
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the month of May 2021

(Commission File No. 001-39308)

CALLIDITAS THERAPEUTICS AB

(Translation of registrant's name into English)

Kungsbron 1, C8

SE-111 22

Stockholm, Sweden

(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Company Announcement and Interim Report

On May 18, 2021, the Company announced its unaudited results for the three months ended March 31, 2021, which are further described in the Company's Interim Report January 1 – March 31, 2021, copies of which are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated by reference herein.

EXHIBIT INDEX

Exhibit	Description
99.1	Company Announcement dated May 18, 2021
99.2	Interim Report – January 1 – March 31, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CALLIDITAS THERAPEUTICS AB

Date: May 18, 2021

By: /s/ Fredrik Johansson
Fredrik Johansson
Chief Financial Officer



Stockholm, Sweden

May 18, 2021

Interim Report Q1, 2021

Filing of New Drug Application submission to the FDA

“Following the positive top line readout of our pivotal Phase 3 trial NefIgArd, which met both the primary and key secondary endpoints with results being statistically significant and clinically relevant we commenced the regulatory filing process which ultimately resulted in the timely filing of the submission to the FDA in Q1 as planned. In April, we received the response from the Food and Drug Administration (FDA) who accepted the submission and granted Priority Review for the New Drug Application (NDA) for Nefecon. The FDA have set a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021. During Q1, we also submitted a request for accelerated assessment to the EMA, which was granted on April 23rd. These grants reflect the perceived unmet medical need in IgAN by regulators and, in my view, also the strength and overall quality of our dossier.

In Q1, we also reported positive data from the Phase 1 study of setanaxib, our lead compound in our NOX inhibition pipeline, paving the way for the use of higher dosing in the pivotal Phase 2/3 study in PBC. We also hosted an R&D day in January where we laid out the clinical development strategy for the year, presenting the plans for our PBC study as well as the Phase 2b proof of concept study in head and neck cancer, both slated to start in the second half of 2021. The substantial preclinical work that has been generated shows compelling data regarding setanaxib’s impact on CAF (cancer associated fibroblasts), paving the way for a significantly improved reach of checkpoint inhibitors.

We also significantly built our US team during the quarter, adding a Head of Marketing, VP Medical Affairs and Head of Sales. We will continue to build our team in order to be ready to commercialize in Q4, if approved.”

Renée Aguiar-Lucander, CEO

Summary of Q1 2021

January 1 – March 31, 2021

- No net sales for the three months ended March 31, 2021 were recognized. For the three months ended March 31, 2020 net sales amounted to SEK 0.5 million.
 - Operating loss amounted to SEK 150.8 million and SEK 72.3 million for the three months ended March 31, 2021 and 2020, respectively.
 - Loss before income tax amounted to SEK 136.2 million and SEK 63.7 million for the three months ended March 31, 2021 and 2020, respectively.
 - Loss per share before and after dilution amounted to SEK 2.51 and SEK 1.65, for the three months ended March 31, 2021 and 2020, respectively.
 - Cash amounted to SEK 867.3 million and SEK 728.6 million as of March 31, 2021 and 2020, respectively.
-

Significant events during Q1 2021, in summary

- In January 2021, Calliditas announced a positive readout of the Phase 1 study with setanaxib, which enables clinical trials with higher dosing levels.
- In January 2021, Calliditas shared the clinical development plan for setanaxib, including planned trials in Primary biliary cholangitis (PBC) and head and neck cancer, and additional data from Part A of NeflgArd study at its R&D Day.
- In March 2021, Calliditas announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Nefecon in patients with primary IgA Nephropathy (IgAN).

Significant events after the end of reporting period, in summary

- In April 2021, Calliditas was granted accelerated assessment procedure by the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP) reducing the maximum timeframe for review of the application for marketing authorization. If approved, Nefecon could be available to patients in Europe in first half of 2022.
- In April 2021, Calliditas announced that the FDA accepted the submission and granted Priority Review for the NDA for Nefecon. The FDA have set a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021. Subject to approval, this would enable commercialization of Nefecon in the US in Q4, 2021.

Investor presentation May 18, 14:30 CET

Audio cast with teleconference, Q1 2021, May 18, 2021, 14:30 (Europe/Stockholm)

Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q1-2021>

Teleconference: SE: +46850558366 UK: + 443333009271 US: 18335268381

Financial calendar

Interim Report for the period January 1 – June 30, 2021

August 19, 2021

Interim Report for the period January 1 – September 30, 2021

November 18, 2021

Year-end Report for the period January 1 – December 31, 2021

February 24, 2022

For further information, please contact:

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Telephone: +46 703 11 99 60

The information was submitted for publication, through the agency of the contact persons set out above, at 07:00 CET on May 18, 2021.

About Calliditas Therapeutics

Calliditas Therapeutics is a biopharma company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of adults with the autoimmune renal disease primary IgA nephropathy (IgAN), for which there is a high unmet medical need and there are no approved treatments. Calliditas has recently read out topline data from Part A of its global Phase 3 study in IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is also planning to start clinical trials with NOX inhibitors in primary biliary cholangitis and head and neck cancer. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.



CALLIDITAS THERAPEUTICS AB (publ)

Interim Report January 1 – March 31, 2021

Filing of New Drug Application submission to the FDA

Key Figures

January 1 – March 31, 2021

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- Loss before income tax amounted to SEK 136.2 million and SEK 63.7 million for the three months ended March 31, 2021 and 2020, respectively.
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- Cash amounted to SEK 867.3 million and SEK 728.6 million as of March 31, 2021 and 2020, respectively.

Significant events during the period January 1 – March 31, 2021, in summary

- In January 2021, Calliditas announced a positive readout of the Phase 1 study with setanaxib, which enables clinical trials with higher dosing levels.
- In January 2021, Calliditas shared the clinical development plan for setanaxib, including planned trials in Primary biliary cholangitis (PBC) and head and neck cancer, and additional data from Part A of NeflgArd study at its R&D Day.
- In March 2021, Calliditas announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Nefecon in patients with primary IgA Nephropathy (IgAN).

