

Q4 2022

YEAR-END REPORT JANUARY 1ST – DECEMBER 31TH 2022

2022: Successful Transformation Into a Commercial Stage Company

Financial Summary For the Group

Key Figures

October 1 - December 31 2022

- » Net sales amounted to SEK 429.0 million, of which TARPEYO® net sales amounted to SEK 167.3 million, for the three months ended December 31, 2022. For the three months ended December 31, 2021 net sales amounted to SEK 31.2 million and no TARPEYO net sales were recognized.
- » Operating profit/(loss) amounted to SEK 32.5 million and (SEK 222.1 million) for the three months ended December 31, 2022 and 2021, respectively.
- » Loss per share before and after dilution amounted to SEK 0.07 and SEK 4.19 for the three months ended December 31, 2022 and 2021, respectively.
- » Cash amounted to SEK 1,249.1 million and SEK 955.5 million as of December 31, 2022 and 2021, respectively.

January 1 - December 31, 2022

- » Net sales amounted to SEK 802.9 million, of which TARPEYO net sales amounted to SEK 372.2 million, for the year ended December 31, 2022. For the year ended December 31, 2021 net sales amounted to SEK 229.3 million and no TARPEYO net sales were recognized.
- » Operating loss amounted to SEK 421.9 million and SEK 524.5 million for the year ended December 31, 2022 and 2021, respectively.
- » Loss per share before and after dilution amounted to SEK 7.78 and SEK 9.84 for the year ended December 31, 2022 and 2021, respectively.
- » For the year ended December 31, 2022 no dividend was proposed.

Investor Presentation February 23, 2023 14:30 CET

Audio cast with teleconference, Q4 2022

Webcast: <https://ir.financialhearings.com/calliditas-therapeutics-q4-2022>

Teleconference: <https://conference.financialhearings.com/teleconference/?id=5009654>

Significant Events in Q4 2022, in Summary

In October 2022, Calliditas announced that Kidney International published the successful results from Part A of the NeflgArd pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter study, on the basis of which the accelerated approval by the FDA for TARPEYO and the conditional marketing authorization by the European Commission for Kinpeygo® in the USA and Europe (EEA), respectively.

In November 2022, Calliditas announced that its partner in China Everest Medicine's New Drug Application for Nefecon was accepted by the Chinese regulatory authority National Medical Products Administration (NMPA).

In December 2022, Calliditas announced that it had entered into an exclusive license agreement with Viatris Pharmaceuticals Japan Inc., to register and commercialize Nefecon for the treatment of IgA nephropathy (IgAN) in Japan. Under the terms of the agreement, Calliditas received an initial upfront payment of USD 20 million upon signing and is entitled to up to an additional USD 80 million in pre-defined development and commercialization milestones. Viatris will also pay mid-teens percentage royalties on net sales.

Significant Events After the End of the Reporting Period, in Summary

In February 2023, Calliditas announced that the MHRA of the United Kingdom has granted Conditional Marketing Authorization (CMA) for Kinpeygo for the treatment of IgAN. Calliditas will transfer the CMA to its partner STADA Arzneimittel AG, which have the right to commercialize Kinpeygo in the European Economic Area (EEA), Switzerland and the UK.

2023 Outlook

For 2023, Calliditas expects accelerated revenue growth in the U.S. where:

Net sales from TARPEYO are estimated to be USD 120-150 million for the year ending December 31, 2023.



Part A NeflgArd Data Published in Kidney International

In October, Kidney International published a peer reviewed article containing the details of Part A of our NeflgArd trial. We were delighted that, with the Phase 3 trial now approaching its completion, we were in a position to share this information. The data was very well received by nephrologists, as reflected by the high level of interest at the American Society of Nephrology's (ASN's) Kidney Week in Orlando in early November. We were very encouraged by the positive feedback from the many interactions during the conference and by the many discussions that took place about TARPEYO in various forums. The strong reduction in proteinuria observed at 9 months in Part A of our NeflgArd trial, which importantly continued to decline across all patients who had reached 12 months, i.e. after 3 months off drug, was commented on as being highly differentiated from other drug candidates, and the strong protection of kidney function, as measured by eGFR, that was seen in the population at highest risk was considered to be very impressive. It is clear from these interactions that as more eGFR data becomes generally available it will ultimately drive treatment decisions, as the goal of treating physicians is to protect kidney function rather than to address symptoms. Proteinuria reduction will certainly continue to be

seen as a requirement, but not necessarily be sufficient on its own. We are therefore excited about also being able to share long term eGFR data in 2023 as Part B top line data becomes available, which we hope to be able to announce in mid-March.

