

Q1 2022

INTERIM REPORT JANUARY 1ST – MARCH 31ST 2022

Start of TARPEYO™ Commercial Launch

Financial summary for the Group

Key Figures

January 1 - March 31, 2022

- » Net sales amounted to SEK 49.7 million, whereof TARPEYO net sales amounted to SEK 18.0 million, for the three months ended March 31, 2022. No net sales were recorded for the three months ended March 31, 2021.
- » Operating loss amounted to SEK 208.4 million and SEK 150.8 million for the three months ended March 31, 2022 and 2021, respectively.
- » Loss per share before and after dilution amounted to SEK 3.95 and SEK 2.62 for the three months ended March 31, 2022 and 2021, respectively.
- » Cash amounted to SEK 825.4 million and SEK 867.3 million as of March 31, 2022 and 2021, respectively.

Significant events in Q1 2022

In January 2022, Calliditas announced commercial availability and initial sales of TARPEYO (budesonide) delayed release capsules, the first and only FDA approved treatment for IgA nephropathy, indicated for reduction of proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, generally considered a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.

In February 2022, Calliditas announced that the first patient had been randomized in the company's pivotal phase 2b/3 TRANSFORM study in patients with primary biliary cholangitis (PBC).

In March 2022, Calliditas expanded its licensing agreement with Everest to extend the territory covered to include South Korea.

Significant events after the reporting period

In May 2022, Calliditas announced that the first patient had been randomized in the company's proof-of-concept Phase 2 study in patients with squamous cell carcinoma of the head and neck (SCCHN) with the NOX 1 and 4 inhibitor, setanaxib.

Investor Presentation May 18, 2022 14:30 CET

Audio cast with teleconference, Q1 2022

Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q1-2022>

Teleconference: SE: +46856642706 UK: +443333009034 US: +16467224956

Successful Start of the Commercial Launch



During the first quarter Calliditas launched its first commercial product, TARPEYO, in the US, supported by 40 experienced specialty sales executives who were trained and in the field in late January.

Our commercial product was already available to ship to patients at the end of January, reflecting the great collaboration between our CMC group and our commercial team in the US.

Our transformation from a primarily R&D based company to a commercial stage, fully integrated business has been a journey, which first started 3 years ago when we brought onboard our first employee in the US. Under the guidance of a small but highly experienced senior team, we started to build our medical affairs and market access teams in preparation for a future regulatory approval. Medical education and interactions to

raise awareness about the pathophysiology of IgA nephropathy (IgAN) were conducted at conferences and congresses, as well as on a one to one basis with nephrologists across the country. Market research was undertaken to understand the existing treatment paradigms in detail, verify the unmet medical need and truly understand the patient journey and burden of disease. In addition, a substantial amount of work was carried out over an extended period relating to the perceived health economic burden of IgAN and the value associated with TARPEYO, (developed under the name of Nefecon), initially based on available Phase 2b clinical data and then further refined when Phase 3 data became available in November 2020.

Over time and as a potential approval drew nearer, US operations added critical resources related to IT, legal, HR and finance, as well as highly experienced sales and marketing expertise and additional key resources in market access and medical affairs. With a fully integrated operation and a streamlined supply and distribution chain in place, the US organization had grown significantly and was by mid-2021 ready for the final step, onboarding of the sales force. When accelerated approval of TARPEYO was granted by the FDA, the entire organization was well prepared and ready. TARPEYO Touchpoints™ was available within hours and prescribers were able to access details regarding the product, the indication and could write prescriptions for appropriate patients. There was hope at last for IgAN patients in the US, as an approved product became available for the first time.

We believe the combination of significant proteinuria reduction at 9 months, positive impact on eGFR and the significant decline in proteinuria (~52%) observed in patients who had reached 12 months at the time of the data cut-off are all supportive of the differentiated approach of TARPEYO in targeting the origin of the disease. This is obviously just the very beginning of the journey, but we are very encouraged by

the strong interest and early successes we have experienced, which have resulted in net product revenues of \$1.9M (SEK 18.0M) for the first couple of months of commercial availability, and we remain fully committed to continuing to build the TARPEYO franchise.

The first quarter also saw the dosing of the first patient in our pivotal study in PBC, TRANSFORM, and the initiation of our Phase 2 clinical trial in head and neck cancer, both of which will investigate the efficacy and safety of setanaxib, the lead candidate from our proprietary NOX platform. Our experienced clinical team has yet again proven its expertise by preparing and supporting both of these trials simultaneously in collaboration with our CRO partners, and in times still defined by COVID 19 and its aftermath.

Setting up and running another global trial, similar in size to NeflgArd, is a major achievement under these circumstances. Recruitment will, as always, be subject to the overall accessibility to appropriate patients, as well as macro factors outside of our control such as global conflicts and pandemics, but we are very excited to have reached these milestones and look forward to progressing these trials as rapidly as possible.

Finally, in Q1 we continued our constructive interactions with EMA regarding a potential approval in IgAN in Europe, and we are targeting an opinion in Q2. We also expanded our licensing collaboration with Everest Medicines to include South Korea. We look forward to continue working with Everest and STADA, our commercial partner in Europe, as we work towards addressing the unmet need of IgAN patients across the world.

Renée Aguiar-Lucander, CEO

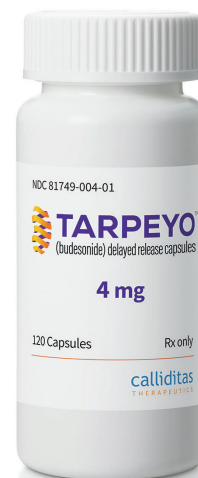
TARPEYO

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) $\geq 1.5\text{g/g}$. 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 $\geq 35\text{ mL/min/1.73m}^2$, and proteinuria (defined as $\geq 1\text{ g/day}$) 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 NeflgArd 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 complete Part B of the ongoing randomized, double-blind, placebo controlled multicenter NeflgArd study in early 2023, subject to any impact from the COVID-19 pandemic to our business.

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.



TARPEYO Commercial Launch

The first sale of TARPEYO took place on January 28, 2022. The experience, dedication and hard work of the entire US commercial organization ensured that we were fully prepared to execute an efficient and effective launch within about a month from receiving approval, including the Christmas and New Year holiday period. We are encouraged by our early success and the strong interest expressed in our product by both patients and nephrologists.