Significant events after the reporting period, in summary

- In April 2021, Calliditas was granted accelerated assessment procedure by the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP) reducing the maximum timeframe for review of the application for marketing authorization. If approved, Nefecon could be available to patients in Europe in first half of 2022.
- In April 2021, Calliditas announced that the FDA accepted the submission and granted Priority Review for the NDA for Nefecon. The FDA have set a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021. Subject to approval, this would enable commercialisation of Nefecon in the US in Q4, 2021.

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Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q1-2021>

Teleconference: SE: +46850558366 UK: + 443333009271 US: 18335268381

CEO Statement

Regulatory filings



Following the positive top line readout of our pivotal Phase 3 trial NefIgArd, which met both the primary and key secondary endpoints with results being statistically significant and clinically relevant (proteinuria showing a 31% reduction versus baseline and eGFR being stabilised in the treated patient population at 9 months), we commenced the regulatory filing process. As a result of these positive results the company took on the enormous task of collating, reviewing and analysing the vast amount of information and data collected from over 10 years of clinical development. Assembling a regulatory file reminds one of a military exercise where every piece has a function, and each function is a critical piece. It is truly a test of how well all the various areas of expertise within the company are interconnected and reflects the importance of alignment and efficient communication between the clinical, CMC and regulatory teams, just to mention a few.

I was incredibly impressed and proud of the discipline and teamwork exhibited by everybody on the submission team, which ultimately resulted in the timely filing of the submission to the FDA in Q1 as planned. Everybody worked tirelessly for months to generate the best possible file for submission, expertly guided by our regulatory team. The work product produced over this period was enormous, considering that the number of A4 pages which ultimately made it into the submission dossier exceeded 75,000! We filed with the FDA on March 15, 2021 and were subsequently granted priority review on April 27. During Q1, we also submitted a request for accelerated assessment to the EMA, which was granted on April 23rd. These grants reflect the perceived unmet medical need in IgAN by regulators and, in my view, also the strength and overall quality of our dossier.

We are looking forward to interacting with the regulatory agencies over the next several months, with the goal of achieving approval of Nefecon as the first approved treatment for IgAN, thereby providing patients with a medication that is specifically designed to target the origin of the disease and that can stabilize eGFR. Nefecon provides hope for patients that there will be a medication available which holds the promise of stopping the decline of their kidney function and hopefully helping to keep them out of dialysis and transplantation. It is truly exciting to be leading the field globally in this indication after many years of development and collaboration within the area of nephrology.

In Q1, we also reported positive data from the Phase 1 study of setanaxib, our lead compound in our NOX inhibition pipeline, paving the way for the use of higher dosing in the pivotal Phase 2/3 study in PBC slated to start in H2 of this year. We also hosted an R&D day in January where we laid out the clinical development strategy for the year, presenting the plans for our PBC study as well as the Phase 2b proof of concept study in head and neck cancer, both slated to start in H2 2021. The substantial preclinical work that has been generated shows compelling data regarding setanaxib's impact on CAF (cancer associated fibroblasts), paving the way for a significantly improved reach of checkpoint inhibitors.

We also significantly built our US team during the quarter, adding a Head of Marketing, VP Medical Affairs and Head of Sales. We will continue to build our team in order to be ready to commercialize in Q4. Finally, there was also a rights issue in Genkyotex to finance the company further that closed in March, which we participated in and after which we control 90.2% of the company. We are committed to pursuing full integration of the two companies as soon as possible.

Positive signals for European biotech

European biotech companies seem to go from strength to strength, supported by more capital availability both in the private and the public domain, as well as the continued growth of research capabilities and high caliber talent. However, despite the progress seen in Europe, the European biotech sector still lags behind the US.

Europe has a complex biotech landscape, with hundreds of companies across a variety of geographies, therapeutic areas and regulatory structures. With regards to start-up activity, some of the largest clusters can be found in the UK, Switzerland, France and the Benelux area, according to a McKinsey report from 2019 that looked at biotech company startups since 2012. The main categories in which research is being conducted are oncology, CNS, immunotherapies and cell and gene therapies. The McKinsey report also showed that oncology and CNS lead the field of companies in Europe, representing 42% of companies and about half of all investment as of the close of 2018.

Total investment in Europe's biotech has more than doubled in 2012-2018 compared to 2005-2011, from around \$5bn to \$12bn. Interestingly, 60% of this investment went to Belgium, Switzerland and the UK. Despite this impressive growth, European companies receive only around 20% of the funding compared to their US counterparts, and this trend is especially pronounced in later stage financing. With regards to venture capital, this is estimated to have tripled over the same period, with European funds being able to successfully raise significantly larger funds. Europe is attractive on a relative basis with pre-money valuations being 30% lower than they are in the US and structural costs being 40% lower because of leaner, more cost-effective operations and lower salaries. As for public markets, biotech IPOs are three times larger on Nasdaq US than on European exchanges, and between 2012 and 2018 approximately 30% of European companies listing on an exchange chose to list on Nasdaq in the US.

So, what has happened to European biotech after 2018? In Q3 2019 and beyond, the amount of funding available to biotech companies was seemingly immense. In 2018 the total value of financing amounted to €3.6bn (across all financing categories), which grew to €5.5bn in 2019 and finally to just over €7.3bn in 2020. The injection of liquidity into the system, a "risk on" attitude from investors and COVID-19 fueling the interest in biotech investment all probably contributed to this environment. With regards to IPOs alone, this was also reflected in growth from €2.8bn in 2018 to €5.4bn in 2020.