We continued to build on our commercial success in the US, seeing record average weekly patient enrollment numbers towards the end of the quarter, despite both Thanksgiving and Christmas holidays. This, in our view, is partly a reflection of the availability of the full clinical data from NeflgArd Part A, and we look forward to seeing continued growth as patient success stories and peer to peer recommendations continue to build. The revenue impact of these enrollments is only partly reflected in Q4 revenues due to the requirement for insurance plan approvals for specialty products under the US healthcare system. Total Q4 revenues were SEK 429.0 million (approx. \$42.4m), out of which net revenues from TARPEYO amounted to SEK 167.3 million (\$16.1m), resulting in an operating profit of SEK 32.5 million (approx. \$3.2m) and a positive cash flow from operating activities of SEK 230.0 million (approx. \$22.7m) for the fourth quarter. Prescribing nephrologists continue to grow bringing total unique prescribers to 642 for the year. New enrolments were 310 in Q4, resulting in a total of 1,039 enrolments for the year. We achieved total revenues of SEK 802.9 million (approx. \$79.3m) for the year 2022, which represent an increase of 250% compared to 2021 and SEK 372.2 million (\$36.8m) of net sales of TARPEYO for the first 11 months of commercialization. We are immensely proud of this result, and we look forward to continuing to support the patient community with a drug which we believe has the potential to be disease modifying and help keep patients out of dialysis. We end the year with a very strong cash position of SEK 1,249 million which reflects a successful non-dilutive capital raising approach, and we believe that we are, based on our guidance for TARPEYO, funded to profitability and well prepared to capitalize on growth and opportunities in 2023.

We expect to achieve net sales from TARPEYO for the year of 2023 of between USD 120-150 million, reflecting continued market penetration now that the full Part A data is available, combined with the streamlining of market access, and increased peer to peer recommendations based on the early patient successes we are starting to hear about. We believe that strong topline data from the Part B from the NeflgArd trial could provide momentum to uptake as the long term eGFR data will provide additional insight into the potential for kidney protection and disease modification achieved by the TARPEYO treatment.

We also made progress with regards to our global Nefecon franchise. In early November our partner, Everest Medicines, received an acceptance of their New Drug Application (NDA) for approval of Nefecon in China, which was followed by a subsequent Priority Review decision recommendation by the NMPA in December. We will be supporting Everest in their dialogue with the agency and look forward to the NMPA's decision expected in 2023 regarding a potential approval. IgA nephropathy is a significant unmet medical need in China, where there are approx. 5 million biopsy proven patients, whose disease burden and unmet medical need we hope to address should Nefecon be approved.

In December we entered into another important partnership deal for the Nefecon global franchise, as we out licensed Nefecon for Japan, which resulted in an additional non-dilutive cash infusion of \$20m. Following a competitive process, we signed an out-licensing agreement regarding Nefecon for the rights in Japan with Viatris Pharmaceuticals Japan, who will develop Nefecon for patients in the Japanese market. We look forward to collaborating with Viatris to bring Nefecon to patients as quickly as possible.

Regarding our pipeline, we have seen significant improvement in the recruitment rate in the setanaxib head and neck cancer study, whilst PBC remains challenging. We look forward to reporting out biomarker data from the setanaxib trial in head and neck in 2023 as previously disclosed. We are also excited to report that we will be starting an additional clinical trial in the renal space, as we are getting ready to initiate a clinical trial in Alport Syndrome using setanaxib. Based on supportive pre-clinical data we plan to run a study with around 20 patients with targeted launch in Q2 of 2023. We will continue to explore additional renal indications in which we believe that setanaxib may have a beneficial effect based on the mode of action.

Finally, I want to thank all of our shareholders for your support through a volatile and often difficult macro backdrop in 2022. We look forward to 2023 which promises to be an exciting year with Part B top line read out, continued commercialization of TARPEYO, potential approval of Nefecon in China and data from the setanaxib platform.

