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 November 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): ☐

Enclosed hereto is a copy of an interim report and announcement published by Calliditas Therapeutics AB on November 18, 2021.

The information contained in this Form 6-K, including Exhibit 99.1, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

EXHIBIT INDEX

Exhibit	Description
99.1	Company interim report dated November 18, 2021
99.2	Company announcement dated November 18, 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: November 18, 2021

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

Q3 2021

INTERIM REPORT JANUARY 1ST – SEPTEMBER 30TH

calliditas THERAPEUTICS

Partnership with STADA Arzneimittel to commercialize Nefecon in Europe

Financial summary for the Group

Key Figures

July 1 - September 30, 2021

- Net sales amounted to SEK 198.2 million for the three months ended September 30, 2021. No net sales were recognized for the three months ended September 30, 2020.
- Operating profit (loss) amounted to SEK 7.9 million and SEK (104.9 million) for the three months ended September 30, 2021 and 2020, respectively.
- Earnings (loss) per share before dilution amounted to SEK 0.21 and SEK (2.77) for the three months ended September 30, 2021 and 2020, respectively.
- Cash amounted to SEK 1,163.8 million and SEK 1,396.9 million as of September 30, 2021 and 2020, respectively.

January 1 - September 30, 2021

- Net sales amounted to SEK 198.2 million and SEK 0.5 million for the nine months ended September 30, 2021 and 2020, respectively.
- Operating loss amounted to SEK 302.3 million and SEK 243.8 million for the nine months ended September 30, 2021 and 2020, respectively.
- Loss per share before dilution amounted to SEK 5.45 and SEK 6.09 for the nine months ended September 30, 2021 and 2020, respectively.

Significant events in Q3 2021

- In July 2021, Calliditas signed a loan agreement of up to the EUR equivalent of $75 million with Kreos Capital.
- In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize Nefecon in the European Economic Area (EEA) member states, Switzerland and the UK valued at a total of EUR 97.5 million ($115m) in initial upfront and potential milestone payments, plus royalties.
- In August 2021, Calliditas received FDA fast track designation for setanaxib in PBC.
- In August 2021, Calliditas completed an accelerated book building procedure and resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of SEK 324.0 million ($37.0m) before transaction costs.
- In September 2021, Calliditas announced that the FDA extended the PDUFA goal date for its New Drug Application (NDA) seeking accelerated approval for Nefecon to December 15, 2021.
- In September 2021, Calliditas announced that the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP) decided to continue the assessment of the marketing authorization application (MAA) for Nefecon under standard procedure assessment timelines.

Investor Presentation November 18, 14:30 CET

Audio cast with teleconference, Q3 2021

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q3-2021

Teleconference: SE: +46856642695 | UK: +443333009264 | US: +16467224903

Deal-making and regulatory review extension

The third quarter is often expected to be somewhat slower in comparison to the other quarters due to the summer period, however that was not the case for us this year.

After the concentrated regulatory submission work carried out in Q1 and Q2, we successfully completed transactions which had been initiated earlier in the year. Following on from the positive top line read out of Part A our Phase 3 study, we initiated a structured process to select our commercial partner for Nefecon in Europe. It is always interesting to go through a diligence process as it tends to highlight the key aspects of the product, its opportunities and differentiated positioning. It is also an excellent learning process for the organization as it often requires cross department interaction and collaboration. In this case, the result of the process was a partnership with Stada Arzneimittel, which has proven to be an excellent match and has seen the two organizations collaborating very well. We look forward to continuing to build on this partnership as we progress through the EMA review process.

We also took the opportunity to investigate and review some alternative capital sources to complement the predominant source of equity capital. After some broad discussions and interactions, we decided to run a competitive process which resulted in several attractive options, after which we ultimately selected to go forward with a $75m credit line from Kreos. This partnership is another key relationship for us as we proceed towards commercialization in the US. Having a more diversified capital structure, which provides some flexibility as the company grows into the commercial phase, is attractive and allows us to appropriately balance capital need with dilution depending on the cost of capital and transactability across the various markets.

In the third quarter, the U.S. Food and Drug Administration (FDA) requested further analysis of data from the NeflgArd clinical trial in connection with our NDA submitted for approval under the FDA's Accelerated Approval Program. The FDA classified the additional analyses received as a major amendment to the NDA and extended the PDUFA goal date by three months from September 15, 2021 to December 15, 2021. This was obviously disappointing; however, this is the first time that this division is reviewing a submission related to an accelerated approval based on proteinuria as a surrogate marker, requiring an in-depth review process. We remain confident that we have presented a compelling data package and look forward to continuing our regulatory interactions with the goal of making an approved treatment available for patients in need. The FDA review of an NDA is a complex and dynamic process, particularly where the agency is reviewing a surrogate endpoint for the first time, and while we cannot speculate as to the ultimate outcome of the review, we believe it is positive that the FDA continues to actively review our submission. The third quarter also saw the European Medicines Agency (EMA) deciding to revert to standard review timelines for our submission, which we estimate will result in the issuance of an opinion in Q1, 2022. We look forward to our interactions with the agency.

These are the realities of being a pioneer, which we have consistently been in this indication since we initiated the very first Phase 2b program in 2012. We are therefore eager to receive feedback from the agency once they have had a chance to review the analyses and data requested. IgA nephropathy is a debilitating disease, which for many leads to a life of dialysis and ultimately kidney transplantation and for which there are no approved treatments today. Patients and physicians have been waiting for a treatment which specifically addresses this disease, and we hope that the FDA will conclude that the clinical results from our two large clinical studies, which both achieved their primary and secondary endpoints, fulfil the criteria for accelerated approval for this at-risk patient population.

We remain ready for commercial launch in the US. Our field medical directors are in dialogue with nephrologists across the country and we are proceeding with market access related conversations as well as other pre-commercial activities. We are excited about our strong US capabilities reflected by the highly experienced and well-prepared team in place.

The art of the deal

Transactions are always complex, multifaceted and fascinating. Doing a deal is most often the result of a long process that involves several stages, including exploring, assessing, analyzing, negotiating, compromising and, if you are lucky, closing. All transactions require a vast number of individual items to align, not only financially and strategically but also operationally and culturally. Hence, only a minority of contemplated transactions actually end up being successfully concluded. More often than not they fall by the wayside due to diligence concerns, cultural differences, or an inability to see eye to eye with regards to valuation.

Doing a deal is, in a way, a journey, one that leads to discoveries not only about yourself but also the true self of your potential partner. During this intricate dance, several facets of your dance partner are revealed and at every turn require you to decide whether to continue, make a turn, or sit the next one out.

Transactions are however also prone to drawing criticism from bystanders, irrespective of whether they have any deal experience or insight into the situation. It is reminiscent of Goldilocks – it's too small, too expensive, too early, too cheap. Deals therefore can generate fanciful speculation and comparisons, often to very different situations and circumstances. This is why it is critical for companies to adhere to a clear strategy which is built on the actual capabilities, strengths, opportunities and strategic objectives which exist in the business. This maximizes the probability of generating shareholder value and ensures that the focus remains on what is actually important.