Prior to approval, Calliditas focused its pre-commercial efforts on disease education, market access and patient advocacy, with the goal of facilitating access to TARPEYO for the appropriate patients for which it can fulfil an unmet medical need. Our medical science liaison team was out in the field beginning in 2020, with the aim of educating and raising awareness about IgA nephropathy and the pathophysiology of the disease. As a result, there was significant awareness of TARPEYO amongst nephrologists, and research demonstrated that those familiar with our product profile rated themselves as 'extremely likely' to prescribe TARPEYO for 70% of their patients¹.

We also made sure that our trade and distribution partners and national account managers were in place and operational well in advance of approval. Furthermore, we established a highly successful support service to make the process of prescribing and obtaining our product as seamless as possible. Our patient support services program, TARPEYO Touchpoints, was fully operational from day one of approval, allowing physicians and patients to have access to dedicated case managers and a designated Rare Pod Team – including nurses, pharmacists, and a fulfilment and distribution team – as well as a financial assistance program where appropriate. Since approval, we have seen a continuous increase in inbound traffic and engagement with TARPEYO Touchpoints from all audiences and we continue to work closely via this platform to maximise access to our product.

Our immediate focus upon approval was to officially onboard and train our rare and specialty experienced sales team of 40 sales reps, 70% of whom join us directly from existing work in the nephrology market. We began promoting to physicians at the end of January, and our sales reach as of March 31st was well over four thousand nephrologists. Our sales efforts since the product became available in late January have resulted in 134 enrolments from 111 unique prescribers resulting in net sales for the first quarter of \$1.9M (SEK 18.0 million).



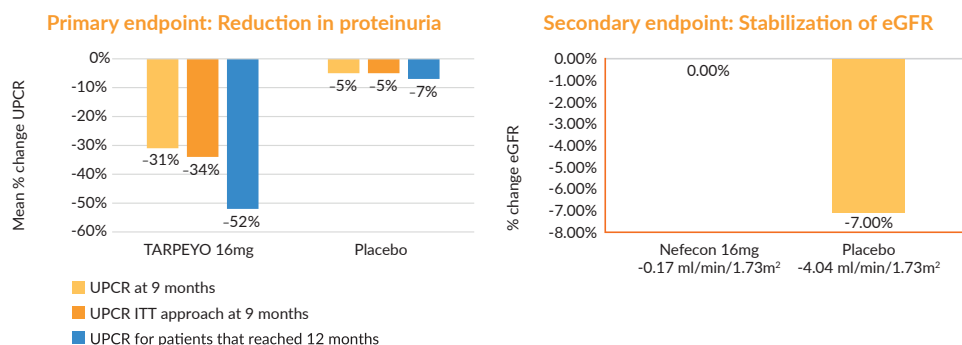
We also built on and continued our engagement with payers, with a focus on key targeted accounts that cover most commercial lives and key federal/state payers. While the average payer takes typically six to nine months to review a newly launch product for coverage and formulary placement, we have made significant progress early in the process. By the end of March, 11 of our targeted accounts, including Cigna, Express Script, and Humana were covering TARPEYO on their predominant formularies. As a result, we estimate about one third of commercial lives had coverage at the end of the first quarter. In addition, TARPEYO is covered by Medicare Part D beginning at launch (as it is the only FDA approved treatment in IgA nephropathy) and for Medicaid patients with the mandatory coverage date of April 1st. In the meantime, our full-service patient and provider support program, TARPEYO Touchpoints is helping patients and prescribers navigate the medical exception process, to allow appropriate patients to receive access to the medication during the review process. To date we have had only one enrolled patient cancel due to payer coverage.

In summary, we are extremely pleased with our execution and result at the end of the first quarter. As expected, the IgA nephropathy market is unsatisfied and eager for a treatment specifically designed to target the cause of the disease.

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 NeflgArd 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 31% reduction in proteinuria from baseline vs 5% in the placebo cohort at 9 months. Furthermore, in the intention to treat (ITT) population, the reduction at 9 months was 34%, and for patients who had reached 12 months at the time of the data cut-off the continued proteinuria reduction was 52%. 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.



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 time-lines. Calliditas expects a CHMP opinion in the second quarter of 2022.



In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize NEFECON® for the treatment of the IgA nephropathy in Europe. 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.

Calliditas also has a commercial partner in China and Singapore, having entered into a license agreement to develop and commercialize NEFECON for IgAN in those markets with Everest Medicines in 2019. Calliditas received an initial upfront payment of 15M USD upon signing, as well as future payments linked to development, regulatory and commercialization milestones up to an additional 106M USD, plus royalties. In March 2022, this agreement was expanded to include South Korea. Everest will look to file with regulators in China in 2022, with a view to target potential approval in 2023.

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 IgA antibodies. IgA 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 signaling 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.

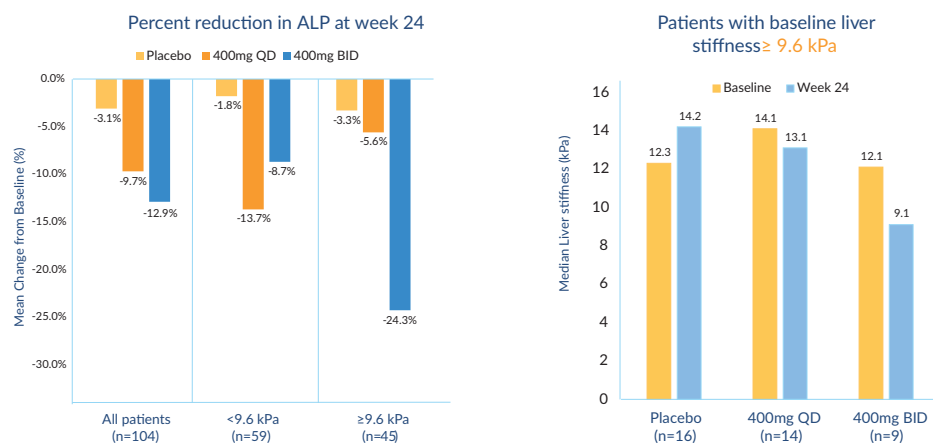
Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, known as Ocaliva, are the only FDA- and EMA-approved treatments for PBC. These drugs are primarily anticholestatic. UDCA is a bile acid analogue which is incorporated into the bile acid pool, replacing other more 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 12.9% vs placebo over the 24-week treatment period ($p < 0.002$). 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 ($p = 0.038$).