Renée Aguiar-Lucander, CEO

A strong quarter to close out our launch year of TARPEYO

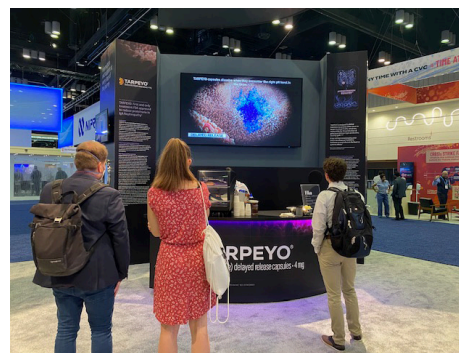
In our fourth quarter of sales of TARPEYO®, our commercial team continued to build on the successful strides made throughout the year. We remain encouraged at the patient and physician enthusiasm for our product and by the progress we have made in our work to bring the first approved medication to those with IgA nephropathy.

In the last quarter of 2022, our specialty sales force recorded net sales of TARPEYO of \$16.1 million (SEK 167.3 million) in the U.S., a growth of 36% over the prior quarter. The expanded commercial sales team has demonstrated an immediate impact on patient enrolments seen as soon as November. Patients continue to be guided through the enrolment and procurement process with the support of our patient services program, TARPEYO Touchpoints™. This white glove service program assists physicians and patients via a designated Rare Pod Team – including nurses, pharmacists, and a fulfilment and distribution team. 310 fourth quarter patient enrolments brings the total to 1,039 enrolments for 2022 written by 642 unique prescribers since TARPEYO launched in late January.

As of the end of Q4, well over 90% of US lives have insurance coverage for TARPEYO. Patients enrolled in TARPEYO Touchpoints have a conversion rate of around 80% across commercial, government and patient assistance programs. To-date, our channel mix remains primarily commercial, approximately 70%, with the majority of the remaining 30% consisting of government subsidized insured patients, which include Medicare and Medicaid. While the average time for a prescription fill continues to be less than 30 days for those prescriptions that have insurance approval, the commercial team continues to focus on improving this rate in an effort to exceed industry standards.

Our marketing team has continued to drive promotional efforts across various channels to boost the product's profile and support the uptake of TARPEYO. Awareness of TARPEYO has continuously increased, with awareness now greater than 90%. In addition, market research conducted with nephrologists continues to demonstrate the effectiveness of our educational and promotional programs, with peer-to-peer programs continuing to emphasize both disease education and the strong clinical benefits of TARPEYO. Peer-to-peer programs increased significantly in Q4, with key opinion leaders (KOLs) educating nephrologists on TARPEYO, its mode of action, and its clinical value.

In October the positive results of Part A of the NeflgArd trial were published in the peer reviewed journal Kidney International. The publication has been well received by practicing nephrologists as it highlights the safety results and efficacy data related to both proteinuria and estimated glomerular filtration rate (eGFR) for patients treated with TARPEYO.



The fourth quarter was highlighted by the American Society of Nephrology Kidney Week, the largest annual nephrology meeting taking place in November in Orlando. This was the first year Calliditas attended the live meeting since the approval of TARPEYO and it was an action-packed week of medical and commercial activities that included a commercial exhibit booth, sponsored relevant symposium and an opportunity to engage with healthcare providers (HCPs) and KOLs. Calliditas' medical team also presented a poster on how "Treatment With Nefecon Reduces Circulating Levels of Galactose-Deficient IgA1 in Patients With IgA Nephropathy in the NeflgArd Clinical Trial". Calliditas also organized a dual product theatre program on the gut-kidney connection in IgAN and on TARPEYO as a novel treatment approach, which was presented by key opinion leaders Dr. Gerald Appel and Dr. Shikha Wadhwani. We had a strong exhibitor presence, where our team engaged with hundreds of HCPs and strengthened our longstanding relationship with patient advocacy groups like the IgA Nephropathy Foundation.

Our Commercial Product

Calliditas' lead product, which was granted accelerated approval by the US Food and Drug Administration (FDA) in December 2021 and conditional marketing authorization by the European Commission in July 2022, is a treatment specifically designed to target the origin of the autoimmune kidney disease IgA Nephropathy (IgAN).

IgAN is a serious progressive disease, in which up to 50% of patients end up at risk of developing end-stage renal disease (ESRD) within ten to twenty years. This product, which was developed under the name Nefecon, is approved under the brand name TARPEYO® in the United States and under the brand name Kinpeygo® in Europe.

Disease Background

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. Patients with IgA nephropathy have elevated levels of mucosal-type IgA, which – in contrast to the majority of the IgA in the blood – 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 secretory 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 which form pathogenic immune complexes that deposit in the glomeruli, the kidney's filtration apparatus. The trapped immune complexes initiate an inflammatory cascade 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.