By another metric, the total market cap of the European listed biotech companies with a market value in excess of €1bn at the end of the year increased by 76% in 2019 and again by 38% in 2020 according to Biotech Radar. This was mainly driven by companies such as Galapagos, Genmab and argenx, but also reflected the growth of the number of companies in this group to 16 at the end of 2020 compared to around 9 companies at the end of 2018. So overall, it appears that the European biotech sector is gaining strength, driven by a variety of positive factors, and we look forward to seeing the continued growth and maturity of the sector.

Renée Aguiar-Lucander, CEO

Business Overview

Nefecon – An Overview

Calliditas is 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. Calliditas' lead product candidate, Nefecon, is a downregulator of Iga1 for the treatment of the autoimmune renal disease IgA nephropathy (IgAN). IgAN is a progressive, chronic disease, for which there is a high unmet medical need and no approved treatments. Over time, it results in deterioration of kidney function in patients, many of whom end up at risk of developing end-stage renal disease (ESRD) with the need for dialysis or kidney transplant. 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, and that is intended to be disease-modifying. Nefecon targets the ileum, the distal region of the small intestine, which is the presumed origin of the pathogenesis of IgAN. The ileum is the location of the highest concentration of the Peyer's patches, which are responsible for the production of the secretory immunoglobulin A (IgA) antibodies that are found in elevated levels in patients with IgAN.

Nefecon is designed to release a high dose of a locally acting immunosuppressive agent in the ileum to reduce the formation of, and/or the leakiness of secretory galactose-deficient IgA antibodies into the blood. Nefecon's active ingredient, budesonide, has demonstrated efficacy and safety in other indications. After the active ingredient has been released and 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 limits systemic immunosuppressive activity and thereby limits any concerning side effects related to systemic immunosuppression.

Calliditas has been granted orphan drug designation for the treatment of IgAN in the United States and the European Union. We retain worldwide rights to Nefecon other than in Greater China and Singapore, where we have established a strategic collaboration and are out-licensing development and commercialization to Everest Medicines.

The NefIgArd study

Calliditas is currently conducting a global, pivotal Phase 3 clinical trial in adults with primary IgAN, referred to as NefIgArd. NefIgArd is a double-blind, placebo-controlled, two-part Phase 3 clinical trial designed to evaluate the same endpoint used in our previously completed Phase 2b NEFIGAN clinical trial. We randomized our first patient in NefIgArd in November 2018. 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 reduction in proteinuria in the first 200 randomized and dosed patients, and a key secondary endpoint is the difference in kidney function between treated and placebo patients as measured by eGFR. In November 2020, we reported positive top-line data from Part A of the trial.

Treatment with Nefecon was associated with a statistically significant and clinically relevant reduction of 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/1.73m² in the placebo group over 9 months compared to a 0.17 ml/min/1.73m² decline in the treatment arm. In addition, the trial showed that Nefecon was generally well-tolerated and in keeping with the Phase 2b safety profile.

On the basis of the positive results from Part A of NefIgArd, Calliditas submitted a New Drug Application (NDA) on March 15, 2021 to the United States Food and Drug Administration (FDA). We sought accelerated approval under Subpart H for the 505(b)(2) application, and also applied for priority review. On April, 28, 2021, Calliditas announced that the FDA had accepted the submission and granted Priority Review for Nefecon, setting a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021.

In April, Nefecon was also granted accelerated assessment procedure by the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP). Calliditas plans to submit a Marketing Authorisation Application (MAA) for conditional approval by the EMA in Q2 2021.

The second part of the NefIgArd study, which we refer to as Part B, is a post-approval confirmatory trial designed to provide evidence of long-term renal benefit. In January 2021, we completed the enrolment of all 360 patients in NefIgArd, which includes the 200 patients previously enrolled in Part A. Part B will assess the difference in kidney function between treated and placebo patients, as measured by eGFR, over a two-year period. Each patient will be dosed for 9 months and then monitored off-drug for the remainder of the trial period, generating an aggregate of 15 months of follow-up data. We intend to report data from Part B in early 2023, subject to any impact from the COVID-19 pandemic to our business. We believe that the key secondary endpoint in Part A, a measure of eGFR over a nine-month period, is informative of the primary endpoint of Part B.

If approved by the FDA, we intend to market and commercialize Nefecon ourselves in the United States as a treatment specifically designed to have a disease-modifying effect for IgAN by preserving kidney function and thereby delaying or avoiding progression to ESRD.

IgA Nephropathy – an orphan disease with great unmet medical need

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.

Although IgAN manifests in the kidney, most scientific studies have found that the pathogenesis of IgAN begins in the ileum, where masses of lymphatic tissue, known as Peyer's patches, are predominantly found. Peyer's patches produce secretory IgA antibodies, which 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 which, potentially in combination with increased intestinal permeability, leads to these antibodies appearing in the blood. The galactose-deficient IgA antibodies are immunogenic when found in the circulation and trigger autoantibodies, which are 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 currently no approved therapy for IgAN. Initially, patients with IgAN are typically given antihypertensive medications, as recommended by the non-profit organization Kidney Disease: Improving Global Outcome (KDIGO). This treatment regimen 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, as a significant proportion of patients experience continued deterioration of kidney function and with no approved treatment options currently available, physicians attempt to control disease progression with a variety of off-label treatments.

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. Also, recent clinical studies indicate that this treatment may not be associated with any benefit with regards to the underlying kidney function.