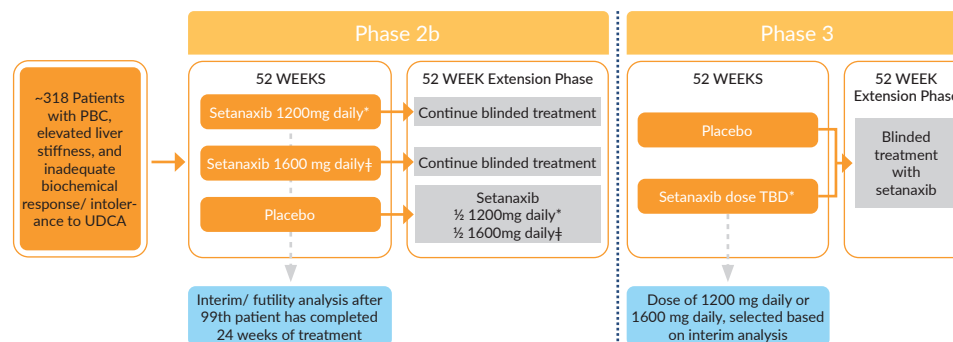


Furthermore, there was a statistically significant impact on fatigue, a very common and frequently disabling symptom of PBC which is not currently addressed by existing therapies, as well as demonstrated positive effects on emotional and social aspects of the disease. Setanaxib has also demonstrated 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. Following the favourable safety data from the Phase 1 study, this trial will evaluate two dosing regimens of 1200mg/daily and 1600mg/daily. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in Q2 or Q3 2023, and will determine which dose of setanaxib will be used for the Phase 3 part of the study, 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

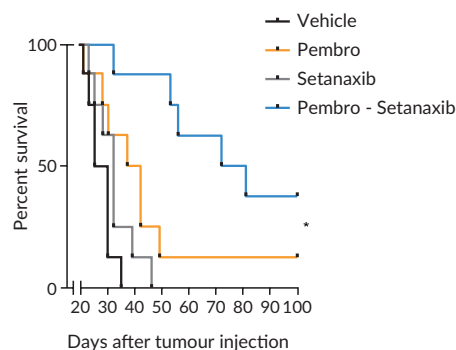
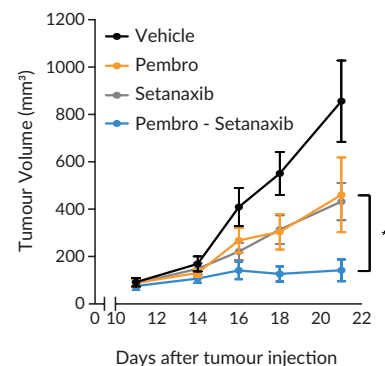
Setanaxib in Squamous Cell Carcinoma of the Head & Neck

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%).

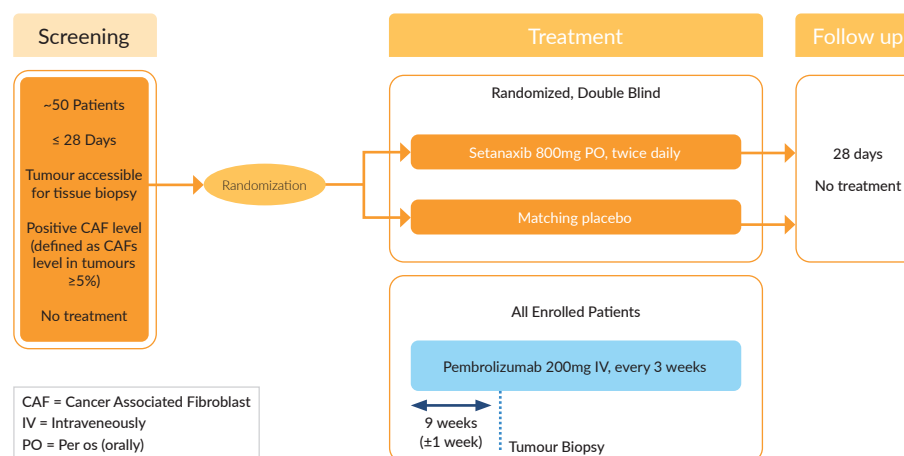
Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:

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



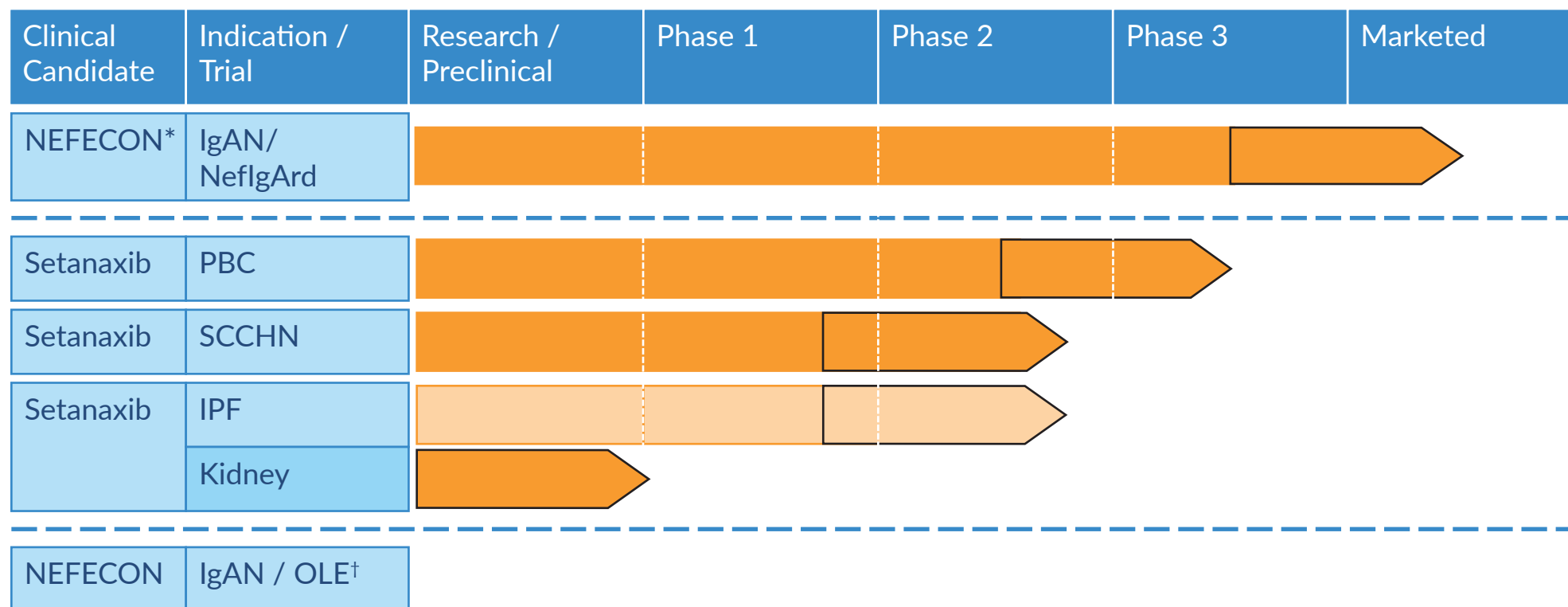
Proof-of-concept study in head and neck cancer