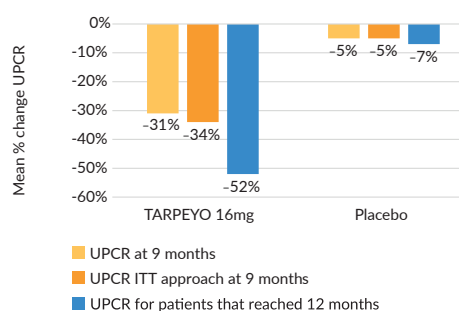
¹Barratt, J., Lafayette, R., Kristensen, J., et al. (2022). Results from part A of the multi-center, double-blind, randomized, placebo controlled NeflgArd trial evaluated targeted-release formulation of budesonide for the treatment of primary <https://doi.org/10.1016/j.kint.2022.09.017>

Calliditas' lead product is an oral, delayed release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism, resulting in limited systemic exposure. It 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 various polymers and budesonide designed to target the area with the highest concentration of Peyer's patches, with the intention of having a disease-modifying effect.

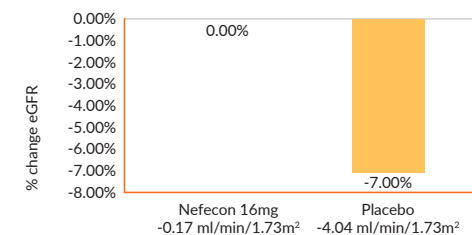
Data

Calliditas' regulatory filings with the FDA and European Medicines Agency (EMA) were based on positive data from Part A of the NeflgArd pivotal Phase 3 study, which read out topline data 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; in the intention to treat (ITT) population, the reduction at 9 months of treated patients was 34%. Furthermore, for patients who had reached 12 months at the time of the data cut-off, the 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. This data has now been published in a peer reviewed article in Kidney International.¹

Primary endpoint: Reduction in proteinuria



Secondary endpoint: Stabilization of eGFR



Our Commercial Product (cont.)

Approval in the US

The product is approved under the accelerated approval pathway under the brand name TARPEYO® in the United States. TARPEYO is 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) ≥ 1.5 g/g. It is the first FDA-approved treatment for IgA nephropathy.

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.



Approval in EU

In July 2022, the product was granted conditional marketing authorization by the European Commission under the brand name Kinpeygo® for the treatment of IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/gram. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in EU.

Kinpeygo will be marketed in the European Economic Area (EEA), Switzerland and the UK exclusively by STADA Arzneimittel AG with whom Calliditas entered into a license agreement in July 2021 to register and commercialize Kinpeygo in the European Economic Area (EEA), Switzerland and the UK. Under the terms of the agreement, Calliditas received an initial upfront payment of EUR 20 million upon signing and has received additional EUR 12.5 million for conditional marketing authorization and commercialization milestones. Calliditas is further entitled to up to an additional EUR 65 million in future payments linked to pre-defined regulatory and commercialization milestones. STADA will also pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

Following the transfer of the conditional marketing authorisation, STADA launched Kinpeygo in Germany in October 2022, with additional European countries to follow. In Germany it is estimated that 3.1 people per 100,000 develop IgAN each year.



Greater China, Singapore and South Korea

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 USD 15 million upon signing, and has received USD 13 million in additional milestones, and may receive future payments linked to regulatory and commercialization milestones up to an additional USD 93 million, plus royalties. In March 2022, this agreement was expanded to include South Korea, resulting in an upfront payment of USD 3 million to Calliditas as well as additional future payments and royalties related to future potential approvals and commercialization of Nefecon in South Korea. Everest Medicine's New Drug Application (NDA) for Nefecon was accepted by the Chinese regulatory authority National Medical Products Administration (NMPA) in November 2022, and in December the Center for Drug Evaluation (CDE) of the NMPA recommended Priority Review. A regulatory decision is expected in 2H 2023.

Japan

At the end of 2022, Calliditas entered into a partnership to commercialize Nefecon in Japan with Viatrix Pharmaceuticals Japan, a subsidiary of Viatrix Inc. (Nasdaq: VTRS). Viatrix is a global health-care company which, while headquartered in the United States, has a presence in over 165 countries and territories, and also operates approximately 40 manufacturing facilities. Calliditas received an initial upfront payment of USD 20 million upon signing and is entitled to up to an additional USD 80 million in pre-defined development and commercialization milestones. Viatrix will also pay mid-teens percentage royalties on net sales.