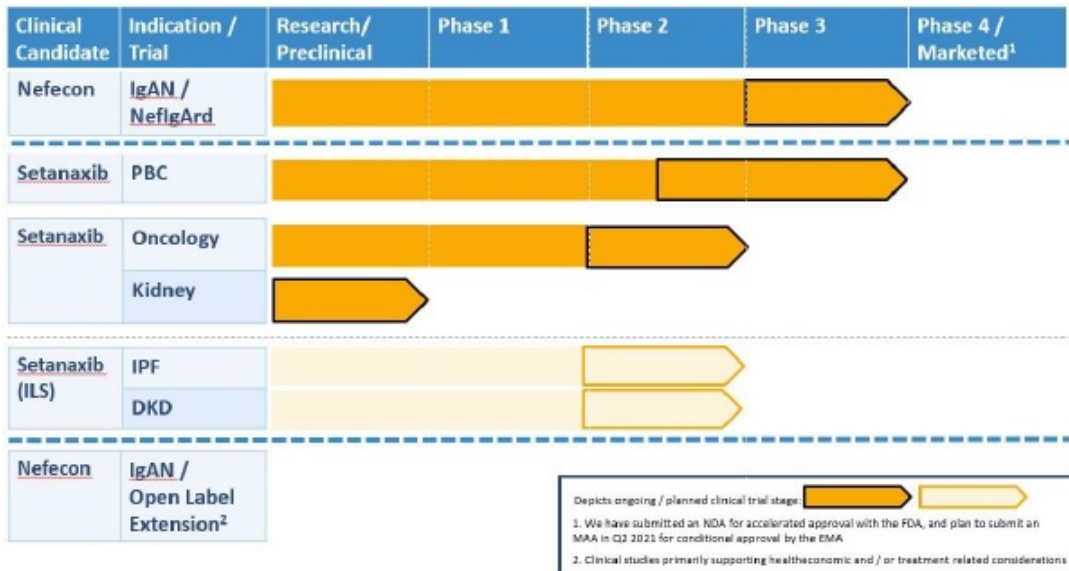
IgAN is an orphan disease that we estimate affects approximately 130,000 to 150,000 people in the United States and approximately 200,000 people in Europe. A significantly higher prevalence has been observed in Asia, including Greater China, where IgAN has historically been a leading cause of ESRD. We estimate that IgAN affects approximately two million people in Greater China. Calliditas estimates the U.S. target market opportunity for Nefecon to be approximately \$4.5 billion to \$5.0 billion annually, based on our estimate of the prevalence of the disease in the United States and primary market research conducted by IQVIA that Calliditas commissioned to assess preliminary reimbursement levels perceived acceptable by U.S.-based payors.

Pipeline: A NOX Inhibitor Platform

Through our recent acquisition of a controlling interest in Genkyotex, we have acquired access to a novel NOX inhibitor platform that includes lead compound setanaxib. 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, which indicated clinically relevant anti-fibrotic activity despite failing to achieve the primary endpoint, 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, we plan 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.

PBC is a progressive and chronic autoimmune disease in which the small bile ducts that drain bile from the liver are damaged. This damage can result in cholestasis and the destruction of the bile ducts, which leads to liver cell damage and ultimately liver failure and 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. There are currently no approved therapies that specifically address the autoimmune response that is believed to drive PBC or the inflammatory consequences of this autoimmune response.

We also intend to explore oncology indications involving fibrotic components such as CAFs using setanaxib administered with checkpoint inhibitors to address tumour drug resistance related to fibroblasts. To this end, we plan 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.



*(ILS) Investigator lead studies

Due to the recent progress, we have decided not to initiate the NefXtend study for Nefecon as previously planned. We believe that there are other alternatives which might be more appropriate post approval which we can pursue to collect relevant information regarding the treatment paradigm.

Calliditas has also exclusively in-licensed Budenofalk 3 mg oral capsules for the U.S. market from the German pharmaceutical company Falk Pharma. Our license covers all indications for the United States market, excluding orphan indications outside of liver targets. Budenofalk is a formulation of budesonide originally developed to treat Crohn’s disease, and has been approved for the treatment of Crohn’s disease and acute episodes of collagenous colitis in several countries in Europe. It has also 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. We therefore believe Budenofalk also has the potential to address AIH for patients in the United States, where there are currently no approved therapies for the treatment of this disease, and to complement our activities in that geography.

AIH is a rare disease associated with chronic inflammation of the liver. Based on the 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 their components, resulting in inflammation that eventually destroys the liver cells 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. 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.

We have received orphan drug designation for the treatment of AIH using budesonide by the FDA, and have discussed the development plans with the FDA for AIH during 2020. However, additional interaction is required before establishing any definitive clinical development plans.

Significant Events During the Period January 1 – March 31, 2021

- In January 2021, Calliditas announced the clinical development plan for setanaxib and additional data from Part A of NefIgArd study at the R&D Day. Calliditas is planning to initiate a pivotal Phase 2/3 study in PBC, starting in 2H 2021, with final design and protocol details subject to feedback from the US Food and Drug Administration (FDA). In addition, Calliditas plans to initiate a Phase 2 proof-of-concept study in head and neck cancer this year which will study administration of setanaxib in conjunction with immunotherapy targeting CAFs (cancer associated fibroblasts).

Calliditas also provided selected data from the recently concluded Part A of the Phase 3 study NefIgArd. The data presented included overall baseline characteristics, rate of discontinuation of study treatment (9.5%) and rate of discontinuation from the study (3.5%). It was also confirmed that no adverse clinical effects were seen with regards to weight gain, blood pressure or HbA1c, reflecting a safety profile in keeping with the Phase 2b trial.

- In March 2021, Calliditas announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Nefecon in patients with primary IgA Nephropathy. Calliditas is seeking accelerated approval under Subpart H for the 505(b)(2) application.

Significant Events After the Reporting Period

- In April 2021, Calliditas announced that its lead product candidate Nefecon, was granted accelerated assessment procedure by the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP). Accelerated assessment, reduces the maximum timeframe for review of the application for marketing authorization to 150 days for the EMA to review a marketing authorization application (MAA). If approved, Nefecon could be available to patients in Europe in the first half of 2022.
- In April 2021, Calliditas announced that the FDA accepted the submission and granted Priority Review for the NDA for Nefecon. The FDA have set a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021.