However, transactions are the very life blood of the life science industry, so everyone has to engage in them regardless of whether they like it or not. Capital raising, in-licensing, out-licensing and partnering are part and parcel of any and all life science companies. It is therefore important that we strive to plan and execute these in the best possible way, taking into consideration existing constraints as well as the macro environment.

During the pandemic of 2020 and 2021 to date, transactions have generated very different statistics dependent on the category. According to EY's 23rd edition of its Global Capital Confidence Barometer, 89% of life sciences executives saw a drop in profits in 2020, with 2/3rds saying that they cancelled or failed to complete a planned acquisition. On the opposite end of the spectrum, Pharmaceutical Executive reports that the surge in pharma sector initial public offerings reached a record during 2020, with around $50 billion being injected between IPOs and follow-ons, double that of the prior year. The biotech index was up 40% in 2020, driven to a large extent by the price increases of the 2020 IPO class.

By mid-2021 however, the group was the worst performing sector to date, reminding us all to remain aware of the inherent volatility of this sector. In terms of M&A, volumes were back up the first half of 2021 compared to the same period the prior year. This market activity is expected to grow throughout Q3 and Q4 of 2021 as life sciences companies continue to evaluate their business plans in response to the ongoing market shifts triggered by the pandemic, which include digitization and telemedicine, potential price pressures driven by increased regulation and the rise of new market players with innovative technologies that have the potential to dislocate existing treatment paradigms. In addition, the recent capital raising boom has armed companies with strong balance sheets, with the top 12 biopharma companies having over $170 billion of dry powder. However, overall investor focus right now seems to be on value plays, which are expected to recover as travel and related activities pick up again. This will probably continue for the rest of 2021 and the first part of 2022, assuming that there is continued recovery from the pandemic.

However, as we all know, at some point value stocks are likely to become rerated and investors will rotate back into growth. This rotation is as old as the market itself. All we can do is to seek to have well-developed and strategically consistent plans for a variety of scenarios and to be ready to put them into action when there is a window and opportunity to do so.

Renée Aguiar-Lucander, CEO

Nefecon – An Overview

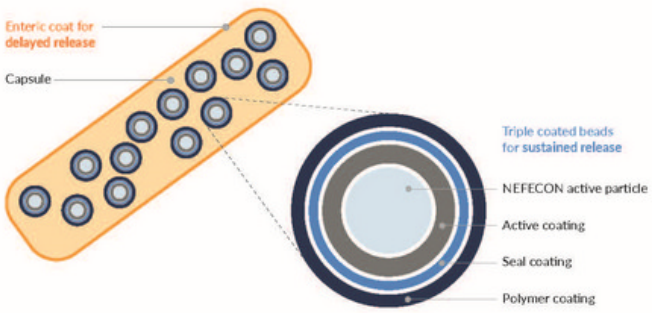
Calliditas is a clinical-stage biopharmaceutical company focused on identifying, developing, and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs.

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 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 Europe, Greater China, and Singapore, and – subject to approval by the FDA – we intend to commercialize Nefecon for IgAN on our own in the United States. In July 2021, Calliditas partnered with STADA Arzneimittel AG to register and commercialize Nefecon in the European Economic Area (EEA) member states, Switzerland and the UK. The deal is valued at a total of 97.5 million EUR ($115m) in intial upfront and potential milestone payments, plus tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties. Calliditas has also out-licensed the development and commercialization of Nefecon in Greater China and Singapore to Everest Medicines.

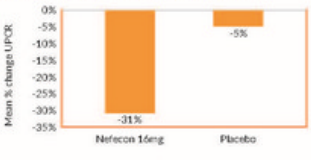


The NeflgArd Study

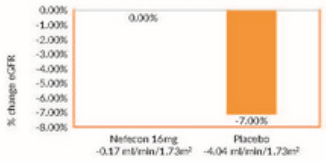
NeflgArd is a double-blind, placebo-controlled, two-part Phase 3 clinical trial designed to evaluate the same endpoint used in our previously completed Phase 2b NEFIGAN clinical trial.

We randomized our first patient in NeflgArd in November 2018. The first part of NeflgArd, 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. On the basis of these results, we filed for regulatory approval with the FDA and the EMA in early 2021. 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.

Primary endpoint: Reduction in proteinuria



Secondary endpoint: Stabilization of eGFR



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 NeflgArd, 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. While the FDA accepted the submission and granted Priority Review for Nefecon in April 2021, setting a Prescription Drug User Fee Act (PDUFA) goal date of September 15, on September 14th the FDA extended the PDUFA goal date to December 15, 2021. In its review of the NDA, the FDA had requested further analyses of the NeflgArd trial data, which Calliditas provided, after which the Agency classified these analyses as a major amendment to the NDA. This amendment mainly provided additional eGFR and other related analyses as further support of the proteinuria data included in the NDA submission, and did not necessitate any new data to be submitted. Calliditas submitted a Marketing Authorisation Application (MAA) for conditional approval to the European Medicine Agency's (EMA) in May, 2021, after having been granted Accelerated Assessment procedure in April 2021. In September, the EMA's Committee for Human Medicinal Products (CHMP) decided to continue the assessment of the MAA for Nefecon under standard procedure assessment timelines. If approved, Nefecon could be available to patients in Europe in mid 2022.

The second part of the NeflgArd 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 NeflgArd, 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, through local delivery to the presumed origin of the disease, to have a disease-modifying effect, thereby preserving kidney function and 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: NOX Inhibitor Platform

Calliditas' pipeline contains development programs based on a first-in-class, novel NOX inhibitor platform that includes lead compound setanaxib, the first NOX inhibitor to reach the clinical trial stage. Calliditas is presently launching trials with setanaxib in Primary Biliary Cholangitis (PBC) and Squamous Cell Carcinoma of the Head & Neck (SCCHN).

NOX Enzymes and Reactive Oxygen Species

NOX enzyme inhibitors are a class of promising novel experimental drugs in redox pharmacology. In July 2019, the WHO approved a new stem, "naxib," which recognizes NOX inhibitors as a new therapeutic class. Several other molecules are currently in use as experimental NOX inhibitors, most frequently diphenylene iodonium (DPI) and apocynin, but these molecules are not specific to NOX enzymes and have several off-target effects. Setanaxib is currently the only NOX inhibitor that specifically and exclusively acts on NOX enzymes, with no off-target effects.

While several human enzymes are capable of producing reactive oxygen species (ROS), the only known enzymes that are solely dedicated to producing ROS as their primary function are nicotinamide adenine dinucleotide phosphate (NADPH) oxidases, otherwise known as NOX enzymes. At appropriate concentrations, ROS have essential functions in cellular signalling processes, helping to regulate cell proliferation, differentiation and migration, as well as modulating the innate immune response, inflammation and fibrosis. However, the disruption of the redox homeostasis has been implicated in multiple disease pathways. Oxidative stress, which causes an excess of ROS, is a likely common underlying mechanism for cardiovascular diseases, neurodegenerative disorders, and cancer disease pathways.