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 50 patients, and the first patient was randomised in Q2 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 Expansion, 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 \geq 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 – March 31, 2022

- In January 2022, Calliditas announced the commercial availability and initial sales of TARPEYO™ (budesonide), the first and only FDA approved treatment for IgA nephropathy, indicated for reduction of proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, generally considered a urine protein-to-creatinine ratio (UPCR) $\geq 1.5\text{g/g}$. Calliditas is committed to working with payers and healthcare providers across the United States to help ensure that all patients prescribed TARPEYO have access to it. To assist patients and their healthcare providers who would prescribe TARPEYO, Calliditas has launched a comprehensive patient support program, TARPEYO Touchpoints™. This program offers services, assistance, and resources designed to help patients access treatment as easily as possible.
- In February 2022, Calliditas announced that the first patient had been randomized in the company's pivotal phase 2b/3 TRANSFORM study in patients with primary biliary cholangitis (PBC). The TRANSFORM trial is a 52-week, randomized, placebo-controlled, double-blind, adaptive Phase 2b/3 trial. It will initially investigate the effect of setanaxib 1200 mg/day and 1600 mg/day versus placebo on alkaline phosphatase (ALP) reduction in patients with PBC and with elevated liver stiffness and intolerance or inadequate response to ursodeoxycholic acid (UDCA). Key secondary endpoints include change from baseline in liver stiffness, assessed by transient elastography (FibroScan®), and change from baseline in fatigue. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected Q2 or Q3 2023. The interim analysis outcome will determine which of the two doses will be selected for the Phase 3 portion of the trial.
- In March 2022, Calliditas announced that the company had expanded its licensing agreement with Everest Medicines II Limited to extend the territory covered to include South Korea. The extension results in an upfront payment of USD 3 million to Calliditas as well as additional payments and royalties related to future potential approvals and commercialization of Nefecon in South Korea. Calliditas and Everest entered into a license agreement in 2019 to develop and commercialize Nefecon in Greater China and Singapore for the chronic autoimmune kidney disease IgA Nephropathy (IgAN).

Significant events after the reporting period

- In May 2022, Calliditas announced that the first patient had been randomized in the company's proof-of-concept Phase 2 study in patients with squamous cell carcinoma of the head and neck (SCCHN) with the NOX 1 and 4 inhibitor, setanaxib. The trial is a randomized, placebo-controlled, double-blind, proof-of-concept Phase 2 study. It will investigate the effect of setanaxib 800 mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks (the standard treatment regimen for this immunotherapy), in approximately 50 patients with moderate or high CAF-density tumours. A tumour biopsy will be taken prior to randomization and then again after at least 9 weeks of treatment. Treatment will continue until unacceptable toxicity or progression, as is typical for oncology trials. Interim biomarker analysis is targeted for Q4 2022, and the study is expected to read out final data (including impact on tumour size) in 2023.

Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended March 31,		Year Ended December 31,
	2022	2021	2021
Net sales	49,734	-	229,347
Research and development expenses	(113,343)	(90,077)	(357,485)
Research and development expenses/Total operating expenses in %	44%	60%	47%
Operating loss	(208,367)	(150,781)	(524,456)
Loss before income tax for the period	(211,434)	(136,174)	(513,373)
Loss per share before and after dilution	(3.95)	(2.62)	(9.84)
Cash flow used in operating activities	(191,423)	(134,179)	(461,588)

(SEK in thousands, except per share amount or as otherwise indicated)	March 31,		December 31,
	2022	2021	2021
Total registered shares at the end of the period	53,172,170	49,941,584	52,341,584
Equity attributable to equity holders of the Parent Company at the end of the period	871,142	1,089,545	1,008,281
Equity ratio at the end of the period in %	65%	81%	69%
Cash at the end of the period	825,409	867,346	955,507

January – March 2022

Revenue

Net sales amounted to SEK 49.7 million for the three months ended March 31, 2022. No net sales were recorded for the three months ended March 31, 2021. The net sales for the three months ended March 31, 2022 primarily originates from a USD 3.0 million milestone fee from Everest for the extension of the license agreement for South Korea and SEK 18.0 million in net sales of TARPEYO in the U.S. For additional information see Note 4.

Total Operating Expenses

Total operating expenses amounted to SEK 257.5 million and SEK 150.8 million for the three months ended March 31, 2022 and 2021, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 113.3 million and SEK 90.1 million for the three months ended March 31, 2022 and 2021, respectively. The increase of SEK 23.2 million for the first quarter is primarily due to the setanaxib trials and the development of setanaxib.

Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 93.9 million and SEK 19.4 million for the three months ended March 31, 2022 and 2021, respectively. The increase of SEK 74.5 million for the first quarter is primarily related to the costs for sales and marketing of TARPEYO in the U.S. including the costs for the sales force.

Administrative Expenses

Administrative expenses amounted to SEK 48.5 million and SEK 39.4 million for the three months ended March 31, 2022 and 2021, respectively. The increase of SEK 9.1 million for the first quarter was primarily related to general cost increases due to a larger organization compared to the same period last year.

