into a commercial relationship with the Company or its affiliates. However, upon request from you, the Company may, in written confirmation, in individual cases release you from this undertaking.

15.7. The parties further agree that during the term of the Employment Agreement and for twelve (12) months from termination of employment, you may not employ, either personally or through any other person, any person employed or employed by the Company or its affiliates or utilize their services other than through the Company. However, upon request from you, the Company may, in written confirmation, in individual cases release you from this undertaking.

16. CONFIDENTIALITY

16.1. Without prejudice to their common law duties, the employee shall not (except in the proper course of his duties, as authorised or required by law or as authorised by the Board, either during Employment or at any time after Termination (however arising):

16.1.1. Use any Confidential Information; or

16.1.2. Make or use any Copies; or

16.1.3. Disclose any Confidential Information to any person, company or other organisation whatsoever.

16.2. The restriction in clause 16 does not apply to any Confidential information which is in or comes into the public domain other than through the Employee's unauthorised disclosure.

16.3. The Employee shall be responsible for protecting the confidentiality of the Confidential Information and shall:

16.3.1. Use their best endeavours to prevent the use or communication of any Confidential Information by any person, company or organisation (except in the proper course of their duties, as required by law or as authorised by the Board; and

16.3.2. Inform the Board immediately on becoming aware, or suspecting, that any such person, company or organisation knows or has used any Confidential Information.

16.4. Any Confidential Information and copies, including all material belonging to the Company and that which you have produced during the course of your Employment, shall be the property of the Company on Termination, or at the request of the Board at any time during Employment with the Company, the Employee shall:

16.4.1. Hand over all Confidential Information or copies to the Company;

16.4.2. Irretrievably delete any Confidential Information (including any copies) stored on any magnetic or optical disk or memory, including personal computer networks, personal e-mail accounts or personal accounts on websites and all matter derived from such sources which is in their possession or under their control outside the Company's premises; and

16.4.3. Provide a signed statement that they have complied fully with their obligations under this clause.

16.5. You agree to return all confidential information immediately upon termination, including material belonging to the Company, and that which you have produced during the course of your employment.

16.6. Nothing in this clause 16 shall prevent the Employee from making a protected disclosure within the meaning of section 43A of the Employment Rights Act 1996.

17. INTELLECTUAL PROPERTY

17.1. The definitions in this clause apply in this agreement.

Appointment: the employment of you by the Company on the terms of this contract.

Intellectual Property Rights: patents, rights to inventions, copyright and related rights, trademarks, trade names and domain names, rights in get-up, goodwill and the right to sue for passing off or unfair competition, rights in designs, rights in computer software, database rights, rights to preserve the confidentiality of information (including know-hoe and trade secrets) and any other intellectual property rights, in each case whether registered or unregisters and including all applications (or rights to apply) for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights and forms of protection which may now or in the future subsist in any part of the world.

Inventions: inventions, ideas and improvements, whether or not patentable, and whether or not recorded in any medium.

17.2. You shall give the Company full written details of all inventions and of all works embodying Intellectual Property Rights made wholly or partially by you at any time during the course of the Appointment which relate to, or are reasonably capable of being used in, the business of the Company. You acknowledge that all Intellectual Property Rights subsisting (or which may in the future subsist) in all such Inventions and works shall automatically, on creation, vest in the Company absolutely. To the extent that they do not vest automatically, you hold them on trust for the Company. You agree promptly to execute all documents and do all acts as may, in the opinion of the Company, be necessary to give effect to this clause.

17.3. You hereby irrevocably waive all moral rights under the Copyright, Designs and Patents Act 1988 (and all similar rights in other jurisdictions) which you have or will have in any existing or future works referred to in this clause.

17.4. You irrevocably appoint the Company to be your attorney in your name and on your behalf to execute documents, use your name and do all things which are necessary or desirable for the Company to obtain for itself or its nominee the full benefit of this clause.

18. DISCIPLINARY & GRIEVANCE

18.1. Your attention is drawn to the disciplinary and grievance procedures applicable to your employment, which are available from the CEO and stated in the Personnel Handbook. These procedures do not form part of your contract of employment and are intended for guidance only. The Company disciplinary rules are however terms and conditions of your employment.

18.2. We reserve the right to suspend you with pay for a reasonable period for the purposes of investigating any allegation of misconduct or neglect against you. Suspension under these circumstances is a neutral act and does not infer any assumption of guilt.

18.3. In exceptional circumstances, suspension from work without pay for an appropriate period of time may be considered at the conclusion of any disciplinary process as an alternative to dismissal.

18.4. In some cases as an alternative to issuing a formal written warning or as an alternative to dismissal, the Company reserves the right to demote you for such period as is necessary to enable you to reach the desired standards. This will be done by notice in writing to you. The Company also reserves the right to impose a reduction in your pay for the period of demotion and the written notice will detail any changes to your terms and conditions of employment arising from such demotion. In particular, the notice will give details of any reduction to your salary and / or loss of benefits arising from the demotion.

19. HEALTH & SAFETY

19.1. You have a duty whilst at work to take reasonable care for the health and safety of yourself and of other persons who may be affected by your acts or omissions. You also have a duty to co-operate with the Company in complying with any statutory duty or requirements concerning health and safety at work.

19.2. As regards to any duty or requirement imposed on the Company or any other person by or under any of the relevant statutory provisions, you must co-operate with the Company so far as is necessary to enable that duty or requirement to be performed or complied with.

19.3. You must at all times use any safety equipment provided by the Company and must adopt a safe and correct practice to all work done by you. You must comply with the Company's Health and Safety Policy from time to time In force. You should note that it may be a criminal offence for you not to wear or use safety equipment that has been provided for your safety.