NADPH oxidases are transmembrane enzymes that transfer electrons from NADPH in the cytoplasm across the cell membrane, which results in the formation of ROS. There are seven NOX members, each differing in composition and modes of activation. NOX1, NOX2, NOX3, and NOX5 transfer electrons from NADPH to molecular oxygen, producing superoxide anion ($O_2^{\cdot-}$). NOX4, DUOX1 and DUOX2, meanwhile, mainly produce hydrogen peroxide (H_2O_2). Setanaxib is designed to inhibit NOX1 and NOX4, enzymes which are implicated in inflammation and fibrosis pathways.

Setanaxib in Primary Biliary Cholangitis

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 this 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 in the destruction of 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, which in turn results in the destruction of liver cells and fibrosis. PBC can eventually lead to liver failure, necessitating the need for a liver transplant. It is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 140,000 patients in the US, where the annual incidence ranges from 0.3 to 5.8 cases per 100,000.

Early symptoms of PBC include fatigue, itchy skin, dry eyes and mouth dryness. As the disease progresses, symptoms range from pain in the upper right abdomen and musculoskeletal pain to oedema, jaundice, osteoporosis, elevated cholesterol and hypothyroidism. If untreated, 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.

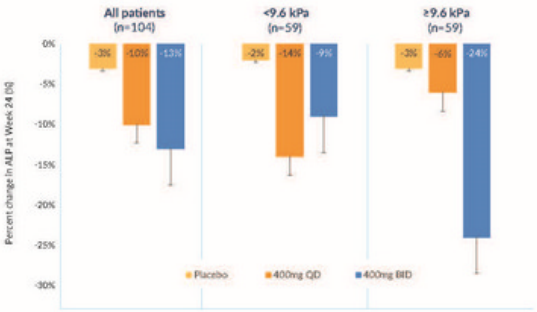
Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, known as Ocaliva, are the only FDA-approved treatments for PBC. Both of these agents are bile acid analogues whose mechanisms of action aim to protect the liver from damage caused by accumulation of endogenous bile acids and inhibition of bile acid synthesis. These drugs are primarily anticholestatic, and neither specifically addresses the autoimmune response that is believed to drive PBC, the inflammatory consequences of the autoimmune response or the increased bile acid levels associated with this indication. Approximately one-third of PBC patients do not respond sufficiently to UDCA and are at risk of disease progression. Octaliva may, to some extent, address this insufficiency, but has side effect issues related to pruritus (itching) and has not been proven in clinical testing to delay or avoid the need for liver transplant.

Pipeline: A NOX Inhibitor Platform

Promising Phase 2 Data in PBC

Setanaxib has previously been investigated in a 24 week Phase 2 trial with 111 adult patients and has received orphan drug designation for the treatment of PBC in the United States and Europe. While the Phase 2 trial did not met the primary endpoint of change in gamma-glutamyl transferase (GGT) at week 24, the study met key secondary endpoints related to change in alkaline phosphatase (ALP), an accepted endpoint for PBC, as well as liver stiffness and important quality of life metrics.

In patients with an estimated liver fibrosis stage of F3 or higher, treatment with setanaxib resulted in a 22% reduction of liver stiffness (a reduction by 2.7 kPA), compared to 4% increase (a mean absolute increase of 0.4 kPa) for the placebo arm. Setanaxib also achieved a reduction of 12% in ALP. In the higher dose and higher liver stiffness subcategory of patients, the ALP reduction was 24%. Furthermore, there was a statistically significant impact on fatigue, a very common and bothersome symptom of PBC which is not currently addressed by existing therapies, as well as demonstrated positive effects on emotional and social aspects.

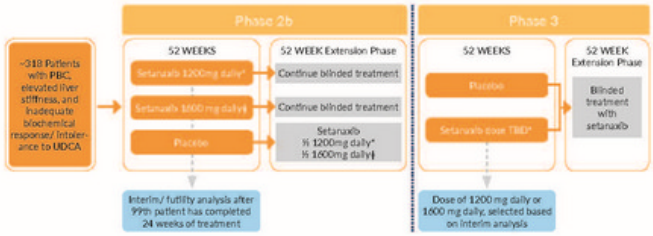


Setanaxib has also demonstrated a favourable safety profile in a Phase 1 clinical study with high-dose setanaxib in healthy subjects, which evaluated the safety and pharmacokinetics of the drug at doses up to 1,600 mg/day.

Phase 2b/3 TRANSFORM Trial

Calliditas will conduct a pivotal 52-week, randomized, placebo-controlled, double-blind, trial with an adaptive phase 2b/3 design.

Setanaxib will be administered at doses of 1200mg/day and 1600mg/day as an add-on therapy to approximately 318 adult PBC patients at up to 150 investigational centres. The primary endpoint will be ALP reduction, and key secondary endpoints include change in liver stiffness, and effect on puritus and fatigue. A futility analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in H2 2023, and the trial is expected to read out final data in late 2024 or early 2025. In August 2021, Calliditas received FDA Fast Track Designation for setanaxib in PBC.



*Dose of 1200 mg daily administered as 800 mg AM and 400 mg PM
‖Dose of 1600 mg daily administered as 800 mg AM and 800 mg PM

Pipeline: A NOX Inhibitor Platform

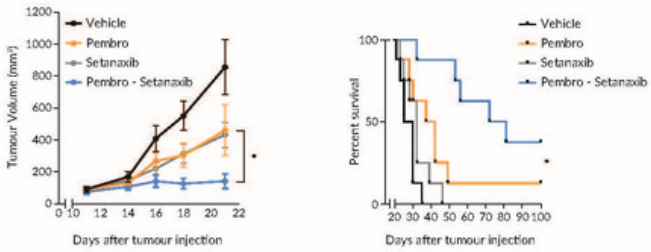
Setanaxib in Scquamous Cell Carcinoma of the Head & Neck

Calliditas also intends to explore setanaxib in head and neck cancer. Immuno-oncology therapies are not very effective in highly fibrotic tumours, which introduces the potential for anti-fibrotic agents to be used to improve treatment. A relationship between cancer associated fibroblasts (CAFs) and prognosis in Squamous Cell Carcinoma of the Head & Neck (SCCHN) has been established.

NOX4 is highly over-expressed in CAFs and drives myofibroblastic activation, where CAFs are enslaved by tumours and shield them from CD8+ (cytotoxic) T-cells. Targeting CAFs with setanaxib could improve patients' responses to immunotherapies, and function as an adjunct therapy. There is increasing use of pembrolizumab as 1st line monotherapy in patients with relapsed or metastatic SCCHN, although response rates are low (ORR approx. 20%).

