Q4 2021

YEAR-END REPORT JANUARY 1ST – DECEMBER 31ST 2021

calliditas THERAPEUTICS

FDA Accelerated Approval of Calliditas' commercial product, TARPEYO™

Financial summary for the Group

Key Figures

October 1 - December 31, 2021

- Net sales amounted to SEK 31.2 million and SEK 0.4 million for the three months ended December 31, 2021 and 2020, respectively.
- Operating loss amounted to SEK 222.1 million and SEK 135.9 million for the three months ended December 31, 2021 and 2020, respectively.
- Loss per share before and after dilution amounted to SEK 4.19 and SEK 3.41 for the three months ended December 31, 2021 and 2020, respectively.
- Cash amounted to SEK 955.5 million and SEK 996.3 million as of December 31, 2021 and 2020, respectively.

January 1 - December 31, 2021

- Net sales amounted to SEK 229.3 million and SEK 0.9 million for the full year ended December 31, 2021 and 2020, respectively.
- Operating loss amounted to SEK 524.5 million and SEK 379.7 million for the full year ended December 31, 2021 and 2020, respectively.
- Loss per share before and after dilution amounted to SEK 9.84 and SEK 9.66 for the full year ended December 31, 2021 and 2020, respectively.

Significant events in Q4 2021

In December 2021, Calliditas announced that the US Food and Drug Administration (FDA) had granted accelerated approval for TARPEYO (budesonide) delayed release capsules indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. TARPEYO is the first and only FDA-approved treatment for this disease and was designed specifically to target the origin of IgA nephropathy. This approval marked the successful transition for Calliditas to a commercial-stage biopharmaceutical company.

TARPEYO™
(budesonide) delayed release capsules • 4 mg

Investor Presentation February 24, 2022 14:30 CET

Audio cast with teleconference, Q4 2021

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q4-2021

Teleconference: SE: +46850558354 UK: +443333009269 US: +16467224902

Approval!

During the fourth quarter the company achieved a monumental milestone, when Nefecon was granted accelerated approval by the FDA in the US under the brand name of TARPEYO.

This is the first time that the cardio renal division has granted an accelerated approval in a nephrology indication, a historic event that we are very proud to be a part of. It is also the very first time that patients suffering from IgA nephropathy have access to an approved medication, which is what we have been working hard to achieve for over a decade. What started as discussions regarding how to target the origin of the disease between Professors Fellström and Hällgren in the late 1990's has now finally made it to patients. The idea of focusing on the production of the IgA antibodies in the gut as the source of this kidney disease was as novel and intriguing then as it is today. To design a drug development program focused on achieving disease modification by targeting the secretory antibodies which result in immune complexes depositing in, and ultimately destroying, the kidney, was a brave and ambitious decision. As we know, development programs of any kind are inherently complex and can run into various problems along the way, so it is therefore extremely gratifying to see this approach produce such strong results to date.

The accelerated approval of TARPEYO was for the indication of reduction of proteinuria, which was the endpoint of Part A of the trial, in adult patients with IgA nephropathy with risk of rapid progression, which is characterized as generally UPCR ≥ 1.5 g/g. It is well established that patients with higher levels of proteinuria have a worse outlook and prognosis as they tend to experience a more rapid decline of their kidney function, as measured by eGFR. These patients are therefore at considerable risk of progressing to ESRD, resulting in the need for dialysis or transplantation. We are obviously thrilled to be able to bring a medication to all these patients, who before now did not have any approved treatment options that addressed their illness. The purpose of the continuing Phase 3 study is to complement the data provided in Part A with longer term outcome data related to the impact of treatment on the kidney function, which would form the basis for a regulatory submission for full approval in IgA nephropathy.

This undertaking has taken well over a decade to reach patients and is the result of the incredibly hard work and dedication of a diverse and extraordinary group of people, working as a team towards a common goal. To date, clinical trials involving over 365 patients across three separate programs have been successfully read out, with over 200 patients still enrolled across our Phase 3 program and open label extension study. The CMC department has not only provided clinical trial material, but has also successfully generated and overseen formulation improvements, upscaling of manufacturing and supply chain management to deliver the commercial product in a timely manner. Our regulatory team has expertly been providing both strategic and tactical insight and support for the entire regulatory journey, including recently managing parallel EMA and FDA processes. Market access and medical affairs have brought insight from healthcare professionals and the payor universe, conducting hundreds of interactions with groups and individuals to inform the organization and provide relevant input for critical decision making. Marketing and commercial have worked to create and implement all of the systems, resources, structures and materials required for the commercial launch, whilst legal, HR, IT and Finance have all worked relentlessly to ensure that our resources, compliance, communication, integration and reporting have kept up with the increasing demands and opportunities of a fast paced and growing organization that is transforming from an R&D focused company to an integrated and global research and commercial business. It has been a privilege to help guide and participate in this amazing journey over the last 4 years, and I am confident that this is just the beginning of our evolution into a broad-based biopharma business with the requisite talent, resources and science to continue to deliver enduring value to all of our stakeholders.

The fourth quarter also saw the completion of our acquisition of Genkyotex, resulting in the company's delisting from Euronext and full integration into Calliditas. We are excited about the potential of this focused discovery engine of NOX inhibitors and look forward to continue to leverage it across orphan diseases. In Q4, we embarked on our development program with the lead candidate setanaxib as we initiated a pivotal study in PBC, for which the first patient was dosed in February. We look forward to initiating additional clinical trials with setanaxib and sharing clinical results from these studies in due course. Finally, I want to thank all of our long term shareholders who have supported us and enabled us to reach this milestone of achieving a product approval in the US, and who I hope share our excitement for what we will deliver in 2022.

Renée Aguiar-Lucander, CEO

TARPEYO

On December 15th, 2021, the US Food and Drug Administration granted accelerated approval of Calliditas' lead product, TARPEYO, indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally defined as a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. TARPEYO (developed under the project name NEFECON) is the first and only FDA-approved treatment for IgA nephropathy.

TARPEYO is an oral, delayed release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. TARPEYO was designed as a 4 mg delayed release capsule with an enteric coating so that it remains intact until it reaches the ileum. Each capsule contains beads coated with polymers and budesonide designed to target mucosal B-cells responsible for the production of the galactose-deficient IgA1 antibodies (Gd-Ag1) that cause IgA nephropathy.

TARPEYO was approved by the FDA under the accelerated approval pathway, based on achieving its primary endpoint of reduction in proteinuria. The effect of TARPEYO was assessed in patients with biopsy-proven IgAN, eGFR ≥35 mL/min/1.73m2, and proteinuria (defined as ≥1 g/day) who were on a stable dose of maximally-tolerated RAS inhibitor therapy. Part A of the study included a 9-month blinded treatment period and a 3-month follow-up period. The primary endpoint was UPCR, and eGFR was a secondary endpoint. The second part of the NefIgArd study, Part B, is a confirmatory validation study in which no TARPEYO treatment is administered and where eGFR is the primary outcome measure. 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. Calliditas intends to report data from Part B of the ongoing randomized, double-blind, placebo controlled multicenter NefIgArd study in early 2023, subject to any impact from the COVID-19 pandemic to our business.