Financial Overview

Key Figures

(SEK in thousands, except share amounts or as otherwise indicated)	Three Months Ended March 31,		Year Ended December 31,
	2021	2020	2020
Net sales	-	474	874
Research and development expenses	(90,077)	(54,106)	(241,371)
Research and development expenses/Total operating expenses in % ¹	60%	74%	63%
Operating loss	(150,781)	(72,326)	(379,720)
Loss before income tax for the period	(136,174)	(63,677)	(436,151)
Loss per share before and after dilution	(2.51)	(1.65)	(9.66)
Cash flow used in operating activities	(134,179)	(18,775)	(309,181)

(SEK in thousands, except share amounts or as otherwise indicated)	March 31,		December 31,
	2021	2020	2020
Total registered shares at the end of period	49,941,584	38,707,638	49,941,584
Equity attributable to equity holders of the Parent Company at the end of the period	1,095,341	724,514	1,210,491
Equity ratio at the end of the period in % ¹	79%	92%	80%
Cash at the end of the period	867,346	728,574	996,304

¹ Alternative performance measure, see definitions on page 25.

January – March 2021

Revenue

No net sales were recognized for the three months ended March 31, 2021. Net sales for the three months ended March 31, 2020 amounted to SEK 0.5 million and derived from the delivery of Nefecon to China as part of the license agreement with Everest Medicines. For additional information see Note 4.

Total Operating Expenses

Operating expenses amounted to SEK 150.8 and SEK 72.8 million for the three months ended March 31, 2021 and 2020, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 90.1 million and SEK 54.1 million for the three months ended March 31, 2021 and 2020, respectively. The increase by SEK 36.0 million is primarily due to the increased cost of the NefgArd study and the preparation and product development for the upcoming setanaxib trials, compared to the same period last year.

Administrative and Selling Expenses

Administrative and selling expenses amounted to SEK 58.8 million and SEK 18.0 million for the three months ended March 31, 2021 and 2020, respectively. The increase by SEK 40.8 million compared to the previous period is mainly due to intensified commercial preparations and medical affairs activities in the US and an increased cost for administration, compared to the same period last year.

Other Operating Incomes/Expenses

No other operating income were recognized for the three months ended March 31, 2021. For the three months ended March 31, 2020, other operating income amounted to SEK 0.8 million. This was primarily relating to favourable exchange rates on accounts receivables.

Other operating expenses amounted to SEK 1.9 million and SEK 1.5 million for the three months ended March 31, 2021 and 2020, respectively. The increase by SEK 0.4 million primarily relates to exchange rate development on operating liabilities.

Net Financial Income and Expenses

Net financial income and (expenses) amounted to SEK 14.6 million and SEK 8.6 for the three months ended March 31, 2021 and 2020 respectively. The increase of financial income by SEK 6.0 million is primarily derived by unrealized foreign currency translation gains on cash accounts.

Tax

Deferred tax assets of SEK 9.3 million have been recognized in the first quarter 2021 due to future temporary differences that such losses can be used to offset and are related to Genkyotex. The Groups tax losses accumulated during the quarter have not been recognized as deferred tax assets. 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.

Result for The Period

For the three months ended March 31, 2021 and 2020 the Group had a net loss of SEK 126.9 million and SEK 63.7 million, respectively and corresponding loss per share before and after dilution amounted to SEK 2.51 and SEK 1.65 for the three months ended, respectively. The decrease in the result for the period is mainly due to the increased activities in R&D and the pre-commercial activities in the US.

Cash Flow and Cash Position

The cash flow used in operating activities amounted to SEK 134.2 million and SEK 18.8 million for the three months ended March 31, 2021 and 2020, respectively. The cash flow used in operating activities during this period is according to plan and is explained by the Group's increased clinical activities as well as work within the Group's administrative and commercial functions.

Cash flow used in investing activities amounted to SEK 0.2 million for the three months ended March 31, 2021. The Group had no cash flows from investing activities for the three months ended March 31, 2020.

Cash flow used in financing activities amounted to SEK 9.6 million and SEK 13.5 million for the three months ended March 31, 2021 and 2020, respectively. The cash used in financing activities in first quarter 2021 are related to purchase of minority shares in Genkyotex, while the cash used in financing activities in the first quarter 2020 originated from US Nasdaq listing preparations.

Net decrease in cash amounted to SEK 144.0 million and SEK 32.3 million for the three months ended March 31, 2021 and 2020, respectively. Cash amounted to SEK 867.3 million and SEK 728.6 million as of March 31, 2021 and 2020, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 1,095.3 million and SEK 724.5 million as of March 31, 2021 and 2020, respectively. The number of shares amounted to 49,941,584 and 38,707,638 as of March 31, 2021 and 2020, respectively. The increase in the number of shares between the periods is due to the initial offering on The Nasdaq Global Selected Market in the United States of 9.2 million new common shares in June 2020 and the following exercise of the partial over-allotment option from the IPO of 0.7 million new common shares in July 2020. Furthermore, the increase is due to the exercise of the Warrant Program 2017/2020 of 1.3 million new common shares.

Employees

The number of employees in the Group was 46 and 17 employees as of March 31, 2021 and 2020, respectively. The total number of full-time equivalent (FTE), including consultants, were 64 and 17 as of March 31, 2021 and 2020 respectively. The average number of employees was 41 and 17 employees for the three months ended March 31, 2021 and 2020, respectively.

Incentive Programs

For the three months ended March 31, 2021, an additional allocation of 496,000 employee stock options have been made for the ESOP 2020 program. For more information on incentive programs, see Note 10.

Parent Company

Since the operations for the Parent Company are consistent with those of the Group in all material respects, the comments for the Group are also relevant for the Parent Company.

Auditor's Review

This report has not been reviewed by the company's auditor.