Other Operating Incomes/Expenses

Other operating income amounted to SEK 0.8 million for the three months ended March 31, 2022. No other operating income was recognized for the three months ended March 31, 2021. Other operating expenses amounted to SEK 2.5 million and SEK 1.9 million for the three months ended March 31, 2022 and 2021, respectively. The increase in other operating expenses for the three months ended March 31, 2022 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 3.1 million) and SEK 14.6 million for the three months ended March 31, 2022 and 2021, respectively. The decrease of SEK 17.7 million for the three months ended March 31, 2022 are primarily derived by interest expenses and a decrease of unrealized foreign currency transaction gains on cash accounts, compared to the same period 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 4.4 million have been recognized in the three months ended March 31, 2022 mainly due to future temporary differences that such losses can be used to offset and are related to Calliditas Therapeutics Suisse. The Group's tax losses carried forward have not otherwise 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 March 31, 2022 and 2021, loss for the period amounted to SEK 207.0 million and SEK 132.9 million, and the corresponding loss per share before and after dilution amounted to SEK 3.95 and SEK 2.62, respectively.

January – March 2022

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 191.4 million and SEK 134.2 million for the three months ended March 31, 2022 and 2021, respectively. The increase in cash flow used in operating activities during the three months ended March 31, 2022 are primarily explained by the increase in sales and marketing expenses for the TARPEYO sales in the U.S. and the Group's increased clinical activities for setanaxib.

Cash flow used in investing activities amounted to SEK 2.7 million and SEK 0.2 million for the three months ended March 31, 2022 and 2021, respectively.

Cash flow from/(used in) financing activities amounted to SEK 60.1 million and (SEK 9.6 million) for the three months ended March 31, 2022 and 2021, respectively. The increase in cash flow from financing activities for the three months ended March 31, 2022, compared to the same period last year, was primarily due to payments related to the exercise of warrant program 2018/2022.

Net decrease in cash amounted to SEK 134.0 million and SEK 144.0 million for the three months ended March 31, 2022 and 2021, respectively. Cash amounted to SEK 825.4 million and SEK 867.3 million as of March 31, 2022 and 2021, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 871.1 million and SEK 1,089.5 million as of March 31, 2022 and 2021, respectively. The number of registered and outstanding shares amounted to 53,172,170 and 49,941,584 as of March 31, 2022 and 2021, 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 and the ongoing issue of 830,586 shares.

Personnel

The number of employees were 71 and 46 employees as of March 31, 2022 and 2021, respectively. The total number of full-time equivalent (FTE), including consultants, were 131 and 64 as of March 31, 2022 and 2021, respectively. The average number of employees were 71 and 41 for the three months ended March 31, 2022 and 2021, respectively.

Incentive Programs

During the three months ended March 31, 2022 a total allocation of 650,000 employee options have been issued. For more information on incentive programs, see Note 10.

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 31.8 million for the three months ended March 31, 2022. No net sales were recognized for the three months ended March 31, 2021. The increase was primarily derived from out-licensing Nefecon with STADA for Europe by SEK 3.0 million and the extension of the Everest Medicine agreement to South Korea by SEK 28.8 million. Operating loss amounted to SEK 102.5 million and SEK 127.9 million for the three months ended March 31, 2022 and 2021, respectively. The decrease was primarily derived from other operating income, which referred to intercompany pass-through to Calliditas Therapeutics Suisse regarding setanaxib trials. Non-current financial assets have increased by SEK 92.5 million to SEK 645.4 million as of March 31, 2022 compared to December 31, 2021, which was primarily derived from intercompany transactions.

Auditor's Review

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

Stockholm, May 18, 2022

Renée Aguiar-Lucander
CEO

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended March 31,		Year Ended December 31,
		2022	2021	2021
Net sales	4	49,734	-	229,347
Cost of goods sold		(614)	-	-
Gross profit		49,119	-	229,347
Research and development expenses		(113,343)	(90,077)	(357,485)
Marketing and selling expenses		(93,897)	(19,426)	(179,603)
Administrative expenses		(48,532)	(39,353)	(210,630)
Other operating income		765	-	259
Other operating expenses		(2,479)	(1,925)	(6,344)
Operating loss		(208,367)	(150,781)	(524,456)
Net financial income/(expenses)		(3,068)	14,607	11,083
Loss before income tax		(211,434)	(136,174)	(513,373)
Income tax		4,387	3,302	3,836
Loss for the period		(207,047)	(132,872)	(509,537)
Attributable to:				
Equity holders of the Parent Company		(207,047)	(130,870)	(500,293)
Non-controlling interests		-	(2,002)	(9,244)
		(207,047)	(132,872)	(509,537)
Loss per share before and after dilution (SEK)		(3.95)	(2.62)	(9.84)

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended March 31,		Year Ended December 31,
	2022	2021	2021
Loss for the period	(207,047)	(132,872)	(509,537)
Other comprehensive income			
<i>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:</i>			
Exchange differences on translation of foreign operations	(1,200)	6,277	(20,111)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods	(1,200)	6,277	(20,111)
<i>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:</i>			
Remeasurement gain on defined benefit plans	1,294	1,416	1,993
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods	1,294	1,416	1,993
Other comprehensive income/(loss) for the period	94	7,693	(18,118)
Total comprehensive income/(loss) for the period	(206,954)	(125,179)	(527,655)
Attributable to:			
Equity holders of the Parent Company	(206,954)	(124,115)	(519,190)
Non-controlling interests	-	(1,064)	(8,466)
	(206,954)	(125,179)	(527,655)