TARPEYO™
(budesonide) delayed release capsules • 4 mg

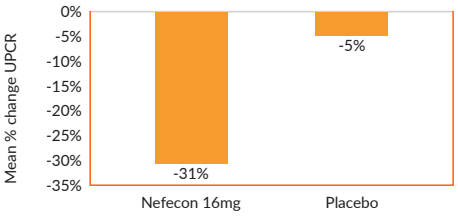
Calliditas has been granted orphan drug designation for the treatment of IgAN in the United States and is commercializing TARPEYO in the United States on its own.

NEFECON

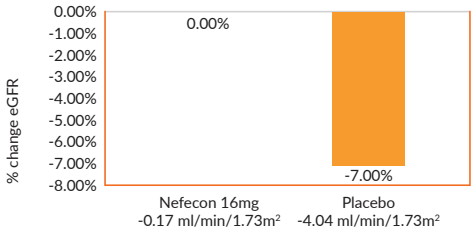
Calliditas is advancing its delayed, targeted-release formulation of budesonide under the development name “NEFECON®” outside of the USA.

Calliditas submitted a Marketing Authorization Application for NEFECON to the European Medicines Agency in May 2021. The submission was based, as was the submission to the FDA, on positive data from Part A of the NefIgArd pivotal Phase 3 study and supported by the Phase 2b NEFIGAN study, which also met both its primary endpoint of proteinuria reduction and key secondary endpoint of eGFR stabilization. Calliditas read out topline data from Part A of the study in November 2020. Patients taking NEFECON showed a statistically significant 34% reduction in proteinuria from baseline vs 5% in the placebo cohort at 9 months. The treatment effects for the primary endpoint of UPCR at 9 months were consistent across key subgroups, including key demographic and baseline disease characteristics. The key secondary endpoint, eGFR, showed a treatment benefit of 7% versus placebo at 9 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. The trial also demonstrated that NEFECON was well-tolerated.

Primary endpoint: Reduction in proteinuria



Secondary endpoint: Stabilization of eGFR



While Calliditas was initially granted Accelerated Assessment procedure by EMA’s Committee for Human Medicinal Products (CHMP), in September 2021 the EMA announced its decision to continue the assessment of the MAA for NEFECON under standard procedure assessment timelines. Calliditas expects a CHMP opinion in the first quarter of 2022.

In July this year, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize NEFECON® for the treatment of the IgA nephropathy in Europe. In July, Calliditas announced a deal with STADA covering European Economic Area (EEA) member states, Switzerland and the UK valued at a total of 97.5 million EUR ($115m), plus royalties. Under the terms of the agreement, Calliditas received an initial upfront payment of 20 million EUR ($24m) upon signing and is entitled to up to an additional 77.5 million EUR ($91m) in future payments linked to pre-defined regulatory and commercialization milestones. STADA is also due to pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

IgAN is designated as an orphan disease in both the US and Europe. In Europe, an orphan disease is defined as a disease or condition affecting no more than five in 10,000 European citizens with no satisfactory method of diagnosis, prevention or treatment. Orphan incentives consist of ten years of market exclusivity from the grant date of marketing approval in the EU, protocol assistance and scientific advice, fee reductions on EMA procedural activities and eligibility for EU grants.

IgA Nephropathy

An orphan disease with great unmet medical need.

IgA nephropathy (IgAN) – also known as Berger's disease – is the most common form of glomerulonephritis, a chronic inflammatory condition of the kidney, in the Western world.

IgAN Disease Background

IgAN is a serious progressive autoimmune disease of the kidney, in which up to 50% of patients end up at risk of developing end-stage renal disease (ESRD) within ten to twenty years. The standard of care for ESRD is dialysis or kidney transplant, which represents a significant health economic burden as well as a material impact on patients' quality of life.

IgAN is an orphan disease that we estimate affects approximately 130,000 – 150,000 people in the US and approximately 200,000 people in Europe. A significantly higher prevalence of IgAN has been observed in Asia, including in Greater China, where it has historically been a leading cause of ESRD and where we estimate that IgAN affects approximately 2,000,000 people.

IgAN Pathophysiology

Although IgAN manifests in the kidney, the evidence indicates that it is a disease that starts in the distal part of the intestine, specifically in the ileum. Peyer's patches, which are concentrated within the gut-associated lymphoid tissue in the ileum, have been identified as a major source of mucosal-type IgA1 antibodies. IgA1 antibodies play a key role in the immune system, protecting the body from foreign substances such as food-derived factors, bacteria and viruses. Patients with IgA nephropathy have elevated levels of mucosal-type IgA, and studies have shown that the type of IgA that deposits in the glomeruli in patients with IgAN is identical to the mucosal-type IgA produced in the gut. The majority of the IgA in the blood circulation is monomeric, heavily O-galactosylated and is derived from bone-marrow-residing plasma cells. In contrast, the mucosal-type IgA antibodies produced by the Peyer's patches are predominately dimeric or polymeric and are galactose deficient. In IgAN patients, a combination of a genetic predisposition and of environmental, bacterial and dietary factors is presumed to lead to an increased production of these galactose-deficient IgA antibodies. This increased production, potentially in conjunction with increased intestinal permeability, leads to these antibodies appearing in the blood.

The galactose-deficient spot at the hinge region of the IgA antibodies is immunogenic when found in the circulation. It therefore generates an autoimmune response, attracting autoantibodies in the form of IgG or IgA and forming pathogenic immune complexes that deposit in the glomeruli, the kidney's filtration apparatus. The trapped immune complexes initiate an inflammatory response which damages the kidney and ultimately destroys its filtration mechanism. This leads to slow, progressive deterioration of renal function, which in many patients ultimately results in the need for dialysis or kidney transplant.

Treatment landscape for IgAN patients

With the exception of TARPEYO, which is approved in the United States, there are currently no approved treatment options for IgAN. Kidney Disease Improving Global Outcomes 2012 (KDIGO) recommended the use of blood pressure lowering agents that inhibit or block the renin angiotensin system (RAS) using either angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs). RAS blockade reduces the pressure in the kidney glomeruli, thereby reducing leakage and protein excretion in urine. Treatment via RAS inhibition is supportive only, and does not address the underlying cause of IgAN.

In the absence of approved treatments, some physicians try to control the disease progression with a variety of off-label treatments that include systemic immunosuppressive agents, usually high doses of systemic corticosteroids. However, research is inconclusive as to whether or not it has any impact on the actual underlying kidney disease as measured by eGFR. In addition, this off label treatment is known to result in serious adverse events. There is therefore a high unmet medical need for a treatment that targets the disease origin and can also be well-tolerated by IgAN patients.