Stockholm May 18, 2021

Renée Aguiar-Lucander

CEO

Financial Statements

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended March 31,		Year Ended December 31,
		2021	2020	2020
Net sales	4	-	474	874
Research and development expenses		(90,077)	(54,106)	(241,371)
Administrative and selling expenses		(58,779)	(18,009)	(141,724)
Other operating income		-	782	2,501
Other operating expenses		(1,925)	(1,467)	-
Operating loss		(150,781)	(72,326)	(379,720)
Net financial income/(expenses)		14,607	8,649	(56,431)
Loss before income tax		(136,174)	(63,677)	(436,151)
Income tax	7	9,305	(38)	(360)
Loss for the period		(126,869)	(63,715)	(436,511)
Attributable to:				
Equity holders of the Parent Company		(125,455)	(63,715)	(433,494)
Non-controlling interests		(1,414)	-	(3,017)
		(126,869)	(63,715)	(436,511)
Loss per share before and after dilution		(2.51)	(1.65)	(9.66)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Notes	Three Months Ended March 31,		Year Ended
		2021	2020	December 31, 2020
Loss for the period		(126,869)	(63,715)	(436,511)
Other comprehensive income				
<i>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:</i>				
Exchange differences on translation of foreign operations		6,666	51	(9,352)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		6,666	51	(9,352)
<i>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:</i>				
Remeasurement gain on defined benefit plans		1,416	-	1,216
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods		1,416	-	1,216
Other comprehensive income/(loss) for the period		8,082	51	(8,137)
Total comprehensive loss for the period		(118,787)	(63,664)	(444,648)
Attributable to:				
Equity holders of the Parent Company		(118,318)	(63,664)	(438,343)
Non-controlling interests		(469)	-	(6,305)
		(118,787)	(63,664)	(444,648)

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	March 31,		December 31,
		2021	2020	2020
ASSETS				
Non-current assets				
Intangible assets	6	470,244	16,066	461,367
Equipment		332	98	163
Right-of-use assets		5,547	5,419	5,244
Non-current financial assets		2,230	1,939	2,225
Deferred tax assets		506	-	600
Total non-current assets		478,859	23,522	469,599
Current assets				
Other current assets	8	40,521	32,150	40,547
Cash		867,346	728,574	996,304
Total current assets		907,867	760,724	1,036,851
TOTAL ASSETS		1,386,726	784,246	1,506,450
EQUITY AND LIABILITIES				
Equity				
Share capital		1,998	1,548	1,998
Additional paid-in capital		2,135,476	1,274,771	2,133,179
Retained earnings, including net loss for the period		(1,042,133)	(551,805)	(924,686)
Equity attributable to equity holders of the Parent Company		1,095,341	724,514	1,210,491
Non-controlling interests		36,834	-	45,809
Total equity	9,10	1,132,175	724,514	1,256,300
Non-current liabilities				
Provisions	10	56,795	250	55,361
Pension Liabilities		7,181	-	8,296
Deferred tax liabilities	7	72,045	-	79,996
Other non-current liabilities		1,319	2,338	878
Total non-current liabilities		137,340	2,588	144,531
Current liabilities				
Accounts payable		57,660	28,363	53,827
Other current liabilities		6,712	3,818	10,406
Accrued expenses and deferred revenue		52,839	24,963	41,386
Total current liabilities		117,211	57,144	105,619
TOTAL EQUITY AND LIABILITIES		1,386,726	784,246	1,506,450

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Notes	March 31,		December 31,
		2021	2020	2020
Opening balance equity attributable to equity holders of the Parent Company		1,210,491	788,071	788,071
Loss for the period		(125,455)	(63,715)	(433,494)
Other comprehensive income/(loss)		7,137	51	(4,849)
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company		(118,318)	(63,664)	(438,343)
Transactions with owners:				
New share issue		-	-	891,388
Cost attributable to new share issue		(982)	-	(97,686)
Exercise of warrants		-	-	59,251
Share-based payments		3,278	107	6,012
Purchase of non-controlling interests		872	-	1,798
Total transactions with owners		3,168	107	860,763
Closing balance equity attributable to equity holders of the Parent Company		1,095,341	724,514	1,210,491
Opening balance equity attributable to non-controlling interests		45,809	-	-
Total comprehensive loss for the period		(469)	-	(6,305)
Contribution from non-controlling interests		2,282	-	-
Non-controlling interests from business combinations		-	-	136,084
Purchase of non-controlling interests		(10,789)	-	(83,970)
Closing balance equity attributable to non-controlling interests		36,834	-	45,809
Closing balance equity		1,132,175	724,514	1,256,300

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Notes	Three Months Ended		Year Ended
		2021	March 31, 2020	December 31, 2020
Operating activities				
Operating loss		(150,781)	(72,326)	(379,720)
Adjustment for non-cash-items		5,007	825	15,465
Interest received		-	-	1,912
Interest paid		(154)	(183)	(393)
Income tax paid		-	-	(528)
Cash flow used in operating activities before changes in working capital		(145,928)	(71,684)	(363,264)
Cash flow used from/(used in) changes in working capital		11,749	52,909	54,083
Cash flow used in operating activities		(134,179)	(18,775)	(309,181)
Cash flow used in investing activities		(199)	-	(172,607)
Cash flow used in investing activities		(199)	-	(172,607)
New share issue		-	-	891,388
Costs attributable to new share issue		(982)	(12,252)	(95,937)
Premiums from warrants issuance		-	-	59,251
Purchase of non-controlling interests		(9,917)	-	(82,172)
Contribution from non-controlling interests		2,282	-	-
Repayment of loans		(1,010)	(1,225)	(3,972)
Cash flow from/(used in) financing activities		(9,627)	(13,477)	768,558
Net increase/(decrease) in cash		(144,005)	(32,252)	286,770
Cash at the beginning of the period		996,304	753,540	753,540
Net foreign exchange gains/(loss) on cash		15,047	7,286	(44,006)
Cash at the end of the period		867,346	728,574	996,304