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 and is a selective NOX 1 and NOX 4 inhibitor. Calliditas is presently running 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 produce 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.

At appropriate concentrations, ROS have essential functions in cellular signaling processes, but disruption of the redox homeostasis has been implicated in multiple disease pathways. Setanaxib inhibits NOX1 and NOX4, enzymes which are implicated in inflammation and fibrosis pathways.

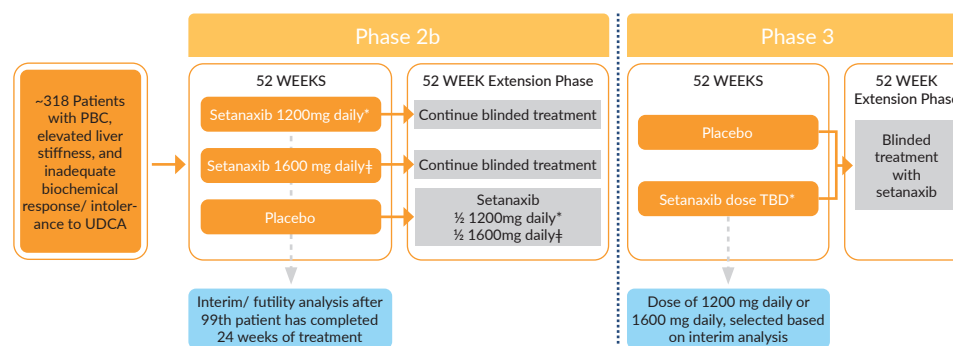
Setanaxib in Primary Biliary Cholangitis

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.

Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, known as Ocaliva, are the only FDA- and European Commission-approved treatments for PBC. 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.

Calliditas has initiated a 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 in 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 in up to 150 investigational centres. The primary endpoint is ALP reduction, with key secondary endpoints including change in liver stiffness and effect on fatigue and pruritus (itching). Following favorable safety data from a 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 the first half of 2024, subject to recruitment rate, and will determine which dose of setanaxib will be used for the Phase 3 part of the study. 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

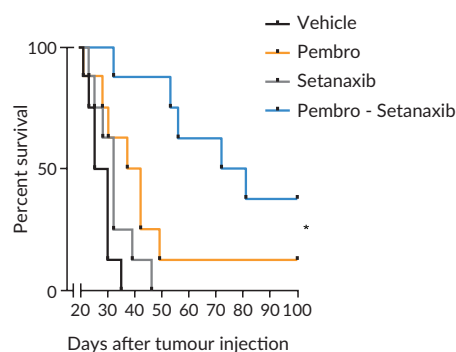
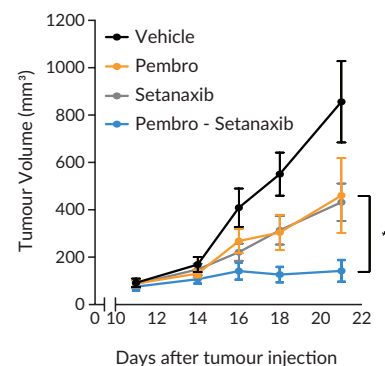
Setanaxib in Squamous Cell Carcinoma of the Head & Neck

Calliditas also intends to evaluate setanaxib in head and neck cancer, building on promising in vivo preclinical data that suggests that setanaxib could function as an adjunct therapy to immuno-oncology therapies. 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%).

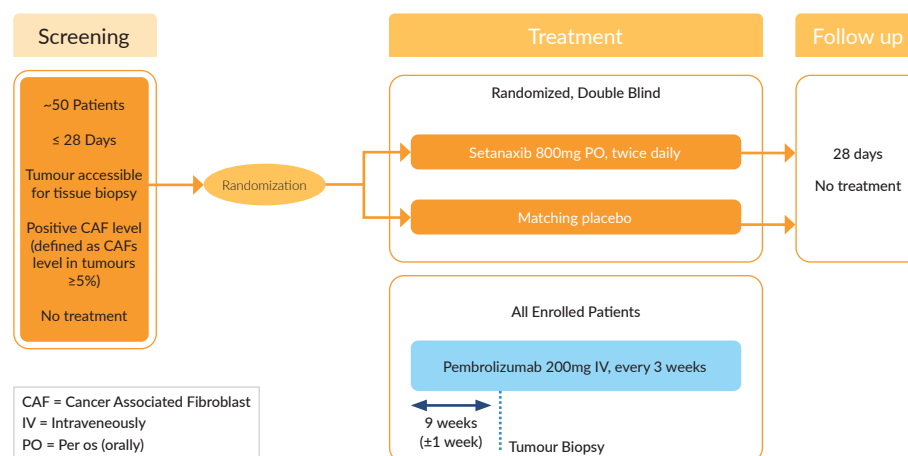
Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:

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



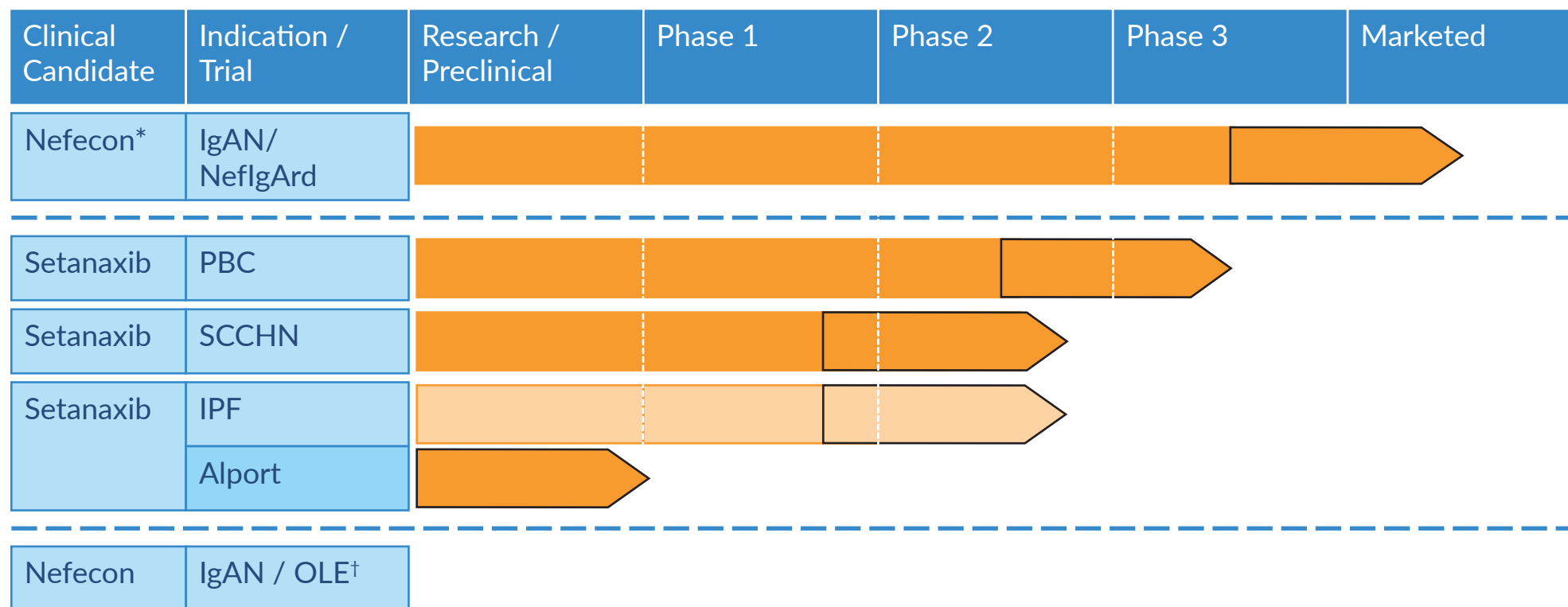
Proof-of-concept study in head and neck cancer

Calliditas is conducting 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 approximately 50 patients. The first patient was randomised in Q2 2022, with an interim biomarker readout expected in mid-2023.

Our Pipeline



Depicts ongoing/planned clinical trial stage:



Depicts Investigator Led Trial:



† Open Label Extension, 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. Approved under conditional marketing authorisation in the EEA and the UK under the tradename Kinpeygo.