Pipeline: NOX Inhibitor Platform

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

NOX Enzymes

NOX enzyme inhibitors are a set of promising novel experimental drugs in a new therapeutic class, recognised by the WHO since 2019 when it approved "naxib" as a new stem. Nicotinamide adenine dinucleotide phosphate (NADPH) oxidases, otherwise known as NOX enzymes, are the only known enzymes that are solely dedicated to producing reactive oxygen species (ROS) as their primary and sole function. They are transmembrane enzymes that transfer electrons from NADPH in the cytoplasm across the cell membrane, which results in the formation of ROS. There are seven NOX members, each differing in composition, modes of activation and the ROS type they produce. NOX1, NOX2, NOX3, and NOX5 transfer electrons from NADPH to molecular oxygen, producing superoxide anion ($O_2^{\cdot-}$). NOX4, DUOX1 and DUOX2, meanwhile, mainly produce hydrogen peroxide (H_2O_2).

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, disruption of the redox homeostasis has been implicated in multiple disease pathways. Oxidative stress, caused by an excess of ROS, is a likely common underlying mechanism for many disorders, including cardiovascular diseases, neurodegenerative disorders, and cancer disease pathways. Setanaxib inhibits 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. 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. 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 formation of fibrous tissue.

Early symptoms of PBC include fatigue, itchy skin, and dry eyes and mouth. 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.

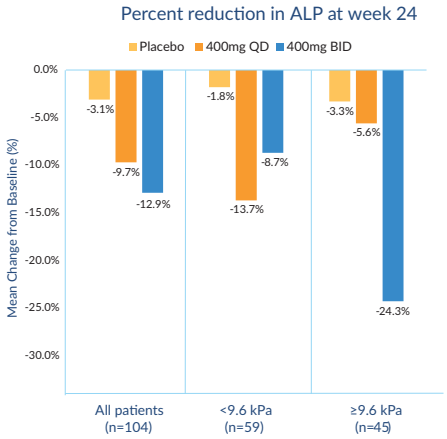
Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, known as Ocaliva, are the only FDA- and EMA-approved treatments for PBC. These drugs are primarily anticholestatic. UDCA is a bile acid analogue which is incorporated into the bile acid pool, replacing other more toxic bile acids and reducing inflammation and cholestasis. However, while it remains the first-line therapy for patients with PBC, only 40% to 60% of patients respond adequately to UDCA. Ocaliva, a modified bile acid, is a farnesoid X receptor (FXR) agonist which modulates bile acid homeostasis, decreasing bile acid synthesis and increasing its clearance. However, despite these treatment options, there is still an unmet medical need among PBC patients, in particular when it comes to important quality of life outcomes.

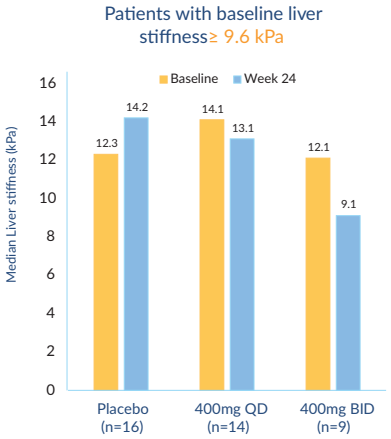
Pipeline: NOX Inhibitor Platform

Promising Phase 2 Data in PBC

Setanaxib previously has been investigated in a 24 week Phase 2 trial with 111 patients and has received orphan drug designation for the treatment of PBC in the United States and Europe. Although the study did not meet its primary endpoint, it met key secondary endpoints related to change in alkaline phosphatase (ALP), liver stiffness and important quality of life metrics.

Setanaxib 400mg BID achieved significant reduction in ALP of 12% vs placebo over the 24-week treatment period (p<0.001). Furthermore, in a pre-defined patient population with an estimated liver fibrosis stage of F3 or higher (defined as liver stiffness of ≥9.6 kPa), setanaxib had a more pronounced effect on ALP reduction and fibrosis. Patients with elevated liver stiffness are at greater risk of disease progression. In patients with a liver stiffness score of ≥9.6 kPa, setanaxib 400mg BID achieved a 24% reduction in ALP over the 24-week treatment period, and a 22% reduction in liver stiffness as compared to a 4% increase for placebo (p=0.038).



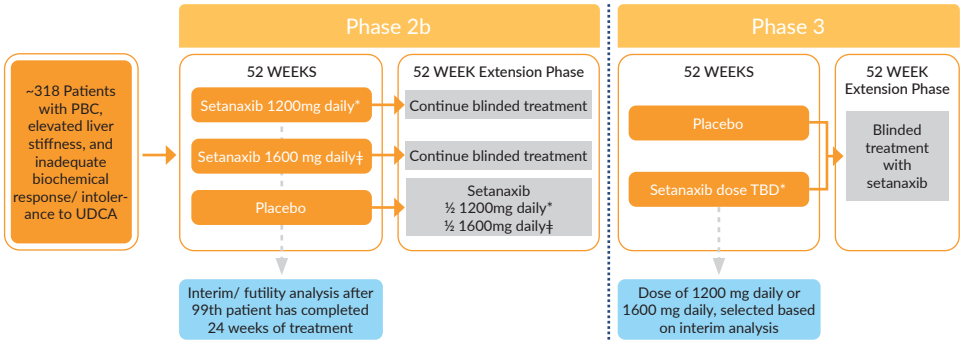


Furthermore, there was a statistically significant impact on fatigue, a very common and frequently disabling symptom of PBC which is not currently addressed by existing therapies, as well as demonstrated positive effects on emotional and social aspects of the disease. Setanaxib has also demonstrated a favourable safety profile in a Phase 1 clinical study in healthy subjects, which evaluated the safety and pharmacokinetics of the drug at doses up to 800 mg twice daily.

Phase 2b/3 TRANSFORM Trial

Calliditas has initiated a pivotal 52-week, randomized, placebo-controlled, double-blind, trial with an adaptive Phase 2b/3 design. Calliditas announced that the first patient was randomised in the TRANSFORM study on 15th February 2022.