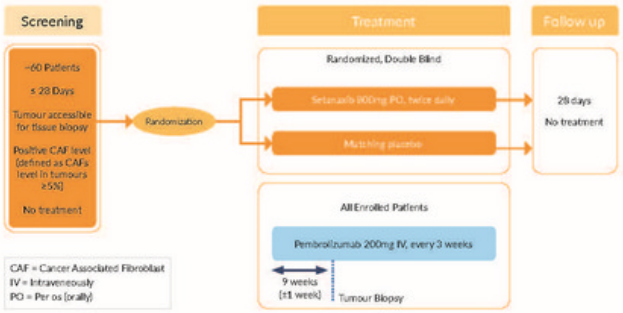
Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:

- Improved penetration of TILs into the centre of the tumour
- Slowing of tumour growth and improved survival



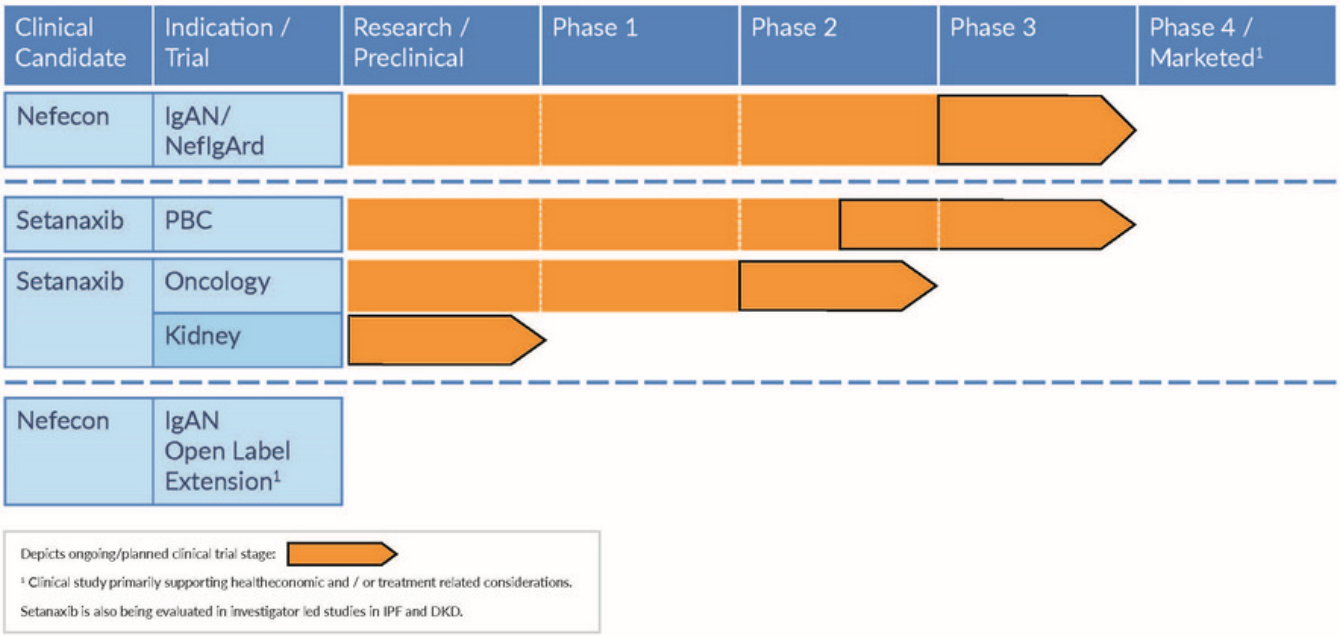
Proof-of-concept study in head and neck cancer

Calliditas is planning a Phase 2 proof-of-concept study in patients with head and neck cancer, which will investigate administration of setanaxib in conjunction with immunotherapy targeting CAFs.



The study will likely involve around 60 patients and the target is to start enrollement in Q1 2022, with an interim readout in late 2022 and final data read out expected in H2 2023.

Our Pipeline



Significant events, January 1 – September 30, 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. 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.
- 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).
- In April 2021, Calliditas announced that the FDA accepted the submission and granted Priority Review for the NDA for Nefecon.
- In May 2021, Calliditas announced that the company submitted a Marketing Authorisation Application (MAA) to the EMA for Nefecon, a novel oral formulation targeting down regulation of IgA1 for the treatment of primary IgA Nephropathy.
- In July 2021, Calliditas signed a loan agreement of up to the EUR equivalent of $75 million with Kreos Capital. The loan facility is divided into three tranches of $25 million each. Drawdown of the first $25 million tranche can be made until 31 December 2021 and will be available after the satisfaction of customary closing conditions. Drawdown of the second tranche of $25 million can be made until 30 June 2022 and will be available subject to accelerated approval of Nefecon by the U.S Food and Drug Administration (FDA). Drawdown of the third and final $25 million tranche can be made until 31 December 2022 and will be available subject to certain revenue milestones and coverage metrics.
- In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize Nefecon for the treatment of IgAN in the EEA member states, Switzerland and the UK valued at a total of EUR 97.5 million ($115m) in initial upfront and potential milestone payments, plus tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.
- In August 2021, Calliditas received FDA fast track designation for setanaxib in PBC.
- In August 2021, Calliditas completed an accelerated book building procedure and resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of SEK 324.0 million before transaction costs.
- In September 2021, Calliditas announced that the FDA extended the PDUFA goal date for its New Drug Application (NDA) seeking accelerated approval for Nefecon to December 15, 2021.
- In September 2021, Calliditas announced that the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP) decided to continue the assessment of the marketing authorization application (MAA) for Nefecon under standard procedure assessment timelines.

Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Year Ended December 31, 2020
Net sales	198,167	-	198,167	474	874
Research and development expenses	(92,098)	(64,887)	(257,194)	(167,379)	(241,371)
Research and development expenses/Total operating expenses in %	48%	62%	51%	69%	63%
Operating profit (loss)	7,856	(104,891)	(302,323)	(243,779)	(379,720)
Profit (loss) before income tax for the period	6,480	(137,942)	(294,906)	(262,878)	(436,151)
Earnings (loss) per share before dilution	0.21	(2.77)	(5.45)	(6.09)	(9.66)
Cash flow used in operating activities	(33,245)	(103,316)	(300,334)	(189,107)	(309,181)

(SEK in thousands, except per share amount or as otherwise indicated)	September 30, 2021	September 30, 2020	December 31, 2020
Total registered shares at the end of period	52,341,584	49,941,584	49,941,584
Equity attributable to equity holders of the Parent Company at the end of the period	1,261,849	1,376,788	1,210,491
Equity ratio at the end of the period in %	71%	96%	80%
Cash at the end of the period	1,163,818	1,396,869	996,304

January – September 2021

Revenue

Net sales for the three months ended September 30, 2021 amounted to SEK 198.2 million. No net sales were recognized for the three months ended September 30, 2020. Net sales for the nine months ended September 30, 2021 amounted to SEK 198.2 million and SEK 0.5 million for the nine months ended September 30, 2020. The net sales for both the three months period and the nine months period 2021, originates from the 20 MEUR upfront fee from Stada Artzneimittel for the Nefecon outlicensing in EU. For additional information see Note 4.