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

Significant Events

Significant Events During the Period January 1 – December 31, 2022

- In January 2022, Calliditas announced the commercial availability and initial sales of TARPEYO (budesonide), the first FDA approved treatment for IgA nephropathy (IgAN), indicated for reduction of proteinuria in adults with primary 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). The TRANSFORM trial is a 52-week, randomized, placebo-controlled, double-blind, adaptive Phase 2b/3 trial that is investigating the effect of NOX 1 and 4 inhibitor setanaxib 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).
- In March 2022, Calliditas announced that the company had expanded its licensing agreement with Everest Medicines to extend the territory covered to include South Korea. The extension resulted 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 Medicines entered into a license agreement in 2019 to develop and commercialize Nefecon for IgAN in Greater China and Singapore.
- In May 2022, Calliditas announced that the first patient had been randomized in the Group'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.
- In May 2022, Calliditas announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the granting of a conditional marketing authorisation for Kinpeygo for the treatment of primary IgAN in adults at risk of rapid disease progression with a UPCR ≥ 1.5 g/gram.
- In May 2022, the Annual General Meeting (AGM) of Calliditas was held and, among other things, the AGM resolved on the election of Henrik Stenqvist and Elisabeth Björk to the Board of Directors and the establishment of a U.S. At-the-Market framework of up to a maximum of 5,908,019 shares, pursuant to which Calliditas may, at its option, sell American Depositary Shares ("ADSs") in the United States at market price, from time to time, in "at the market" transactions on The Nasdaq Global Select Market.
- In July 2022, Calliditas announced that the European Commission (EC) granted conditional marketing authorization for Kinpeygo for the treatment of IgAN in adults at risk of rapid disease progression with a UPCR ≥ 1.5 g/gram. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in Europe. Kinpeygo will be marketed in the European Economic Area (EEA), the UK and Switzerland exclusively by Calliditas' European commercial partner STADA Arzneimittel AG.
- In October 2022, Calliditas announced that Kidney International published the successful results from Part A of the NeflgArd pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter study, on the basis of which the accelerated approval by the FDA for TARPEYO and the conditional marketing authorization by the European Commission for Kinpeygo in the USA and Europe (EEA), respectively.
- In November 2022, Calliditas announced that its China partner Everest Medicine's New Drug Application for Nefecon was accepted by the Chinese regulatory authority National Medical Products Administration (NMPA).
- In December 2022, Calliditas announced that it had entered into an exclusive license agreement with Viatris Pharmaceuticals Japan Inc., a subsidiary of Viatris Inc, to register and commercialize Nefecon for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in Japan. Under the terms of the agreement, Calliditas received an initial upfront payment of USD 20 million upon signing and is entitled to up to an additional USD 80 million in pre-defined development and commercialization milestones. Viatris will also pay mid-teens percentage royalties on net sales.

Significant Events After the End of the Period

- In February 2023, Calliditas announced that the MHRA of the United Kingdom has granted Conditional Marketing Authorization (CMA) for Kinpeygo for the treatment of IgA nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/gram. Calliditas will transfer the CMA to its partner STADA Arzneimittel AG, who have the right to commercializing Kinpeygo in the European Economic Area (EEA), Switzerland and the UK.

Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Net sales	429,042	31,180	802,879	229,347
Research and development expenses	(102,239)	(100,291)	(414,749)	(357,485)
Research and development expenses/Total operating expenses in %	26%	40%	34%	47%
Operating profit/(loss)	32,495	(222,133)	(421,943)	(524,456)
Profit/(loss) before income tax for the period	10,066	(218,467)	(409,417)	(513,373)
Loss per share before/after dilution (SEK)	(0.07)	(4.19)	(7.78)	(9.84)
Cash flow from/(used in) operating activities	230,029	(161,254)	(311,354)	(461,588)

(SEK in thousands, except per share amount or as otherwise indicated)	December 31,	
	2022	2021
Total registered and subscribed but not registered shares, including shares held by Calliditas, at the end of the period	59,580,087	52,341,584
Equity attributable to equity holders of the Parent Company at the end of the period	766,264	1,008,281
Equity ratio at the end of the period in %	39%	69%
Cash at the end of the period	1,249,094	955,507

January – December 2022

Revenue

Net sales amounted to SEK 429.0 million and SEK 31.2 million for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, net sales amounted to SEK 802.9 million and SEK 229.3 million, respectively. Net sales for the three months and year ended December 31, 2022, primarily originates from net sales of TARPEYO in the U.S. and milestones from our partnerships in Europe, China and Japan. Net sales from TARPEYO amounted to SEK 167.3 million for the three months ended December 31, 2022, and SEK 372.2 million for the year ended December 31, 2022. Milestones and royalties from our partnerships amounted to SEK 260.2 million for the three months ended December 31, 2022, and SEK 427.4 million for the year ended December 31, 2022. For additional information see Note 4.