Setanaxib will be administered to approximately 318 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to UDCA in a global trial conducted at up to 150 investigational centres. The primary endpoint is ALP reduction, with key secondary endpoints including change in liver stiffness, and effect on pruritus (itching) and fatigue. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in H1 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: NOX Inhibitor Platform

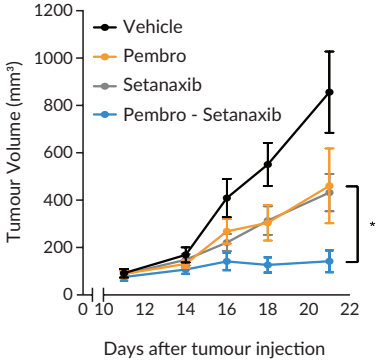
Setanaxib in Scquamous Cell Carcinoma of the Head & Neck

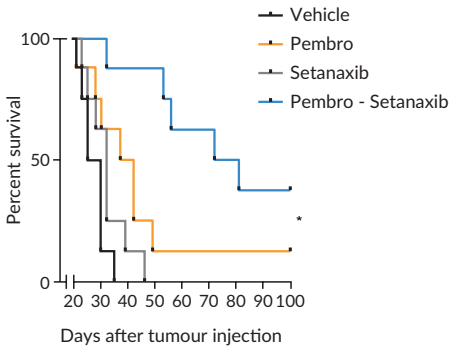
Calliditas also intends to evaluate setanaxib in head and neck cancer. The response to immuno-oncology therapies can be affected by the tumour microenvironment, in particular by the numbers of tumour-infiltrating lymphocytes (TILs) and cancer-associated fibroblasts (CAFs) in the tumour. A relationship 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 within tumours, shielding them from CD8+ TILs. Targeting CAFs with setanaxib could improve patients' responses to immunotherapies, and function as an adjunct therapy. There is increasing use of pembrolizumab as 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:

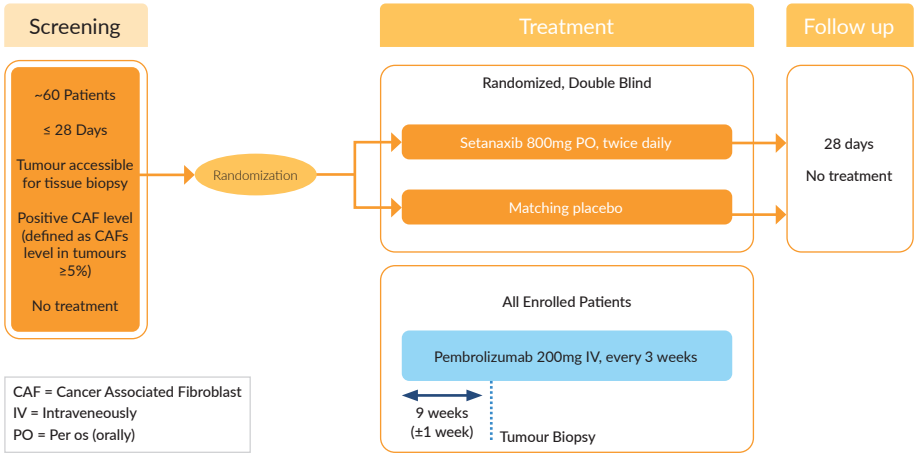
- Improved penetration of TILs into the centre of the tumour
- Slowing of tumour growth and improved survival





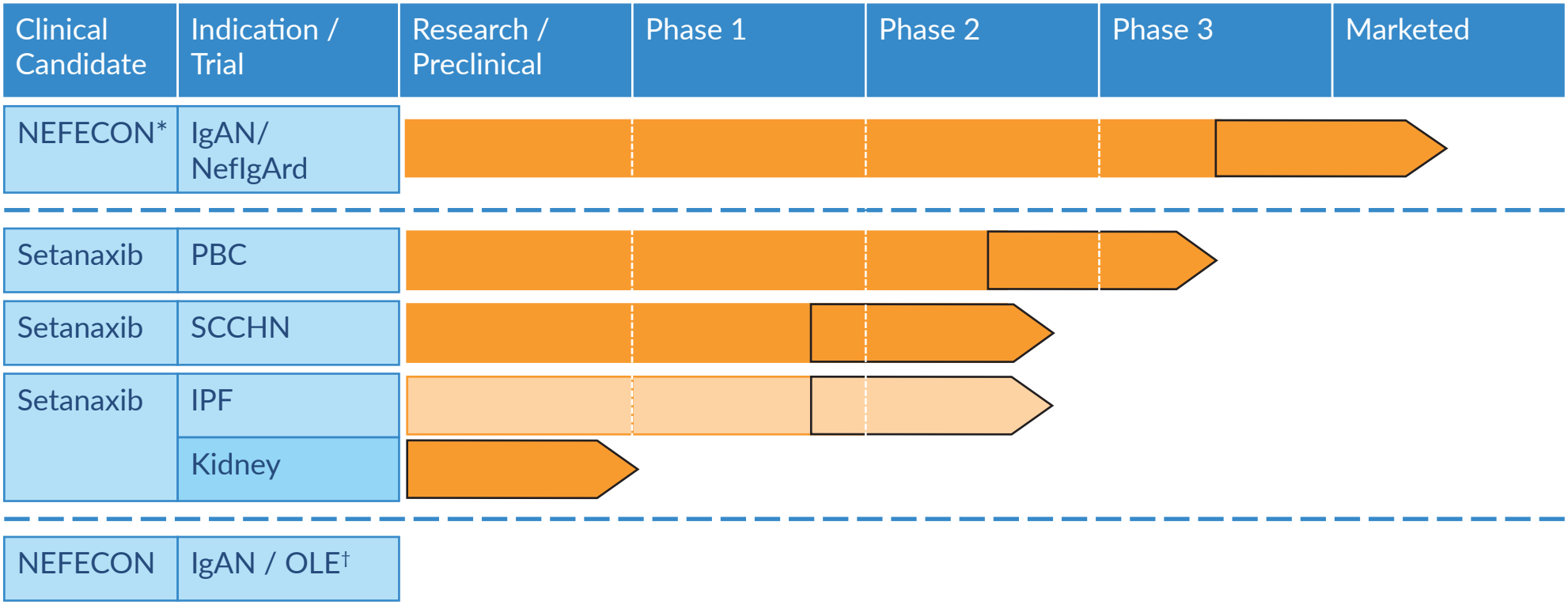
Proof-of-concept study in head and neck cancer

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 expected in late 2022 and final data read out expected in H2 2023.

Our Pipeline



Depicts ongoing/planned clinical trial stage: Depicts Investigator Led Trial:

† Open Label Expension, intended to primarily support treatment-related considerations.

* Approved under accelerated approval in the USA under the tradename TARPEYO. TARPEYO™ (budesonide) delayed release capsules is a prescription medicine used to reduce levels of protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN) who are at high risk of rapid disease progression, generally UPCR ≥ 1.5g/g. Calliditas submitted a Marketing Authorization Application for NEFECON to the European Medicines Agency in May 2021.

Setanaxib is also being evaluated in an investigator led trial in DKD (Diabetic Kidney Disease).

Significant events, January 1 – December 31, 2021

- In January 2021, Calliditas announced the clinical development plan for setanaxib and additional data from Part A of NefIgArd study at the company's R&D Day. Calliditas set out plans to initiate a pivotal Phase 2/3 study in PBC in 2H 2021. In addition, Calliditas set out plans to initiate a Phase 2 proof-of-concept study in head and neck cancer which would 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 IgAN. Calliditas was seeking accelerated approval under Subpart H for the 505(b)(2) application.