Total Operating Expenses

Total operating expenses amounted to SEK 190.3 million and SEK 104.9 million for the three months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, total operating expenses amounted to SEK 500.5 million and SEK 244.3 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 92.1 million and SEK 64.9 million for the three months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, research and development expenses amounted to SEK 257.2 million and SEK 167.4 million, respectively. The increase of SEK 27.2 million for the third quarter is primarily due to increased cost for the preperation of the upcoming setanaxib trials, compared to the same period last year. During the third quarter, there has been a contract adjustment for the Nefigard trial resulting in a reduced expense for the trial in the quarter. The increase of SEK 89.8 million for the nine months ended September 30, 2021 is, besides the cost for the upcoming setanaxib trials, primarily due to increased cost of the NeflgArd studies, compared to the same period last year.

Administrative and Selling Expenses

Administrative and selling expenses amounted to SEK 95.4 million and SEK 41.0 million for the three months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, administrative and selling expenses amounted to SEK 238.5 million and SEK 77.8 million, respectively. The increase of SEK 54.3 million for the third quarter and SEK 160.7 million for the nine months ended September 30, 2021 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

Other operating income amounted to SEK 2.2 million and SEK 1.0 million for the three months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, other operating income amounted to SEK 2.5 million and SEK 1.0 million, respectively. The increase in operating income was primarily relating to favourable exchange rates on operating liabilities.

Other operating expenses amounted to SEK 5.0 million for the three months ended September 30, 2021. Other operating expenses amounted to SEK 7.3 million for the nine months ended September 30, 2021. No other operating expenses were recognized for the three months or the nine months ended September 30, 2020. The increase in other operating expenses primarily relates to unfavorable exchange rate development on operating liabilities and receivables.

Net Financial Income and Expenses

Net financial income and (expenses) amounted to SEK (1.4) million and SEK (33.1) million for the three months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, net financial income and (expenses) amounted to SEK 7.4 million and SEK (19.1 million), respectively. The increase of SEK 31.7 million for third quarter and the increase of SEK 26.5 million for the nine months ended September 30, 2021 are primarily derived by a decrease of unrealized foreign currency transaction losses on cash accounts, compared to the same periods last year.

Tax

Deferred tax assets of SEK 11.4 million have been recognized in the nine months ended September 30, 2021 due to future temporary differences that such losses can be used to offset and are related to Genkyotex. The Group's tax losses accumulated have otherwise not been valued and not 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 September 30, 2021, the Group had a net income of SEK 6.5 million and for the three months ended September 30,2020 the Group had a net loss of SEK 138.0 million. Corresponding profit (loss) per share before and after dilution amounted to SEK 0.21 and SEK (2.77) for the three months ended September 30 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020 the Group had a net loss of SEK 283.5 million and SEK 263.1 million, respectively and the corresponding profit/(loss) per share before dilution amounted to SEK (5.45) and SEK (6.09), respectively.

January – September 2021

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 33.2 million and SEK 103.3 million for the three months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, cash flow used in operating activities amounted to SEK 300.3 million and SEK 189.1 million, respectively. The cash flow used in operating activities during these periods 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 September 30, 2021. For the nine months ended September 30, 2021, cash flow used in investing activities amounted to SEK 19.0 million. The cash flow used in investing activities amounted for the nine months period ending September 30, 2021, are mainly derived from a EUR 1.5 million milestone payment for the Budenofalk license. The Group had non-material cash flows used in investing activities for both the three months and the nine months ended September 30, 2020.

Cash flow from financing activities amounted to SEK 486.8 million and SEK 70.2 million for the three months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, cash flow from financing activities amounted to SEK 476.5 million and SEK 847.9 million, respectively. The cash from financing activities for both the three months and the nine months ending September 30, 2021 are primarily related to the new share issue in August of net SEK 304.0 million and the September draw down of the first tranche of the Kreos loan facility of net SEK 199.5 million.

Net increase/(decrease) in cash amounted to SEK 453.3 million and SEK (33.1 million) for the three months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021 and 2020, net increase/(decrease) in cash amounted to SEK 157.1 million and SEK 658.8 million, respectively. Cash amounted to SEK 1,163.8 million and SEK 1,396.9 million as of September 30, 2021 and 2020, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 1,261.8 million and SEK 1,376.8 million as of September 30, 2021 and 2020, respectively. The number of shares amounted to 52,341,584 and 49,941,584 as of September 30, 2021 and 2020, respectively. The increase in number of shares between the periods is due to a new share issue in August 2021 of 2.4 million shares.

Employees

The number of employees were 65 and 23 employees as of September 30, 2021 and 2020, respectively. The total number of full-time equivalent (FTE), including consultants, were 81 and 34 people as of September 30, 2021 and 2020, respectively. The average number of employees was 62 and 24 employees for the three months ended September 30, 2021 and 2020, respectively, and 51 and 20 for the nine months ended September 30, 2021 and 2020, respectively.

Incentive Programs

For the three months ended September 30, 2021, an allocation of 340,000 employee stock options has been made for the ESOP 2021 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.

Stockholm, November 18, 2021

Renée Aguiar-Lucander
CEO

Review report

Calliditas Therapeutics AB, corporate identity number 556659-9766

Introduction

We have reviewed the condensed interim report for Calliditas Therapeutics AB as at September 30, 2021 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm 18 November 2021

Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

FINACIAL STATEMENTS

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amount)	Notes	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Year Ended December 31, 2020
Net sales	4	**198,167**	-	**198,167**	474	**874**
Research and development expenses		(92,098)	(64,887)	(257,194)	(167,379)	(241,371)
Administrative and selling expenses		(95,372)	(41,037)	(238,522)	(77,843)	(141,724)
Other operating income		2,153	1,033	2,536	969	2,501
Other operating expenses		(4,994)	-	(7,309)	-	-
Operating profit (loss)		**7,856**	**(104,891)**	**(302,323)**	**(243,779)**	**(379,720)**
Net financial income/(expenses)		(1,375)	(33,051)	7,417	(19,099)	(56,431)
Profit (loss) before income tax		**6,480**	**(137,942)**	**(294,906)**	**(262,878)**	**(436,151)**
Income tax		(31)	(80)	11,415	(185)	(360)
Profit (loss) for the period		**6,449**	**(138,022)**	**(283,491)**	**(263,063)**	**(436,511)**
Attributable to:						
Equity holders of the Parent company		10,835	(138,022)	(274,460)	(263,063)	(433,494)
Non-controlling interests		(4,385)	-	(9,031)	-	(3,017)
		6,449	**(138,022)**	**(283,491)**	**(263,063)**	**(436,511)**
Profit (loss) per share before dilution (SEK)		0.21	(2.77)	(5.45)	(6.09)	(9.66)
Profit (loss) per share after dilution (SEK)		0.21	(2.77)	(5.45)	(6.09)	(9.66)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Year Ended December 31, 2020
Net income (loss) for the period	6,449	(138,022)	(283,491)	(263,063)	(436,511)
Other comprehensive income					
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:					
Exchange differences on translation of foreign operations	2,546	(22)	5,061	(20)	(9,352)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:	**2,546**	**(22)**	**5,061**	**(20)**	**(9,352)**
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:					
Remeasurement gain on defined benefit plans	236	-	1,761	-	1,216
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:	**236**	**-**	**1,761**	**-**	**1,216**
Other comprehensive income/(loss) for the period	**2,782**	**(22)**	**6,822**	**(20)**	**(8,136)**
Total comprehensive income (loss) for the period	**9,231**	**(138,044)**	**(276,669)**	**(263,083)**	**(444,647)**
Attributable to:					
Equity holders of the Parent company	13,279	(138,044)	(268,417)	(263,083)	(438,343)
Non-controlling interests	(4,047)	-	(8,253)	-	(6,305)
	9,231	**(138,044)**	**(276,669)**	**(263,083)**	**(444,648)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	September, 30 2021	2020	December 31, 2020
ASSETS				
Non-current assets				
Intangibe assets	6	484,686	16,066	461,367
Equipment		1,190	89	163
Right-of-use assets		20,086	4,144	5,244
Non-current financial assets		3,944	1,938	2,225
Deferred tax assets		2,600	173	600
Total non-current assets		**512,505**	**22,410**	**469,599**
Current assets				
Other current receivables	8	55,474	4,106	22,801
Prepaid expenses		36,867	16,798	17,746
Cash		1,163,818	1,396,869	996,304
Total current assets		**1,256,159**	**1,417,773**	**1,036,851**
TOTAL ASSETS		**1,768,664**	**1,440,183**	**1,506,450**
EQUITY AND LIABILITIES				
Equity				
Share capital		2,094	1,998	1,998
Additional paid-in-capital		2,451,979	2,126,016	2,133,179
Retained earnings, including net loss for the period		(1,192,224)	(751,226)	(924,686)
Equity attributable to equity holders of the Parent Company		**1,261,849**	**1,376,788**	**1,210,491**
Non-controlling interests		28,677	-	45,810
Total equity	**9.10**	**1,290,526**	**1,376,788**	**1,256,300**
Non-current liabilities				
Provisions	10	61,461	1,931	55,361
Pensions Liabilities		5,713	-	8,296
Deferred tax liabilities	7	69,025	-	79,996
Non-current interesting-bearing liabilities	11	187,427	-	-
Other non-current liabilities		14,441	1,034	878
Total non-current liabilities		**338,067**	**2,965**	**144,531**
Currents liabilities				
Accounts payable		74,855	19,872	53,827
Other current liabilities		10,642	3,922	10,406
Accrued expenses and deferred revenue		54,574	36,636	41,386
Total current liabilities		**140,072**	**60,430**	**105,619**
TOTAL EQUITY AND LIABILITIES		**1,768,664**	**1,440,183**	**1,506,450**

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	September, 30 2021	September, 30 2020	December 31, 2020
Opening balance equity attributable to equity holders of the Parent Company	**1,210,491**	**788,071**	**788,071**
		-	
Loss for the period	(274,460)	(263,063)	(433,494)
Ohter comprehensive income/(loss)	6,043	(20)	(4,849)
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	**(268,417)**	**(263,083)**	**(438,343)**
Transactions with owners			
New share issue	324,000	891,388	891,388
Cost attributable to new share issue	(20,909)	(97,686)	(97,686)
Exercise of warrants	-	54,919	59,251
Share-based payments	15,805	3,179	6,012
Purchase of non-controlling interests	879	-	1,798
Total transactions with owners	**319,775**	**851,800**	**860,763**
Closing balance equity attributable to equity holders of the Parent Company	**1,261,849**	**1,376,788**	**1,210,491**
Opening balance equity attributable to non-controlling interests	**45,809**	**-**	**-**
Total comprehensive loss for the period	(8,253)	-	(6,305)
Contribution from non-controlling interests	2,282	-	-
Non-controlling interests from business combinations	-	-	136,084
Purchase of non-controlling interests	(11,162)	-	(83,970)
Closing balance equity attributable to non-controlling interests	**28,677**	**-**	**45,809**
Closing balance equity	**1,290,526**	**1,376,788**	**1,256,300**

Condensed Consolidated Statements of Cash Flows

Amounts in SEK 000s	Three Months Ended September 30		Nine Months Ended September 30		Year Ended December 31
	2021	2020	2021	2020	2020
Operating activities					
Operating profit (loss)	7,856	(104,891)	(302,323)	(243,779)	(379,720)
Adjustment for non-cash-items	8,912	4,937	24,136	6,866	15,465
Interest received	-	-	-	-	1,912
Interest paid	(327)	(60)	(536)	(321)	(393)
Income tax paid	(477)	(427)	(1,470)	(427)	(528)
Cash flow used in operating activities before changes working capital	**15,963**	**(100,441)**	**(280,193)**	**(237,661)**	**(363,264)**
Cash flow from/(used in) changes in working capital	(49,208)	(2,875)	(20,141)	48,554	54,083
Cash flow used in operating activities	**(33,245)**	**(103,316)**	**(300,334)**	**(189,107)**	**(309,181)**
Cash flow used in investing activities	(236)	(1)	(19,003)	(2)	(172,607)
Cash flow used in investing activities	**(236)**	**(1)**	**(19,003)**	**(2)**	**(172,607)**
New share issue	324,000	63,388	324,000	891,388	891,388
Costs attributable to new share issue	(19,927)	(19,157)	(20,909)	(95,937)	(95,937)
Premiums from warrants issuance	-	26,591	-	54,919	59,251
Purchase of non-controlling interests	-	-	(10,283)	-	(82,172)
Contribution from non-controlling interests	-	-	2,282	-	-
Borrowing	199,524	-	199,524	-	-
Costs attributable to loan	(14,858)	-	(14,858)	-	-
Repayment of loans (lease liabilities)	(1,944)	(636)	(3,305)	(2,488)	(3,972)
Cash flow from /(used in) financing activities	**486,795**	**70,186**	**476,451**	**847,882**	**768,558**
Net increase/(decrease) in cash	**453,314**	**(33,131)**	**157,114**	**658,773**	**286,770**
Cash at the beginning of period	**709,306**	**1,459,569**	**996,304**	**753,540**	**753,540**
Net foreign exchange gains/(loss) on cash	1,198	(29,569)	10,400	(15,444)	(44,006)
Cash at the end of period	**1,163,818**	**1,396,869**	**1,163,818**	**1,396,869**	**996,304**