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	March 31,		December 31,
		2022	2021	2021
ASSETS				
Non-current assets				
Intangible assets	6,12	400,952	426,854	399,418
Equipment		6,793	332	6,309
Right-of-use assets		30,720	5,547	33,300
Non-current financial assets		5,842	2,230	3,915
Deferred tax assets		3,557	506	4,196
Total non-current assets		447,862	435,469	447,138
Current assets				
Inventories		1,133	-	889
Accounts receivable		6,328	-	-
Other current receivables		12,965	30,032	11,343
Prepaid expenses and accrued income		50,644	10,489	45,032
Cash		825,409	867,346	955,507
Total current assets		896,478	907,867	1,012,772
TOTAL ASSETS		1,344,340	1,343,336	1,459,910
EQUITY AND LIABILITIES				
Equity				
Share capital		2,094	1,998	2,094
Additional paid-in-capital		2,529,556	2,135,476	2,459,741
Retained earnings, including net loss for the period		(1,660,507)	(1,047,929)	(1,453,554)
Equity attributable to equity holders of the Parent Company		871,142	1,089,545	1,008,281
Non-controlling interests		-	36,238	-
Total equity	9,10	871,142	1,125,783	1,008,281
Non-current liabilities				
Provisions	10	9,220	13,293	17,712
Contingent consideration		56,300	50,683	54,399
Deferred tax liabilities	7,12	26,112	35,047	30,856
Non-current interest-bearing liabilities	11	192,632	-	189,164
Lease liabilities		21,859	1,319	24,052
Total non-current liabilities		306,123	100,342	316,183
Current liabilities				
Accounts payable		100,051	57,660	67,971
Other current liabilities		14,098	6,712	13,922
Accrued expenses and deferred revenue		52,926	52,839	53,553
Total current liabilities		167,075	117,211	135,446
TOTAL EQUITY AND LIABILITIES		1,344,340	1,343,336	1,459,910

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Three Months Ended March 31,		Year Ended December 31,
	2022	2021	2021
Opening balance equity attributable to equity holders of the Parent Company	1,008,281	1,210,491	1,210,491
Loss for the period	(207,047)	(130,870)	(500,293)
Other comprehensive income/(loss)	94	6,755	(18,897)
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	(206,954)	(124,115)	(519,190)
Transactions with owners:			
New share issue	-	-	324,000
Costs attributable to new share issue	-	(982)	(20,909)
Exercise of warrants	61,713	-	-
Share-based payments	8,103	3,278	23,567
Purchase of non-controlling interests	-	872	(9,678)
Total transactions with owners	69,815	3,169	316,980
Closing balance equity attributable to equity holders of the Parent Company	871,142	1,089,545	1,008,281
Opening balance equity attributable to non-controlling interests	-	45,809	45,809
Total comprehensive loss for the period	-	(1,064)	(8,466)
Contribution from non-controlling interests	-	2,282	2,282
Purchase of non-controlling interests	-	(10,789)	(39,625)
Closing balance equity attributable to non-controlling interests	-	36,238	-
Closing balance equity	871,142	1,125,783	1,008,281

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended March 31,		Year Ended December 31,
	2022	2021	2021
Operating activities			
Operating loss	(208,367)	(150,781)	(524,456)
Adjustment for non-cash-items	5,067	5,007	66,676
Interest received	-	-	102
Interest paid	(5,408)	(154)	(5,432)
Income taxes paid	-	-	(3,949)
Cash flow used in operating activities before changes in working capital	(208,708)	(145,928)	(467,058)
Cash flow from/(used in) changes in working capital	17,285	11,749	5,470
Cash flow used in operating activities	(191,423)	(134,179)	(461,588)
Cash flow used in investing activities	(2,651)	(199)	(24,340)
Cash flow used in investing activities	(2,651)	(199)	(24,340)
New share issue	-	-	324,000
Costs attributable to new share issue	-	(982)	(20,909)
Exercise of warrants	61,713	-	-
Purchase of non-controlling interests	-	(9,917)	(49,303)
Contribution from non-controlling interests	-	2,282	2,282
New borrowings	-	-	199,524
Costs attributable to new loans	-	-	(14,857)
Repayment of lease liabilities	(1,658)	(1,010)	(5,575)
Cash flow from/(used in) financing activities	60,054	(9,627)	435,162
Net increase/(decrease) in cash	(134,020)	(144,005)	(50,766)
Cash at the beginning of the period	955,507	996,304	996,304
Net foreign exchange gains/(loss) on cash	3,921	15,047	9,969
Cash at the end of the period	825,408	867,346	955,507

FINANCIAL STATEMENTS

Condensed Parent Company Statements of Income

(SEK in thousands)	Notes	Three Months Ended March 31,		Year Ended December 31,
		2022	2021	2021
Net sales	4	31,771	-	229,347
Cost of goods sold		(614)	-	-
Gross profit		31,157	-	229,347
Research and development expenses		(103,681)	(72,150)	(275,950)
Marketing and selling expenses		(24,407)	-	(151,125)
Administrative expenses		(44,344)	(54,553)	(226,349)
Other operating income		39,895	-	70,234
Other operating expenses		(1,153)	(1,237)	(1,874)
Operating loss		(102,534)	(127,940)	(355,718)
Net financial income/(expenses)		(3,396)	15,126	1,312
Loss before income tax		(105,929)	(112,814)	(354,405)
Income tax		-	-	-
Loss for the period		(105,929)	(112,814)	(354,405)

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended March 31,		Year Ended December 31,
	2022	2021	2021
Loss for the period	(105,929)	(112,814)	(354,405)
Other comprehensive income/(loss)	-	-	-
Total comprehensive income/(loss)	(105,929)	(112,814)	(354,405)

FINANCIAL STATEMENTS

Condensed Parent Company Balance Sheet

Condensed Parent Company Balance Sheet (SEK in thousands)		Notes	March 31,		December 31,
			2022	2021	2021
ASSETS					
Non-current assets					
Intangible assets	6	32,132	16,066	32,132	
Equipment		735	74	514	
Non-current financial assets		645,442	357,902	552,924	
Total non-current assets		678 309	374,042	585,570	
Current assets					
Inventories		1,133	-	889	
Other current receivables		16,020	14,536	5,699	
Prepaid expenses and accrued income		37,622	9,695	41,825	
Cash		753,407	828,360	894,455	
Total current assets		808,182	852,591	942,868	
TOTAL ASSETS		1,486,491	1,226,633	1,528,439	
SHAREHOLDERS' EQUITY AND LIABILITIES					
Restricted Shareholders' equity					
Share capital		2,094	1,998	2,094	
On-going issue of shares		33	-	-	
Statutory reserve		3,092	3,092	3,092	
Total restricted Shareholders' equity		5,219	5,090	5,186	
Non-restricted shareholders' equity					
Share premium reserve		2,484,537	2,116,721	2,420,698	
Retained earnings		(1,211,638)	(883,463)	(863,175)	
Net loss for the period		(105,929)	(112,814)	(354,405)	
Total non-restricted shareholders' equity		1,166,970	1,120,444	1,203,117	
Total shareholders' equity	9,10	1,172,189	1,125,534	1,208,303	
Non-current liabilities					
Provisions	10	5,128	4,664	9,075	
Non-current interest-bearing liabilities	11	192,632	-	189,164	
Other non-current liabilities		105	105	105	
Total non-current liabilities		197,865	4,769	198,344	
Current liabilities					
Accounts payable		67,306	49,711	51,711	
Other current liabilities		18,101	7,181	33,466	
Accrued expenses and deferred revenue		31,031	39,438	36,615	
Total current liabilities		116,438	96,330	121,792	
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,486,491	1,226,633	1,528,439	