- In May 2021, Calliditas announced that the company submitted a Marketing Authorisation Application (MAA) to the EMA for NEFECON.

- 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 was made in the third quarter 2021. Drawdown of the second tranche of $25 million can be made until 30 June 2022. 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 EMA's Committee for Human Medicinal Products (CHMP) decided to continue the assessment of the MAA for NEFECON under standard procedure assessment timelines.

- In December 2021, Calliditas announced that the US Food and Drug Administration (FDA) had granted accelerated approval for TARPEYO (budesonide) delayed release capsules indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. TARPEYO is the first and only FDA-approved treatment for this disease and was designed specifically to target the origin of IgA nephropathy. This approval marked the successful transition for Calliditas to a commercial-stage biopharmaceutical company.

Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Year Ended December 31, 2021	Year Ended December 31, 2020
Net sales	31,180	400	229,347	874
Research and development expenses	(100,291)	(73,992)	(357,485)	(241,371)
Research and development expenses/Total operating expenses in %	40%	54%	47%	63%
Operating profit (loss)	(222,133)	(135,941)	(524,456)	(379,720)
Profit (loss) before income tax for the period	(218,467)	(173,273)	(513,373)	(436,151)
Earnings (loss) per share before dilution	(4.19)	(3.41)	(9.84)	(9.66)
Cash flow used in operating activities	(161,254)	(120,074)	(461,588)	(309,181)

(SEK in thousands, except per share amount or as otherwise indicated)	December 31, 2021	December 31, 2020
Total registered shares at the end of period	52,341,584	49,941,584
Equity attributable to equity holders of the Parent Company at the end of the period	1,008,281	1,210,491
Equity ratio at the end of the period in %	69%	80%
Cash at the end of the period	955,507	996,304

January – December 2021

Revenue

Net sales amounted to SEK 31.2 million and SEK 0.4 million for the three months ended December 31, 2021 and 2020, respectively. Net sales amounted to SEK 229.3 million and SEK 0.9 million for the year ended December 31, 2021 and 2020, respectively. The net sales for the three months ended December 31, 2021 primarily originates from a 3 MUSD milestone fee from Everest. Additionally, for the 12 months period 2021, net sales also includes 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 253.3 million and SEK 136.3 million for the three months ended December 31, 2021 and 2020, respectively. For the year ended December 31, 2021 and 2020, total operating expenses amounted to SEK 753.8 million and SEK 380.6 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 100.3 million and SEK 74.0 million for the three months ended December 31, 2021 and 2020, respectively. For the year ended December 31, 2021 and 2020, research and development expenses amounted to SEK 357.5 million and SEK 241.4 million, respectively. The increase of SEK 26.3 million for the fourth quarter is primarily due to the impairment of SEK 28.0 million regarding the SIIL contract, which originated from the Genkyotex aquisition. The increase of SEK 116.1 million for the twelwe months ended December, 2021 is, besides the impairment of the SIIL contract, primarily related to the setanaxib trials and the development of setanaxib.

Administrative and Selling Expenses

Administrative and selling expenses amounted to SEK 151.7 million and SEK 63.9 million for the three months ended December 31, 2021 and 2020, respectively. For the year ended December 31, 2021 and 2020, administrative and selling expenses amounted to SEK 390.2 million and SEK 141.7 million, respectively. The increase of SEK 87.8 million for the fourth quarter and SEK 248.5 million for the year ended December 31, 2021 compared to the same periods 2020, was primarily related to the preperations for commercialisation of Tarpeyo in the US, compared to the same period last year.

Other Operating Incomes/Expenses

Other operating income amounted to negative SEK 2.3 million and SEK 1.5 million for the three months ended December 31, 2021 and 2020, respectively. For the year ended December 31, 2021 and 2020, other operating income amounted to SEK 0.3 million and SEK 2.5 million, respectively.

The decrease in other operating income for the year ended December 31, 2021 was primarily related to disadvantageous exchange rate development on operating liabilities. Other operating expense amounted to positive SEK 1.0 million for the three months ended December 31, 2021. No other operating expenses were recognized for the three months ended December 31, 2020, as well as, for the year ended December 31, 2020. For the year ended December 31, 2021 other operating expenses amounted to SEK 6.3 million. The increase in other operating expenses for the year ended December 31, 2021 was primarily related to a more disadvantageous exchange rate development on operating liabilities.

Net Financial Income and Expenses

Net financial income/(expenses) amounted to SEK 3.7 million and (SEK 37.3 million) for the three months ended December 31, 2021 and 2020, respectively. For the year ended December 31, 2021 and 2020, net financial income/(expenses) amounted to SEK 11.1 million and (SEK 56.4 million), respectively. The increase of SEK 41.0 million for the three months ended December 31, 2021 and the increase of SEK 67.5 million for the year ended December 31, 2021, compared to the same periods last year, are primarily derived by an increase of unrealized foreign currency transaction gains on cash accounts, compared to unrealized foreign currency transaction losses for the same periods last year.

Tax

Income tax expenses, in all material respects, primarily relates to the U.S. subsidiaries of Calliditas Therapeutics. Deferred tax assets of SEK 5.1 million have been recognized in the twelve months ended December 31, 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 December 31, 2021 and 2020, loss for the period amounted to SEK 218.7 million and SEK 173.5 million, and the corresponding loss per share before and after dilution amounted to SEK 4.19 and SEK 3.41, respectively. For the year ended December 31, 2021 and 2020, loss for the period amounted to SEK 509.5 million and SEK 436.5 million, and the corresponding loss per share before and after dilution amounted to SEK 9.84 and SEK 9.66 for the year ended December 31 2021 and 2020, respectively.

January – December 2021

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 161.3 million and SEK 120.1 million for the three months ended December 31, 2021 and 2020, respectively. For the year ended December 31, 2021 and 2020, cash flow used in operating activities amounted to SEK 461.6 million and SEK 309.2 million, respectively. The cash flow used in operating activities during these periods are 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 5.3 million and SEK 172.6 million for the three months ended December 31, 2021 and 2020, respectively. Cash flow used in investing activities amounted to SEK 24.3 million and SEK 172.6 million for the year ended December 31, 2021 and 2020, respectively. Cash flow used in investing activities in 2021 originates primarily from a milestone payment for the Budenofalk license, and cash flow used in investing activities in 2020 originates primarily from the aqcusition of the shareholder majority in Genkyotex SA.