Condensed Parent Company Statements of Income

(SEK in thousands, except per share amount)	Notes	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Year Ended December 31, 2020
Net sales	4	198,167	-	198,167	474	874
Research and development expenses		(79,258)	(64,888)	(210,631)	(167,380)	(227,027)
Administrative and selling expenses		(91,756)	(36,236)	(226,138)	(73,582)	(128,896)
Other operating income		26,362	187	41,035	969	2,482
Other operating expenses		(3,746)	845	(4,199)	-	-
Operating profit (loss)		**49,769**	**(100,092)**	**(201,766)**	**(239,519)**	**(352,567)**
Net financial income/(expenses)		(865)	(32,980)	8,441	(18,741)	(54,796)
Profit (loss) before income tax		**48,903**	**(133,072)**	**(193,326)**	**(258,260)**	**(407,363)**
Income tax		-	-	-	-	-
Profit (loss) for the period		**48,903**	**(133,072)**	**(193,326)**	**(258,260)**	**(407,363)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Year Ended December 31, 2020
Profit (loss) for the period	48,903	(133,072)	(193,326)	(258,260)	(407,363)
Other comprehensive income/(loss)	-	-	-	-	-
Total comprehensive profit (loss)	**48,903**	**(133,072)**	**(193,326)**	**(258,260)**	**(407,363)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	September, 30 2021	2020	December 31, 2020
ASSETS				
Non-current assets				
Intangibe assets	6	32,132	16,066	16,066
Equipment		-	86	80
Non-current financial assets		399,515	3,665	298,683
Total non-current assets		**431,646**	**19,817**	**314,829**
Current assets				
Other current receivables	8	84,857	3,983	10,998
Prepaid expenses		34,981	22,683	14,490
Cash		1,131,555	1,396,277	978,208
Total current assets		**1,251,392**	**1,422,943**	**1,003,696**
TOTAL ASSETS		**1,683,039**	**1,442,760**	**1,318,525**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Restricted Shareholders' equity				
Share capital		2,094	1,998	1,998
Statutory reserve		3,092	3,092	3,092
Total restricted Shareholders' equity		**5,186**	**5,090**	**5,090**
Non-restricted shareholders' equity				
Share premium reserve		2,420,698	2,116,721	2,116,721
Retained earnings		(870,937)	(482,211)	(479,379)
Net loss for the period		(193,326)	(258,260)	(407,363)
Total non-restricted shareholders' equity		**1,356,435**	**1,376,250**	**1,229,979**
Total shareholders' equity	9.10	**1,361,621**	**1,381,340**	**1,235,069**
Non-current liabilities				
Provisions	10	5,024	1,931	4,972
Non-current interesting-bearing liabilities	11	187,427	-	-
Other non-current liabilities		105	105	105
Total non-current liabilities		**192,557**	**2,036**	**5,077**
Currents liabilities				
Accounts payable		70,382	19,636	42,469
Other current liabilities		21,374	3,973	5,123
Accrued expenses and deferred revenue		37,106	35,775	30,787
Total current liabilities		**128,861**	**59,384**	**78,379**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,683,039**	**1,442,760**	**1,318,525**

NOTES

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 nine months ended September 30, 2021 and September 30, 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 November 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. Significant accounting principles can be found on pages 45-49 of the Annual Report for 2020.

During 2020, Calliditas 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 29. In July, 2021, Calliditas secured a loan facility of the euroekvivalent of 75 million dollar. In September, 2021, Calliditas made a draw down of the first 25 million dollar. The loan is accounted in Non-current interest-bearing liabilities net of transaction costs in the amount of SEK 21.3 million and a deposit on the borrowing for the last cash payment to be made of SEK 6.8 million.

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 lack of 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 trial, 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 and EUR to meet future expected costs in USD and EUR in connection with a potential commercialization of Nefecon in the United States and the clinical development programs. 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

	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
(SEK in thousands)	2021	2020	2021	2020	2020
Type of goods or services					
Provisions of Drugs	-	-	-	474	874
Out-licencing	198,167	-	198,167	-	-
Total	**198,167**	**-**	**198,167**	**-**	**-**
Geographical markets					
Europe	198,167	-	198,167	-	-
China, Hong Kong, Macau, Taiwan and Singapore	-	-	-	474	874
Total	**198,167**	**-**	**198,167**	**474**	**874**

The Group's revenues for both periods 2021 consisted of up-front fee from Stada for the outlicensing of the commercial rights of Nefecon in EU.

Revenue for out-licensing is reported at a time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreement with Stada was signed. Variable remuneration (for example, attributable to future regulatory milestones) is recognized when there is no longer any significant uncertainty as to whether these will occur.

Compensation attributable to sales-based milestones or royalties are not recognized until the sale that results in the right to milestones or royalties arises.
Calliditas have identified three performance commitments under the agreement: 1) Out-licensing of the product candidate Nefecon as is at the time of signing , 2) Contractual obligation to perform the regulatory process with the EMA to obtain Conditional Regulatory Approval and 3) The obligation to supply Nefecon. The share of the transaction amount attributable to the EMA regulatory process has not been recognized as revenue and has been calculated based on the estimated cost to finish this process. The proportion attributable to out-licensing has been calculated as a residual of the remaining transaction price after deduction of other performance commitments, since the product candidate has not been approved for market by the regulatory authorities and no commercial pricing occur.

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)	September 30, 2021	September 30, 2020	December 31, 2020
Cost at opening balance	461,367	16,066	16,066
Business Combinations	-	-	460,253
Acquisition license	16,066	-	-
Exchange difference on translation	7,253	-	(14,952)
Cost at closing balance	**484,686**	**16,066**	**461,367**
Amortisation at closing balance	**-**	**-**	**-**
Net book value	**484,686**	**16,066**	**461,367**

As of September 30, 2021 intangible assets consist of licenses and similar rights of SEK 436,664 thousand and goodwill of SEK 48,022 thousand.

Business combinations:

The acquisition of Genkyotex SA in 2020 resulted in the Group acquiring the rights to the NOX platform and the SIIL agreement, as well as goodwill.
The net book value of the NOX platform amounts to SEK 376,120 thousand as of September 30, 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 28,413 thousand as of September 30, 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 48,022 thousand as of September 30, 2021.

Note 7 - Deferred Tax Liabilities

(SEK in thousands)	September 30, 2021	September 30, 2020	December 31, 2020
Cost at opening balance	79,396	-	-
Business Combinations	-	-	79,396
Tax loss carried forward	(11,415)	-	-
Exchange difference on translation	1,044	-	-
Cost at closing balance	**69,025**	**-**	**79,396**

Deferred tax assets of SEK 24.7 million have been offset against deferred tax liabilities in the statement of financial position as of September 30, 2021 due to future temporary differences that such losses can be used to offset.

Note 8 - Financial Instruments

The Group's 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 derivates existed as of September 30, 2021. Currency options amounted to SEK 851 thousand as of September 30, 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)	September 30, 2021	September 30, 2020	December 31, 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	2,400,000	11,233,946	11,233,946
Total registered shares at the end of period	**52,341,584**	**49,941,584**	**49,941,584**
Share capital at the end of period	2,094	1,998	1,998
Equity attributable to equity holders of the Parent Company	1,261,849	1,376,788	1,210,491
Non-controlling interests	28,677	-	45,810
Equity at the end of period	**1,290,526**	**1,376,788**	**1,256,300**

	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2021	2020	2021	2020	2020
Earnings (loss) per share before dilution	0.21	(2.77)	(5.45)	(6.09)	(9.66)
Weighted-average number of shares outstanding for the period, before dilution	51,063,323	49,751,058	50,829,255	43,165,505	44,873,448

Reserves for translation from foreign operations amounted to SEK 1,807 thousand and SEK -20 thousand, which are included in equity as of September 30, 2021 and 2020, respectively.