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") conducts commercial and development activities in pharmaceuticals. These interim condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the three months ended March 31, 2022 and 2021, 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 May 18, 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, 2022, have had a significant impact on the Group's financial reporting. Significant accounting principles can be found on pages 41-46 of the Annual Report for 2021.

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 30.

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.

Calliditas has a product in the commercial phase, TARPEYO, which has been approved for marketing in the U.S.. There is a risk that commercialization will not go according to plan or that the uptake of prescribing physicians will be worse than planned or that the drug will not have sufficient effect or show unwanted side effects, which may affect the sales negatively.

COVID-19

The COVID-19 virus has rapidly spread from an initial event and infections have been reported globally. Calliditas has clinical trial sites based in areas currently affected by this coronavirus. Calliditas has not yet experienced any major disturbances in the trials. The extent to which the coronavirus impacts the operations and the trials, 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 maintains 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 2021.

For more information and full disclosure regarding the operational- and financial risks, reference is made to the Annual Report for 2021 and the Annual Report on Form 20-F, filed with the SEC in April 2022.

Note 4 - Revenue from Contracts with Customers

(SEK in thousands)	Three Months Ended March 31,		Year Ended December 31,
	2022	2021	2021
Type of goods or services			
Product sales	17,963	-	-
Outlicensing of the product candidate	28,804	-	225,252
Performance of certain regulatory services	2,967	-	4,095
Total	49,734	-	229,347
Geographical markets			
USA	17,963	-	-
Europe	2,967	-	201,878
Asia	28,804	-	27,469
Total	49,734	-	229,347

The Group's revenues for the first quarter 2022 primarily originates from a USD 3.0 million milestone fee from Everest Medicines related to the out-licencing of the commercial rights of Nefecon for the South Korea territory and SEK 18.0 million in TARPEYO product sales in the U.S.

Revenue from product sales is recognized at the transaction price of goods sold excluding VAT,

rebates and returns. At the time of delivery, when the control of the goods passes to the customer, the revenue is recognized in full, as this represents the single performance obligation in the transaction. The customer is defined as the specialty pharmaceutical who dispenses the good to the end user. As the final price is related to the rebate paid to the patients' insurance company, the transaction price is not known upon delivery. This is regulated by an accrued estimated rebate deduction in the Group based on calculation models considering statistical data, actual amounts incurred and/or historical trends. These liabilities for expected returns and rebates are based on estimates of the amounts earned or to be claimed on the related sales. Furthermore, the Group estimates the liability for expected returns of obsolete medicines that is recognized in the accounts. The total liability for expected return and rebates amounts to SEK 1.8 million. In addition, there are no other performance obligations.

Revenue attributable to out-licensing Nefecon consisted of the agreement with STADA for Europe and the expansion of Everest Medicine to South Korea. Revenue for out-licensing is recognized at a point in time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreements with both parties 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 obligations under the agreement with STADA: 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 obligations, since the product candidate has not been approved for market by the regulatory authorities and no commercial pricing occur. Calliditas has completed all the performance obligations within the agreement with Everest Medicines.

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)	March 31,		December 31,
	2022	2021	2021
Cost at opening balance	427,393	418,825	418,825
Acquisition license	-	-	16,066
Exchange difference on translation	1,533	8,029	(7,498)
Cost at closing balance	428,926	426,854	427,393
Amortisation and impairment at closing balance	(27,975)	-	(27,975)
Net book value	400,951	426,854	399,418

Intangible assets consist of licenses and similar rights of SEK 363.6 million and goodwill of SEK 37.4 million as of March 31, 2022. As of March 31, 2021, intangible assets consist of licenses and similar rights of SEK 388.1 million and goodwill of SEK 38.7 million.

Note 7 - Deferred Tax Liabilities

(SEK in thousands)	March 31,		December 31,
	2022	2021	2021
Cost at opening balance	30,857	37,454	37,454
Tax loss carried forward	(5,135)	(3,431)	(5,065)
Exchange difference on translation	390	1,024	(1,532)
Cost at closing balance	26,112	35,047	30,857

Tax loss carried forward of SEK 20.3 million have been offset against deferred tax liabilities in the statement of financial position as of March 31, 2022 due to future temporary differences that such losses can be used to offset.

Note 8 - Financial Instruments

The Group's financial assets comprise of non-current financial assets, accounts receivables and cash, which are recognized at amortized cost. The Group's financial liabilities comprise of contingent consideration, non-current interest-bearing liabilities, lease liabilities, accounts payable and other current liabilities, all of which except contingent consideration, are recognized at amortized cost. Contingent considerations are recognized at fair value, measured at Level 3 of the IFRS value hierarchy. The carrying amount is an approximation of the fair value.

Note 9 - Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	March 31,		December 31,
	2022	2021	2021
Total registered shares at the beginning of the period	52,341,584	49,941,584	49,941,584
New issue of shares during the period	-	-	2,400,000
Outstanding of shares during the period	830,586	-	-
Total registered and outstanding shares at the end of the period	53,172,170	49,941,584	52,341,584
Share capital at the end of the period	2,094	1,998	2,094
Equity attributable to equity holders of the Parent Company	871,142	1,089,545	1,008,281
Non-controlling interests	-	36,238	-
Equity at the end of the period	871,142	1,125,783	1,008,281
(SEK in thousands, except per share amounts and number of shares)	Three Months Ended March 31,		Year Ended December 31,
	2022	2021	2021
Loss per share before and after dilution, SEK	(3.95)	(2.62)	(9.84)
Weighted-average number of shares outstanding for the period, before and after dilution	52,381,402	49,941,584	50,829,255

Reserves for translation from foreign operations amounted to (SEK 1.2 million) and SEK 6.3 million which are included in equity as of March 31, 2022 and 2021, respectively.