Cash flow used in financing activities amounted to SEK 41.3 million and SEK 79.3 million for the three months ended December 31, 2021 and 2020, respectively. For the year ended December 31, 2021 and 2020, cash flow from financing activities amounted to SEK 435.2 million and SEK 768.6 million, respectively. The increase in cash flow used in financing activities for the three months ended December 31, 2021 and 2020, were primarily derived from purchase of non-controlling interest in Genkyotex. During the year ended 2021, the cash from financing activities were primarily related to the new share issue of net SEK 304.0 million and the draw down of the first tranche of the Kreos loan facility of net SEK 199.5 million, compared to the SEK 768.6 million in cash from financing activities for the year 2020, which were primarily derived from the initial public offering on The Nasdaq Global Select Market and the exercise of the warrant program 2017/2020 and reduced by the cash flow used in a simplified public mandatory cash offer of Genkyotex SA .

Net increase/(decrease) in cash amounted to (SEK 207.9 million) and (SEK 372.0 million) for the three months ended December 31, 2021 and 2020, respectively. For the year ended December 31, 2021 and 2020, net increase/(decrease) in cash amounted to (SEK 50.8 million) and SEK 286.8 million, respectively. Cash amounted to SEK 955.5 million and SEK 996.3 million as of December 31, 2021 and 2020, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 1,008.3 million and SEK 1,210.5 million as of December 31, 2021 and 2020, respectively. The number of shares amounted to 52,341,584 and 49,941,584 as of December 31, 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 66 and 34 employees as of December 31, 2021 and 2020, respectively. The total number of full-time equivalent (FTE), including consultants, were 86 and 46 as of December 31, 2021 and 2020, respectively. The average number of employees was 66 and 31 employees for the three months ended December 31, 2021 and 2020, respectively, and 56 and 23 for the twelve months ended December 31, 2021 and 2020, respectively.

Incentive Programs

During the three months ended December 31, 2021 no allocation of employee stock options has been made. For more information on incentive programs, see Note 10.

Parent Company

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

Auditor's Review

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

Stockholm, February 24, 2022

Renée Aguiar-Lucander
CEO

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amount)	Notes	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Year Ended December 31, 2021	Year Ended December 31, 2020
Net sales	4	**31,180**	**400**	**229,347**	**874**
Research and development expenses		(100,291)	(73,992)	(357,485)	(241,371)
Administrative and selling expenses		(151,710)	(63,881)	(390,232)	(141,724)
Other operating income		(2,277)	1,532	259	2,501
Other operating expenses		965	-	(6,344)	-
Operating profit (loss)		**(222,133)**	**(135,941)**	**(524,456)**	**(379,720)**
Net financial income/(expenses)		3,666	(37,332)	11,083	(56,431)
Profit (loss) before income tax		**(218,467)**	**(173,273)**	**(513,373)**	**(436,151)**
Income tax		(199)	(175)	3,836	(360)
Profit (loss) for the period		**(218,666)**	**(173,448)**	**(509,537)**	**(436,511)**
Attributable to:					
Equity holders of the Parent company		(219,170)	(170,431)	(500,293)	(433,494)
Non-controlling interests		503	(3,017)	(9,244)	(3,017)
		(218,666)	(173,448)	(509,537)	(436,511)
Profit (loss) per share before and after dilution (SEK)		(4.19)	(3.41)	(9.84)	(9.66)

Condensed Consolidated Statements of Comprehensive Income

	Three Months Ended December 31,		Year Ended December 31,	
(SEK in thousands)	2021	2020	2021	2020
Net income (loss) for the period	(218,666)	(173,448)	(509,537)	(436,511)
Other comprehensive income				
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	(33,220)	(9,332)	(28,301)	(9,352)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:	**(33,220)**	**(9,332)**	**(28,301)**	**(9,352)**
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:				
Remeasurement gain on defined benefit plans	232	1,216	1,993	1,216
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:	**232**	**1,216**	**1,993**	**1,216**
Other comprehensive income/(loss) for the period	**(32,988)**	**(8,117)**	**(26,308)**	**(8,137)**
Total comprehensive income (loss) for the period	**(251,654)**	**(181,565)**	**(535,845)**	**(444,648)**
Attributable to:				
Equity holders of the Parent company	(252,161)	(175,260)	(527,379)	(438,343)
Non-controlling interests	507	(6,305)	(8,466)	(6,305)
	(251,654)	**(181,565)**	**(535,845)**	**(444,648)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	December 31, 2021	2020
ASSETS			
Non-current assets			
Intangible assets	*6,12*	399,418	418,825
Equipment		6,309	163
Right-of-use assets		33,300	5,244
Non-current financial assets		3,915	2,225
Deferred tax assets		4,196	600
Total non-current assets		**447,138**	**427,057**
Current assets			
Inventories		889	-
Other current receivables	*8*	11,343	22,801
Prepaid expenses		45,032	17,746
Cash		955,507	996,304
Total current assets		**1,012,772**	**1,036,851**
TOTAL ASSETS		**1,459,910**	**1,463,908**
EQUITY AND LIABILITIES			
Equity			
Share capital		2,094	1,998
Additional paid-in-capital		2,459,741	2,133,179
Retained earnings, including net loss for the period		(1,453,554)	(924,686)
Equity attributable to equity holders of the Parent Company		1,008,281	1,210,491
Non-controlling interests		-	45,809
Total equity	***9,10***	**1,008,281**	**1,256,300**
Non-current liabilities			
Provisions	*10*	68,929	55,361
Pensions Liabilities		3,182	8,296
Deferred tax liabilities	*7,12*	30,856	37,454
Non-current interesting-bearing liabilities	*11*	189,164	-
Lease liabilities		24,052	878
Total non-current liabilities		**316,184**	**101,989**
Currents liabilities			
Accounts payable		67,971	53,827
Other current liabilities		13,922	10,406
Accrued expenses and deferred revenue		53,553	41,386
Total current liabilities		**135,446**	**105,619**
TOTAL EQUITY AND LIABILITIES		**1,459,910**	**1,463,908**

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Year Ended December 31, 2021	2020
Opening balance equity attributable to equity holders of the Parent Company	**1,210,491**	**788,071**
Profit/Loss for the period	(500,293)	(433,494)
Ohter comprehensive income/(loss)	(27,087)	(4,849)
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	**(527,379)**	**(438,343)**
Transactions with owners		
New share issue	324,000	891,388
Cost attributable to new share issue	(20,909)	(97,686)
Exercise of warrants	-	59,251
Share-based payments	23,567	6,012
Purchase of non-controlling interests	(1,488)	1,798
Total transactions with owners	**325,169**	**860,763**
Closing balance equity attributable to equity holders of the Parent Company	**1,008,281**	**1,210,491**
Opening balance equity attributable to non-controlling interests	**45,809**	**-**
Total comprehensive loss for the period	(8,466)	(6,305)
Contribution from non-controlling interests	2,282	-
Non-controlling interests from business combinations	-	136,084
Purchase of non-controlling interests	(39,625)	(83,970)
Closing balance equity attributable to non-controlling interests	**-**	**45,809**
Closing balance equity	**1,008,281**	**1,256,300**