Note 10 - Incentive Programs

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of September 30, 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
Board LTIP 2021	-	-	26,968	26,968
ESOP 2020	-	1,455,000	-	1,455,000
ESOP 2021	-	850,000	-	850,000
Total Outstanding as of September 30, 2021	**1,279,086**	**2,305,000**	**109,738**	**3,693,824**

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of September 30, 2020
Incentive Programs				
Warrant program 2018/2022	856,586	-	-	856,586
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2019	-	-	57,032	57,032
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**	**88,403**	**2,456,489**

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 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 ("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.

Board LTIP 2021:

This is a performance-based long-term incentive program for Calliditas Board members. A total of 26,968 share awards were granted under the program during the second quarter of 2021. The share rights are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2021 Annual General Meeting to July 1, 2024.

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.

ESOP 2021:

In 2021, 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.

Note 11 - Non-current interest-bearing liabilities

	September 30,		December 31,
(SEK in thousands)	2021	2020	2020
Opening balance	-	-	-
Acquisition of loan - net	187,427	-	-
Amortization of loan	-	-	-
Closing balance	**187,427**	**-**	**-**

In July 2021, Calliditas signed a loan agreement of up to the euroequivalent of 75 million dollar with Kreos Capital. The loan facility is divided into three tranches of 25 million dollar each. Drawdown of the first 25 million dollar tranche was made in September, 2021. Drawdown of the second tranche of 25 million dollar can be made until 30 June 2022 and will be available subject to accelerated approval of Nefecon by the U.S Food and Drug Administration (FDA). Drawdown of the third and final 25 million dollar tranche can be made until 31 December 2022 and will be available subject to certain revenue milestones and coverage metrics. The interest rate on the loan is 9% per annum with a maturity to December 2025. The loan has no covenants.

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 Group's 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 otherwise indicated)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Year Ended December 31, 2020
Research and development expenses/Total operating expenses in %					
Research and development expenses	(92,098)	(64,887)	(257,194)	(167,379)	(241,371)
Administrative and selling expenses	(95,372)	(41,037)	(238,522)	(77,843)	(141,724)
Other operating income/expenses	(2,842)	1,033	(4,773)	969	2,501
Total operating expenses	**(190,311)**	**(104,891)**	**(500,490)**	**(244,253)**	**(380,594)**
Research and development expenses/Total operating expenses in %	48%	62%	51%	69%	63%

(SEK in thousands or otherwise indicated)	September 30, 2021	September 30, 2020	December 31, 2020
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	1,261,849	1,376,788	1,210,491
Total assets at the end of the period	1,768,664	1,440,183	1,506,450
Equity ratio at the end of the period in %	**71%**	**96%**	**80%**

NOTES

Financial Calendar

Year-end Report for the period January 1 – December 31, 2021	February 24, 2022

Contact

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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 interim report, 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.

This report has been prepared in a Swedish original and has been translated into English. In case of differences between the two, the Swedish version shall apply.

calliditas
THERAPEUTICS

Exhibit 99.2

Stockholm, Sweden **November 18, 2021**

Interim Report Q3, 2021

A quarter of deal making and regulatory review

“Following on from the positive top line read out of Part A our Phase 3 study, we initiated a structured process to select our commercial partner for Nefecon in Europe. In this case, the result of the process was a partnership with Stada Arzneimittel, which has proven to be an excellent match. We also took the opportunity to complement our predominant source of equity capital with a $75m credit line from Kreos.

In the third quarter, the U.S. Food and Drug Administration (FDA) requested further analyses of data from the NeflgArd clinical trial in connection with our NDA submitted for approval under the FDA’s Accelerated Approval Program. The FDA classified the additional analyses received as a major amendment to the NDA and extended the PDUFA goal date by three months from September 15, 2021 to December 15, 2021. The third quarter also saw the European Medicines Agency (EMA) deciding to revert to standard review timelines for our submission, which we estimate will result in the issuance of an opinion in Q1, 2022. We remain confident that we have presented a compelling data package and look forward to continuing our regulatory interactions with the goal of making an approved treatment available for patients in need.

We remain ready for commercial launch in the US. Our field medical directors are in dialogue with nephrologists across the country and we are proceeding with market access related conversations as well as other pre-commercial activities. We are excited about our strong US capabilities reflected by the highly experienced and well-prepared team in place.“

Renée Aguiar-Lucander, CEO

Summary of Q3 2021

July 1 – September 30, 2021

- Net sales amounted to SEK 198.2 million for the three months ended September 30, 2021. No net sales were recognized for the three months ended September 30, 2020.
- Operating profit (loss) amounted to SEK 7.9 million and SEK (104.9 million) for the three months ended September 30, 2021 and 2020, respectively.
- Earnings (loss) per share before dilution amounted to SEK 0.21 and SEK (2.77) for the three months ended September 30, 2021 and 2020, respectively.
- Cash amounted to SEK 1,163.8 million and SEK 1,396.9 million as of September 30, 2021 and 2020, respectively.

Significant events during Q3 2021, in summary

- In July 2021, Calliditas signed a loan agreement of up to the EUR equivalent of $75 million with Kreos Capital.
- In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize Nefecon in the European Economic Area (EEA) member states, Switzerland and the UK valued at a total of EUR 97.5 million (approx. $115m) in initial upfront and potential milestone payments, plus royalties.
- In August 2021, Calliditas received FDA fast track designation for setanaxib in PBC.
- In August 2021, Calliditas completed an accelerated book building procedure and resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of SEK 324.0 million (approx. $37m) before transaction costs.
- In September 2021, Calliditas announced that the FDA extended the PDUFA goal date for its New Drug Application (NDA) seeking accelerated approval for Nefecon to December 15, 2021.
- In September 2021, Calliditas announced that the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP) decided to continue the assessment of the marketing authorization application (MAA) for Nefecon under standard procedure assessment timelines.

Investor presentation November 18, 14:30 CET
Audio cast with teleconference, Q3 2021, November 18, 2021, 14:30 (Europe/Stockholm)
Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q3-2021
Teleconference: SE: +46856642695 | UK: +443333009264 | US: +16467224903

Financial calendar
Year-end Report for the period January 1 – December 31, 2021 February 24, 2022

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The information was submitted for publication, through the agency of the contact persons set out above, at 07:00 CET on November 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, the potential for and timing of FDA approval of its regulatory marketing application for Nefecon, the potential for FDA's review extension on the NDA for Nefecon to lead to marketing approval, 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.