Condensed Parent Company Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended March 31,		Year Ended
		2021	2020	December 31, 2020
Net sales	4	-	474	874
Research and development expenses		(72,150)	(54,106)	(227,027)
Administrative and selling expenses		(54,553)	(18,220)	(128,896)
Other operating income		-	782	2,482
Other operating expenses		(1,237)	(1,467)	-
Operating loss		(127,940)	(72,537)	(352,567)
Net financial income and expenses		15,126	8,854	(54,796)
Loss before income tax		(112,814)	(63,683)	(407,363)
Income tax expense		-	-	-
Loss for the period		(112,814)	(63,683)	(407,363)

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Notes	Three Months Ended March 31,		Year Ended
		2021	2020	December 31, 2020
Loss for the period		(112,814)	(63,683)	(407,363)
Other comprehensive income/(loss)		-	-	-
Total comprehensive loss		(112,814)	(63,683)	(407,363)

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	March 31,		December 31,
		2021	2020	2020
ASSETS				
Non-current assets				
Intangible assets	6	16,066	16,066	16,066
Equipment		74	98	80
Non-current financial assets		357,902	2,040	298,683
Total non-current assets		374,042	18,204	314,829
Current assets				
Other current assets	8	24,231	32,715	25,488
Cash		828,360	727,753	978,208
Total current assets		852,591	760,468	1,003,696
TOTAL ASSETS		1,226,633	778,672	1,318,525
SHAREHOLDERS' EQUITY AND LIABILITIES				
Restricted Shareholders' equity				
Share capital		1,998	1,548	1,998
Statutory reserve		3,092	3,092	3,092
		5,090	4,640	5,090
Non-restricted shareholders' equity				
Share premium reserve		2,116,721	1,268,334	2,116,721
Retained earnings		(883,463)	(485,068)	(479,379)
Net loss for the period		(112,814)	(63,683)	(407,363)
		1,120,444	719,583	1,229,979
Total shareholders' equity	9,10	1,125,534	724,223	1,235,069
Non-current liabilities				
Provisions	10	4,664	250	4,972
Other non-current liabilities		105	50	105
Total non-current liabilities		4,769	300	5,077
Current liabilities				
Accounts payable		49,711	27,769	42,469
Other current liabilities		7,181	1,924	5,123
Accrued expenses and deferred revenue		39,438	24,456	30,787
Total current liabilities		96,330	54,149	78,379
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,226,633	778,672	1,318,525

Notes to Condensed Consolidated Financial Statements

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 three months ended March 31, 2021 and March 31, 2020.

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, in the form of ADSs, on the Nasdaq Global Select Market in the United States with the ticker “CALT”.

These interim condensed consolidated financial statements were approved by the Board of Directors (the “Board”) for publication on May 18, 2021.

This report may include forward-looking statements. Actual outcomes may deviate from what has been stated. Internal factors such as successful management of research projects, and intellectual property rights may affect future results. There are also external conditions, (e.g. the economic climate, political changes, and competing research projects) that may affect the Group’s results.

Note 2 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, 2021, have had a significant impact on the Group’s financial reporting. Relevant accounting principles can be found on pages 45-49 of the Annual Report for 2020.

During 2020, the Group has acquired a company (Genkyotex SA) that has defined benefit pension plans, which is recognized in the condensed consolidated statements of financial position under “Pension liabilities” and will be revalued due to actuarial changes.

The ESMA (European Securities and Markets Authority) guidelines on alternative key performance ratios are applied, which means disclosure requirements regarding financial measures that are not defined in accordance with IFRS. For key ratios not defined by IFRS, see the Definitions and reconciliations of alternative performance measures on page 24.

Note 3 Risks and uncertainties in the Group and the Parent Company

Operational risks

Research and drug development up to approved 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 approvals and price changes.

COVID-19

The COVID-19 virus has rapidly spread from an initial event and infections have been reported globally. Calliditas has clinical trial sites in the NefIgArd trial based in areas currently affected by this coronavirus. Calliditas has not yet experienced any major disturbances in the NefIgArd trial. The extent to which the coronavirus impacts the operations and the NefIgArd, or any planned trials for Nefecon or setanaxib, 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 impact of the coronavirus outbreak for Calliditas have been limited so far, but 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.

The Group is primarily affected by foreign exchange risk, since the development costs for Nefecon and setanaxib 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 the United States. Regarding the Group and the Parent Company's financial risk management, the risks are essentially unchanged compared with the description in the Annual Report for 2020.

For more information and full disclosure regarding the operational- and financial risks, reference is made to the annual report for 2020 and the annual report on form 20-F, filed with the SEC in April 2021.

Note 4 Revenue from Contracts with Customers

The Group's revenues during 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 completed all performance obligations within the agreement as of the delivery of study-related drugs to Everest Medicines for the year ended December 31, 2020.

No revenue was recognized for the three months ended March 31, 2021.

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

(SEK in thousands)	Three Months Ended March 31,		Year Ended December 31,
	2021	2020	2020
Type of good or service			
Provision of drugs	-	474	874
Total	-	474	874
Geographical markets			
China, Hong Kong, Macau, Taiwan and Singapore	-	474	874
Total	-	474	874

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 10.

Note 6 Intangible Assets

(SEK in thousands)	Three Months Ended March 31,		Year Ended December 31,
	2021	2020	2020
Cost at opening balance	461,367	16,066	16,066
Business Combinations	-	-	460,253
Exchange difference on translation	8,877	-	(14,952)
Cost at closing balance	470,244	16,066	461,367
Amortization at closing balance	-	-	-
Net book value	470,244	16,066	461,367

Intangible assets consist of licenses and similar rights of SEK 422,050 thousand and goodwill of SEK 48,194 thousand.

Business combinations:

The acquisition of Genkyotex SA in 2020 resulted in the Group acquiring the rights to the NOX platform and SIIL agreement, as well as goodwill.

The net book value of the NOX platform amounts to SEK 377,469 thousand as of March 31, 2021. The estimated fair value of the NOX platform was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence.

The net book value of the SIIL agreement, which is an out-license agreement with Serum Institute of India (SIIL) for the use of a vaccine technology, amounts to SEK 28,515 thousand as of March 31, 2021. The estimated fair value of the SIIL agreement and extensions was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence.