Condensed Consolidated Statements of Cash Flows

Amounts in SEK 000s	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating activities				
Operating profit (loss)	(222,133)	(135,941)	(524,456)	(379,720)
Adjustment for non-cash-items	42,540	8,599	66,676	15,465
Interest received	102	1,912	102	1,912
Interest paid	(4,896)	(72)	(5,432)	(393)
Income tax paid	(2,479)	(101)	(3,949)	(528)
Cash flow used in operating activities before changes working capital	**(186,865)**	**(125,603)**	**(467,058)**	**(363,264)**
Cash flow from/(used in) changes in working capital	25,611	5,529	5,470	54,083
Cash flow used in operating activities	**(161,254)**	**(120,074)**	**(461,588)**	**(309,181)**
Cash flow used in investing activities	(5,337)	(172,605)	(24,340)	(172,607)
Cash flow used in investing activities	**(5,337)**	**(172,605)**	**(24,340)**	**(172,607)**
New share issue	-	-	324,000	891,388
Costs attributable to new share issue	-	-	(20,909)	(95,937)
Premiums from warrants issuance	-	4,332	-	59,251
Purchase of non-controlling interests	(39,020)	(82,172)	(49,303)	(82,172)
Contribution from non-controlling interests	-	-	2,282	-
New borrowings	-	-	199,524	-
Costs attributable to new loans	-	-	(14,857)	-
Repayment of lease liabilities	(2,269)	(1,484)	(5,575)	(3,972)
Cash flow from /(used in) financing activities	**(41,289)**	**(79,324)**	**435,162**	**768,558**
Net increase/(decrease) in cash	**(207,880)**	**(372,003)**	**(50,766)**	**286,770**
Cash at the beginning of period	**1,163,819**	**1,396,869**	**996,304**	**753,540**
Net foreign exchange gains/(loss) on cash	(432)	(28,562)	9,969	(44,006)
Cash at the end of period	**955,507**	**996,304**	**955,507**	**996,304**

Condensed Parent Company Statements of Income

(SEK in thousands, except per share amount)	Notes	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Year Ended December 31, 2021	Year Ended December 31, 2020
Net sales	4	31,180	400	229,347	874
Research and development expenses		(65,319)	(59,647)	(275,950)	(227,027)
Administrative and selling expenses		(151,337)	(55,314)	(377,475)	(128,896)
Other operating income		29,199	1,513	70,234	2,482
Other operating expenses		2,325	-	(1,874)	-
Operating profit (loss)		**(153,951)**	**(113,048)**	**(355,718)**	**(352,567)**
Net financial income/(expenses)		(7,128)	(36,055)	1,312	(54,796)
Profit (loss) before income tax		**(161,080)**	**(149,103)**	**(354,405)**	**(407,363)**
Income tax		-	-	-	-
Profit (loss) for the period		**(161,080)**	**(149,103)**	**(354,405)**	**(407,363)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended December 31, 2021	Three Months Ended December 31, 2020	Year Ended December 31, 2021	Year Ended December 31, 2020
Profit (loss) for the period	(161,080)	(149,103)	(354,405)	(407,363)
Other comprehensive income/(loss)	-	-	-	-
Total comprehensive profit (loss)	**(161,080)**	**(149,103)**	**(354,405)**	**(407,363)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	December 31, 2021	2020
ASSETS			
Non-current assets			
Intangibe assets	*6*	32,132	16,066
Equipment		514	80
Non-current financial assets		552,924	298,683
Total non-current assets		**585,570**	**314,829**
Current assets			
Inventories		889	-
Other current receivables	*8*	5,699	10,998
Prepaid expenses		41,825	14,490
Cash		894,455	978,208
Total current assets		**942,868**	**1,003,696**
TOTAL ASSETS		**1,528,439**	**1,318,525**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Restricted Shareholders' equity			
Share capital		2,094	1,998
Statutory reserve		3,092	3,092
Total restricted Shareholders' equity		**5,186**	**5,090**
Non-restricted shareholders' equity			
Share premium reserve		2,420,698	2,116,721
Retained earnings		(863,175)	(479,379)
Net loss for the period		(354,405)	(407,363)
Total non-restricted shareholders' equity		**1,203,117**	**1,229,979**
Total shareholders' equity	***9,10***	**1,208,303**	**1,235,069**
Non-current liabilities			
Provisions	*10*	9,075	4,972
Non-current interesting-bearing liabilities	*11*	189,164	-
Other non-current liabilities		105	105
Total non-current liabilities		**198,344**	**5,077**
Currents liabilities			
Accounts payable		51,711	42,469
Other current liabilities		33,466	5,123
Accrued expenses and deferred revenue		36,615	30,787
Total current liabilities		**121,792**	**78,379**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,528,439**	**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 year-end condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the twelve months ended December 31, 2021 and 2020, respectively.

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, D5, 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 February 24, 2022.

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.

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.

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 commercialization of Tarpeyo 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 December 31,		Year Ended December 31,	
(SEK in thousands)	2021	2020	2021	2020
Type of goods or services				
Provisions of Drugs	-	400	-	874
Out-licencing	31,180	-	229,347	-
Total	**31,180**	**400**	**229,347**	**874**
Geographical markets				
Europe	4,095	-	202,262	-
China, Hong Kong, Macau, Taiwan and Singapore	27,085	400	27,085	874
Total	**31,180**	**400**	**229,347**	**874**

The Group's revenues for the forth quarter 2021 primarily originates from a USD 3 million milestone fee from Everest Medicines related to the out-licencing of the commercial rights of Nefecon for the Greater China and Singapore territories. For the twelve months period 2021, revenue also consisted of a EUR 20 million up-front fee from Stada for the out-licensing of the commercial rights of Nefecon in EU.

Revenue for outlicensing is reported at a point in time, which occurs when control over the intangible asset is transferred to the counterparty, which for the EU outlicensing 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

	December 31,	
(SEK in thousands)	2021	2020
Cost at opening balance	418,825	16,066
Business Combinations	-	416,282
Acquisition license	16,066	-
Impairment	(27,975)	-
Exchange difference on translation	(7,498)	(13,523)
Cost at closing balance	**399,418**	**418,825**
Amortisation at closing balance	**-**	**-**
Net book value	**399,418**	**418,825**

As of December 31, 2021 intangible assets consist of licenses and similar rights of SEK 362.2 million and goodwill of SEK 37.2 million.

Intangible assets with a definite useful life were tested for impairment when an indication for impairment was identified. The tests resulted in impairment of SEK 28.0 million and was related to the SIIL contract, where SIIL's development of the product did not develop in such a way during the year that it can be expected to generate future cash flows. The SIIL contract has no remaining value as of December 31, 2021.