As of March 31, 2022, there was an on-going issue of shares of 830,586 common shares under registration, which referred to the exercise of the Warrant Program 2018/2022. Regarding the calculation of the weighted-average number of shares outstanding for the period, shares in on-going issue of shares have been taken into account.

Note 10 - Incentive Programs

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of March 31, 2022
Incentive Programs				
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	-	1,495,000	-	1,495,000
Total Outstanding as of March 31, 2022	422,500	2,939,000	109,738	3,471,238

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of March 31, 2021
Incentive Programs				
Warrant program 2018/2022	856,586	-	-	856,586
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2019	-	-	51,399	51,399
Board LTIP 2020	-	-	31,371	31,371
ESOP 2020	-	1,485,000	-	1,485,000
Total Outstanding as of March 31, 2021	1,279,086	1,485,000	82,770	2,846,856

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. As of March 31, 2022, 856,586 warrants have been exercised.

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 awards 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 awards 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

(SEK in thousands)	March 31,		December 31,
	2022	2021	2021
Opening balance	189,164	-	-
New borrowings	-	-	199,524
Transaction costs paid	-	-	(14,858)
Interest expense	1,196	-	2,145
Exchange difference on translation	2,271	-	2,353
Closing balance	192,632	-	189,164

In July 2021, Calliditas signed a loan agreement of up to the euroequivalent of USD 75 million with Kreos Capital. The loan facility is divided into three tranches of USD 25 million each. Drawdown of the first USD 25 million tranche was made in 2021. Drawdown of the second tranche of USD 25 million can be made until June 30, 2022. Drawdown of the third and final USD 25 million tranche can be made until December 31, 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 financial covenants.

Note 12 - Change of presentation of expenses and IFRS 3 adjustment

Change of Presentation of Expenses

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

Update of Purchase Price Allocation

The fair value of the acquired assets and assessed liabilities for the acquisition of Calliditas Therapeutics Suisse S.A in 2020 was preliminarily established for the first 12 months and have thereafter been finalized in 2021. The fair value of the acquisitions of Calliditas Therapeutics Suisse S.A have changed due to allocation of assets and liabilities to Switzerland and therefore IFRS adjustments were made to the acquisition values. The effects of the change in the statement of income for the preceding periods are shown below:

(SEK in thousands)	Three Months Ended March 31,			2021	Year Ended December 31,		
	2021	Adjustment	Re-classification		2021	Re-classification	2021
Net sales	-	-	-	-	229,347	-	229,347
<i>Operating expenses</i>							
Research and development expenses	(90,076)	-	-	(90,076)	(357,485)	-	(357,485)
Marketing and selling expenses	-	-	(19,426)	(19,426)	-	(179,603)	(179,603)
Administrative expenses	(58,779)	-	19,426	(39,353)	(390,232)	179,603	(210,629)
Other operating income/expenses	(1,925)	-	-	(1,925)	(6,085)	-	(6,085)
Operating loss	(150,781)	-	-	(150,781)	(524,456)	-	(524,456)
Net financial income/(expenses)	14,607	-	-	14,607	11,083	-	11,083
Loss before income tax	(136,174)	-	-	(136,174)	(513,373)	-	(513,373)
Income tax	9,305	(6,004)	-	3,302	3,836	-	3,836
Loss for the period	(126,869)	(6,004)	-	(132,872)	(509,537)	-	(509,537)

NOTES

The below table describes the adjustment for the three months ended March 31, 2021, compared to what prior has been published for the same period, regarding the statements of financial position from the finalization of the fair value.

(SEK in thousands)	March 31,		2021
	2021	Adjustment	
ASSETS			
Non-current assets			
Other intangible assets	377,469	(33,942)	343,527
Goodwill	48,194	(9,448)	38,746
Other non-current assets	53,195	-	53,195
Total non-current assets	478,859	(43,390)	435,469
Current assets	907,867	-	907,867
TOTAL ASSETS	1,386,726	(43,390)	1,343,336
EQUITY AND LIABILITIES			
Equity			
Share capital	1,998	-	1,998
Additional paid in capital	2,135,476	-	2,135,476
Retained earnings, including net loss for the period	(1,042,133)	(5,796)	(1,047,929)
Equity attributable to equity holders of the Parent Company	1,095,341	(5,796)	1,089,545
Non-controlling interests	36,834	(596)	36,238
Total equity	1,132,175	(6,392)	1,125,783
Non-current liabilities			
Deferred tax liabilities	72,045	(36,998)	35,047
Other non-current liabilities	65,295	-	65,295
Total non-current liabilities	137,340	(36,998)	100,342
Current liabilities	117,211	-	117,211
TOTAL EQUITY AND LIABILITIES	1,386,726	(43,390)	1,343,336

Definitions of Performance Measures and Reconciliations of Alternative Performance Measures

Definitions of Performance Measures

Performance Measures	Definitions
Earnings/(loss) per share before and 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 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, marketing and selling expenses, administrative expenses and 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 March 31,		Year Ended December 31,
	2022	2021	2021
Research and development expenses/Total operating expenses in %			
Research and development expenses	(113,343)	(90,077)	(357,485)
Marketing and selling expenses	(93,897)	(19,426)	(179,603)
Administrative expenses	(48,532)	(39,353)	(210,630)
Other operating income/expenses	(1,715)	(1,925)	(6,085)
Total operating expenses	(257,486)	(150,781)	(753,803)
Research and development expenses/Total operating expenses in %	44%	60%	47%

(SEK in thousands or otherwise indicated)	March 31,		December 31,
	2022	2021	2021
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	871,142	1,089,545	1,008,281
Total assets at the end of the period	1,344,340	1,343,336	1,459,910
Equity ratio at the end of the period in %	65%	81%	69%

Financial Calendar

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

Contact

Renée Aguiar-Lucander
Chief Executive Officer
Phone: +46 (0)8 411 3005
Email: renee.lucander@calliditas.com

Calliditas Therapeutics AB
Kungsbron 1, SE-111 22 Stockholm,
Sweden
www.calliditas.com

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, commercialization of TARPEYO, 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.