Goodwill amounts to SEK 48,194 thousand as of March 31, 2021.

Note 7 Deferred Tax Liabilities

(SEK in thousands)	Three Months Ended March 31,		Year Ended December 31,
	2021	2020	2020
Cost at opening balance	79,996	-	-
Business Combinations	-	-	79,996
Tax loss carried forward	(9,305)	-	-
Exchange difference on translation	1,354	-	-
Cost at closing balance	72,045	-	79,996

Deferred tax assets of SEK 22.3 million have been offset against deferred tax liabilities in the statement of financial position as of March 31, 2021 due to future temporary differences that such losses can be used to offset.

Note 8 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. No currency options or derivatives existed as of March 31, 2021. Further, presented as Other current assets the Group had transaction costs for a potential offering of the Parent Company's securities in the United States amounted to SEK 26,062 thousand as of March 31, 2020. The Group's financial liabilities comprise of accounts payable and other current liabilities, which are recognized at amortized cost. The carrying amount is an approximation of the fair value.

Note 9 Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	March 31,		December 31,
	2021	2020	2020
Total registered shares at the beginning of period	49,941,584	38,707,638	38,707,638
New issue of shares during the period	-	-	11,233,946
Total registered shares at the end of period	49,941,584	38,707,638	49,941,584
Share capital at the end of period	1,998	1,548	1,998
Equity attributable to equity holders of the Parent Company	1,095,341	724,514	1,210,491
Non-controlling interests	36,834	-	45,809
Equity at the end of period	1,132,175	724,514	1,256,300
Loss per share before and after dilution	(2.51)	(1.65)	(9.66)
Weighted-average number of shares outstanding for the period, before and after dilution	49,941,584	38,707,638	44,873,448

Reserves for translation from foreign operations amounted to SEK 6,666 thousand and SEK 51 thousand, which are included in equity as of March 31, 2021 and 2020, respectively.

Note 10 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 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 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.

Board LTIP 2019

This is a performance-based long-term incentive program for some members of Calliditas' board. A total of 57,032 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 ("AGM") to June 1, 2022.

Board LTIP 2020

This is a performance-based long-term incentive program for 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 services to, Calliditas. Once the options are vested, they can be exercised within a one-year period. Each vested option entitles the holder to acquire one share in Calliditas at a predetermined price. The price per share is to be equivalent to 115% of the weighted average price that the company's shares were traded for on Nasdaq Stockholm during the ten trading days preceding the allotment date. The options have, at the time of issue, been valued according to the Black & Scholes valuation model.

Summary of Outstanding Incentive Programs

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of March 31, 2021
Incentive programs				
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	-	1,485,000	-	1,485,000
Total outstanding as of March 31, 2021	1,279,086	1,485,000	82,770	2,846,856

	Warrants Outstanding	Share Awards Outstanding	Total Outstanding as of March 31, 2020
Incentive programs			
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 March 31, 2020	2,575,586	57,032	2,632,618

Definitions of Performance Measures and Reconciliations of Alternative Performance Measures

Definitions of Performance Measures

Performance Measures	Definitions
Earnings (loss) per share before/after dilution	Earnings (loss) for the period divided by the average number of share before and after dilution. Diluted earnings per share is calculated by adjusting the weighted average number of common share outstanding to assume conversion of all dilutive potential common shares, which is in accordance with IAS 33 Earnings Per Share.
Share capital at the end of the period	Share capital at the end of respective period. The measure is extracted from the statements of financial position.
Total outstanding shares at the beginning of period	Total outstanding shares at the beginning of respective period.
Total outstanding shares at the end of period	Total outstanding shares at the end of respective period.
Average number of outstanding shares during the period	Average number of outstanding shares of respective period.
Equity ratio at the end of the period	Equity position at the end of respective period. The measure is extracted from the statements of financial position.
Cash at the end of the period	Cash at the end of respective period. The measure is extracted from the statements of financial position.

Definitions of Alternative Performance Measures

Alternative Key Performance Indicator	Definitions	Reason for Inclusion
Research and development expenses/Total operating expenses in %	Research and development expenses, divided by total operating expenses, which is the sum of research and development expenses, administrative and selling expenses, other operating income and expenses.	The key performance indicator helps the reader of the interim financial statements to analyse the portion of the Groups expenses that are attributable to the Group's research and development activities.
Equity ratio at the end of the period in %	The ratio at the end of respective period is calculated by dividing total shareholders' equity by total assets.	The equity ratio measures the proportion of the total assets that are financed by shareholders.

Reconciliations of Alternative Performance Measures

(SEK in thousands or as otherwise indicated)	Three Months Ended March 31,		Year Ended December 31,
	2021	2020	2020
<i>Research and development expenses/Total operating expenses in %</i>			
Research and development expenses	(90,077)	(54,106)	(241,371)
Administrative and selling expenses	(58,779)	(18,009)	(141,724)
Other operating income/expenses	(1,925)	(685)	2,501
Total operating expenses	(150,781)	(72,800)	(380,594)
Research and development expenses/Total operating expenses in %	60%	74%	63%

(SEK in thousands or as otherwise indicated)	March 31,		December 31,
	2021	2020	2020
<i>Equity ratio at the end of the period in %</i>			
Equity attributable to equity holders of the Parent Company at the end of the period	1,095,341	724,514	1,210,491
Total assets at the end of the period	1,386,726	784,246	1,506,450
Equity ratio at the end of the period in %	79%	92%	80%

Financial Calendar

Interim Report for the period January 1 – June 30, 2021
Interim Report for the period January 1 – September 30, 2021
Year-end Report for the period January 1 – December 31, 2021

August 19, 2021
November 18, 2021
February 24, 2022



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Forward-Looking Statements

This interim report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this interim report are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines for development and potential approvals, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this interim report represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.