Note 7 - Deferred Tax Liabilities

	December 31,	
(SEK in thousands)	2021	2020
Cost at opening balance	37,454	-
Business Combinations	-	38,712
Tax loss carried forward	(5,065)	-
Exchange difference on translation	(1,532)	(1,258)
Cost at closing balance	**30,856**	37,454

Deferred tax assets of SEK 5.1 million have been offset against deferred tax liabilities in the statement of financial position as of December 31, 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 December 31, 2021 and 2020, respectively. The Group's financial liabilities comprise of accounts payable and other current liabilities, which are recognized at amortized cost. The carrying amount is an approximation of the fair value.

Note 9 - Shareholders' Equity

(SEK in thousands, except per share amount or as otherwise indicated)	December 31, 2021	2020
Total registered shares at the beginning of period	49,941,584	38,707,638
New issue of shares during the period	2,400,000	11,233,946
Total registered shares at the end of period	**52,341,584**	**49,941,584**
Share capital at the end of period	2,094	1,998
Equity attributable to equity holders of the Parent Company	1,008,281	1,210,491
Non-controlling interests	-	45,810
Equity at the end of period	**1,008,281**	**1,256,300**

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Earnings (loss) per share before and after dilution, SEK	(4.19)	(3.41)	(9.84)	(9.66)
Weighted-average number of shares outstanding for the period, before dilution	52,341,584	49,941,584	50,829,255	44,873,448

Reserves for translation from foreign operations amounted to SEK -35.2 million and SEK -6.1 million which are included in equity as of December 31, 2021 and 2020, respectively.

Note 10 - Incentive Programs

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of December 31,2021
Incentive Programs				
Warrant program 2018/2022	856,586	-	-	856,586
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2019	-	-	51,399	51,399
Board LTIP 2020	-	-	31,371	31,371
Board LTIP 2021	-	-	26,968	26,968
ESOP 2020	-	1,444,000	-	1,444,000
ESOP 2021	-	845,000	-	845,000
Total Outstanding as of December 31, 2021	**1,279,086**	**2,289,000**	**109,738**	**3,677,824**

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of December 31,2020
Incentive Programs				
Warrant program 2018/2022	856,586	-	-	856,586
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2019	-	-	51,399	51,399
Board LTIP 2020	-	-	31,371	31,371
ESOP 2020	-	1,089,000	-	1,089,000
Total Outstanding as of December 31, 2020	**1,279,086**	**1,089,000**	**82,770**	**2,450,856**

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

	Year Ended December 31,	
(SEK in thousands)	2021	2020
Opening balance	-	-
New borrowings - net	193,039	-
Amortization of loan	(6,765)	-
Exchange difference on translation	2,890	-
Closing balance	189,164	-

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. 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, which is recognized at Net financial income/(expenses). The loan has no covenants.

Note 12 - Business combinations

On November 3, 2020, Calliditas acquired a controlling interest in Genkyotex SA, a biopharmaceutical company specializing in NOX therapies with offices in France and Switzerland. Its unique platform enables the identification of orally available small molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis and inflammation. The purpose of the acquisition is that it adds a late-stage orphan pipeline asset and platform in inflammation and fibrosis to the Groups product portfolio in orphan diseases. The fair value of the acquired assets and assessed liabilities for the acquisition of Genkyotex SA in 2020 was preliminarily established for the first 12 months and have thereafter been finalized. The fair value of the acquisitions of Genkyotex have changed due to allocation of assets and liabilities to Switzerland and therefore IFRS adjustments were made to the acquisition values.

(SEK in thousands)	Preliminary	Adjustments	Final
The assets and liabilities recognized in conjunction with the acquisition are as follows:			
Intangible assets: NOX Platform	382,521	(34,397)	348,124
Intangible assets: Other licenses	28,893	-	28,893
Non-current assets	2,438	-	2,438
Other current assets	10,022	-	10,022
Cash	32,265	-	32,265
Pension liabilities	(9,410)	-	(9,410)
Deferred tax liabilities	(82,683)	43,971	(38,712)
Other non-current liabilities	(643)	-	(643)
Other current liabilities	(20,677)	-	(20,677)
Acquired identified assets	**342,726**	**9,574**	**352,300**
Non-controlling interests	(136,084)	-	(136,084)
Goodwill	48,839	(9,574)	39,265
Acquired net assets	**255,481**	**-**	**255,481**

The below table describes the adjustments to the Group opening balance sheet from the finalization of the fair value.

	December 31,		
(SEK in thousands)	2020	Adjustment	2020
ASSETS			
Non-current assets			
Intangible assets	461,367	(42,542)	418,825
Equipment	163	-	163
Right-of-use assets	5,244	-	5,244
Non-current financial assets	2,225	-	2,225
Deferred tax assets	**600**	**-**	**600**
Total non-current assets	**469,599**	**(42,542)**	**427,057**
Current assets			
Total current assets	**1,036,851**	**-**	**1,036,851**
TOTAL ASSETS	**1,506,450**	**(42,542)**	**1,463,908**
EQUITY AND LIABILITIES			
Equity			
Total equity	**1,256,300**	**-**	**1,256,300**
Non-current liabilities			
Provisions	55,361	-	55,361
Pensions Liabilities	8,296	-	8,296
Deferred tax liabilities	79,996	(42,542)	37,454
Lease liabilities	878	-	878
Total non-current liabilities	**144,531**	**(42,542)**	**101,989**
Currents liabilities			
Total current liabilities	**105,619**	**-**	**105,619**
TOTAL EQUITY AND LIABILITIES	**1,506,450**	**(42,542)**	**1,463,908**

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 December 31, 2021	Three Months Ended December 31, 2020	Year Ended December 31, 2021	Year Ended December 31, 2020
Research and development expenses/Total operating expenses in %				
Research and development expenses	(100,291)	(73,992)	(357,485)	(241,371)
Administrative and selling expenses	(151,710)	(63,881)	(390,232)	(141,724)
Other operating income/expenses	(1,312)	1,532	(6,085)	2,501
Total operating expenses	**(253,313)**	**(136,341)**	**(753,803)**	**(380,594)**
Research and development expenses/Total operating expenses in %	40%	54%	47%	63%

(SEK in thousands or otherwise indicated)	December 31, 2021	December 31, 2020
Equity ratio at the end of the period in %		
Total shareholders' equity at the end of the period	1,008,281	1,256,300
Total assets at the end of the period	1,459,910	1,463,908
Equity ratio at the end of the period in %	**69%**	**86%**

Financial Calendar

Annual Report 2021	April 27, 2022
Interim Report for the period January 1 - March 31, 2022	May 18, 2022
Annual General Meeting 2022	May 19, 2022
Interim Report for the period January 1 - June 30, 2022	August 18, 2022
Interim Report for the period January 1 - September 30, 2022	November 17, 2022

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Forward Looking Statements

This interim report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this interim report are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this 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.

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