19.4. You are responsible for acquainting yourself with all the health and safety and fire procedures. In the event you are unclear or unsure or have any genuine safety concerns or observations then you must report these to the CEO immediately.

19.5. Any failure to comply with any of these health and safety requirements may lead to disciplinary action being taken against you.

20. DATA PROTECTION (GDPR)

20.1. Employee's personal data - The Company will collect and process information relating to you in accordance with the privacy notice. You required to sign and date the privacy notice provided to you, and return the same to the CEO with a signed copy of this contract.

20.2. Employee's responsibilities when handling personal data — You shall comply with the GDPR Data Protection policy when handling personal data in the course of employment including personal data relating to any employee, customer, client, supplier or agent of the Company. You will also comply with the Company's IT and Communications Systems Policy and Social Media Policy.

20.3. Failure to comply with the GDPR Data Protection Policy or any of the policies listed above in clause 20.2 may be dealt with under our disciplinary procedure and, in serious cases, may be treated as gross misconduct leading to summary dismissal.

21. MONITORING

21.1. The Company's systems enable the Company to monitor telephone, email, voicemail, intemet and other communications. In order to carry out its legal obligations as an employer (such as ensuring the Employee's compliance with the Company's IT related policies), and for other business reasons, the Company may monitor use of systems including the telephone and computer systems, and any personal use of them, by automated software or otherwise. Monitoring is only carried out to the extent permitted or as required by law and as necessary and justifiable for business purposes.

22. WARRANTY

22.1. You warrant that you have the right to work in the UK and further agree to immediately notify the Company should there be any change in your circumstances which may affect your right to work in the UK. The Company reserves the right to terminate your employment (with or without notice, as appropriate) should your right to work in the UK be withdrawn. Any misrepresentation of your employment status is a serious disciplinary offence which may result in your summary dismissal.

22.2. You represent and warrant to us that, by entering into this agreement or performing any of their obligations under it, you will not be in breach of any court order or any express or implied terms of any contract or other obligation binding on them and undertake to indemnify us against any claims, costs, damages, liabilities or expenses which we may incur as a result if you are in breach of any such obligations.

23. TERMINATION WITHOUT PREJUDICE

23.1. Any termination of the employment of the Employee will be without prejudice to your continuing obligations under this contract.

24. DUTIES ON TERMINATION

24.1. Promptly deliver up to the Company all Company property, including but not limited to any mobile phone, laptop, documents, records, manuals, computer files or software, visual or audio tapes or other materials containing information (including, without limitation, confidential information) relating to the Company's business created by, in the possession of, or under the control of you.

25. ALTERATION OF TERMS AND CONDITIONS

25.1. The Company reserves the right to make any reasonable changes to the terms and conditions of employment set out in this document from time to time if this shall be deemed necessary for the Company's business and/or efficiency. This will normally be undertaken through consultation and providing employees with as much notice as possible.

25.2. Whilst the Company will only alter such terms out of necessity in order to safeguard, promote, maintain or operate more efficiently in response to business needs, it shall consult and consider all reasonable objections by the employees.

25.3. You will be notified of minor changes of detail by way of a general notice to all employees and any such changes take effect from the date of such notice.

26. ENTIRE UNDERSTANDING

26.1. Except as otherwise expressly provided by its terms, this contract represents the entire understanding and supersedes any previous agreement between the parties in relation to the employment of you by the Company.

26.2. This contract should be read in conjunction with the Personnel Handbook which gives further details on the rules, regulations and guidelines of the Company.

27. JURISDICTION

27.1. This contract and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

28. ACCEPTANCE

28.1. I acknowledge that I have carefully considered the above terms and conditions and acknowledge that I fully understand the stated terms and in particular the stated conditions and agree to be contractually bound by them.

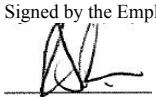
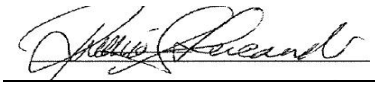
Signed by the Employee	Signed on behalf of the Company
	
Richard Philipson R S Philipson	Renee Aguir-Lucander, CEO
Date: 26 MAR 2020	Date

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated February 28, 2020, in the Registration Statement (Form F-1) and related Prospectus of Calliditas Therapeutics AB dated January 26, 2021.

/s/ Ernst & Young AB
Stockholm, Sweden
January 26, 2021

Exhibit 23.2

Consent of Independent Auditors

We consent to the use of our report dated January 25, 2021, with respect to the consolidated statements of financial position of Genkyotex S.A and its subsidiary as of September 30, 2020 and December 31, 2019 and the related consolidated income statements, consolidated statements of comprehensive income (loss), statements of changes in consolidated shareholders' equity and consolidated statements of cash flows for the nine month period ended September 30, 2020 and the year ended December 31, 2019, and the related notes to the consolidated financial statements, included in Calliditas Therapeutics AB's Registration Statement on Form F-1 and to the reference to our firm under the heading "Experts" in the prospectus.

Our report dated January 25, 2021 expresses a qualified opinion and includes a Basis for Qualified Opinion paragraph stating that as disclosed in Note 2.1 to the consolidated financial statements, the consolidated financial statements have been prepared to meet the reporting requirements of Rule 3-05 of Regulation S-X for purposes of a filing with the U.S. Securities and Exchange Commission and do not include comparative financial information as required by IAS 1 "Presentation of Financial Statements".

Lyon, France

January 26, 2021

KPMG Audit

Division of KPMG S.A.

Stephane Devin	Bertrand Roussel
Partner	*Partner*