Cost of Sales

Cost of sales amounted to SEK 7.9 million for the three months ended December 31, 2022, and for the year ended December 31, 2022, cost of sales amounted to SEK 15.2 million. For the three months and year ended December 31, 2021, no cost of sales was recognized.

Total Operating Expenses

Total operating expenses amounted to SEK 388.7 million and SEK 253.3 million for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, total operating expenses amounted to SEK 1,209.6 million and SEK 753.8 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 102.2 million and SEK 100.3 million for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, research and development expenses amounted to SEK 414.7 million and SEK 357.5 million, respectively. The increase of SEK 1.9 million for the three months ended December 31, 2022, and SEK 57.2 million for the year ended December 31, 2022, was primarily due to clinical activities for the setanaxib platform, including the ongoing setanaxib trials, compared to the corresponding periods of the prior year.

Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 191.9 million and SEK 70.6 million for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, marketing and selling expenses amounted to SEK 515.2 million and SEK 179.6 million, respectively. The increase of SEK 121.3 million for the three months ended December 31, 2022, and SEK 335.6 million for the year ended December 31, 2022, was primarily related to the costs for sales and marketing of TARPEYO in the U.S., including the costs for the sales force compared to the corresponding periods of the prior year, where no sales force existed.

Administrative Expenses

Administrative expenses amounted to SEK 81.0 million and SEK 81.1 million for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, administrative expenses amounted to SEK 259.5 million and SEK 210.6 million, respectively. The increase of SEK 48.9 million for the year ended December 31, 2022, compared to the previous year, was primarily related to general cost increases due to a larger organization and increased regulatory requirements compared to the corresponding periods of the prior year.

Other Operating Incomes/Expenses, net

Other operating income/(expenses), net amounted to (SEK 13.5 million) and (SEK 1.3 million) for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, other operating income/(expenses), net amounted to (SEK 20.2 million) and (SEK 6.1 million), respectively. The increase in other operating income/(expenses), net for the three months and year ended December 31, 2022, was primarily related to a more unfavorable exchange rate development on operating liabilities compared to the corresponding period of the prior year.

Net Financial Income and Expenses

Net financial income/(expenses) amounted to (SEK 22.4 million) and SEK 3.7 million for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, net financial income/(expenses) amounted to SEK 12.5 million and SEK 11.1 million, respectively. The decrease of SEK 26.1 million for the three months ended December 31, 2022, was primarily derived from interest expenses from the Kreos loan and currency effect related to external and internal loans compared to the corresponding period of the prior year. The increase of SEK 1.4 million for the year ended December 31, 2022, was primarily derived from currency effect related to intercompany loan and unrealized foreign currency transaction gains on cash accounts compared to the prior year.

FINANCIAL OVERVIEW

Tax

Total income tax/(expense) amounted to (SEK 13.7 million) and (SEK 0.2 million) for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, income tax/(expense) amounted to (SEK 2.9 million) and SEK 3.8 million, respectively. The increase for the three months and year ended December 31, 2022 were primarily explained by recognized taxable profit for the U.S. subsidiaries. The Group's tax losses carried-forward have not been recognized as deferred tax assets, other than to the extent such tax losses can be used to offset temporary differences.

Result for the Period

For the three months ended December 31, 2022 and 2021, loss for the period amounted to SEK 3.7 million and SEK 218.7 million, and the corresponding loss per share before and after dilution amounted to SEK 0.07 and SEK 4.19, respectively. For the year ended December 31, 2022 and 2021, loss for the period amounted to SEK 412.3 million and SEK 509.5 million, and the corresponding loss per share before and after dilution amounted to SEK 7.78 and SEK 9.84, respectively.

Cash Flow and Cash Position

Cash flow from/(used in) operating activities amounted to SEK 230.0 million and (SEK 161.3 million) for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, cash flow used in operating activities amounted to SEK 311.4 million and SEK 461.6 million, respectively. The increase in cash flow from operating activities for the three months and the year ended December 31, 2022, were primarily explained by the increase in sales for TARPEYO in the U.S. and the outlicensing milestone revenue from Viatrix, compared to the corresponding periods of the prior year.

Cash flow used in investing activities amounted to SEK 1.5 million and SEK 5.3 million for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, cash flow used in investing activities amounted to SEK 5.1 million and SEK 24.3 million, respectively. The decrease in cash flow used in investing activities for the year ended December 31, 2022, was mainly derived from a EUR 1.5 million milestone payment for the Budenofalk license, which occurred in the corresponding period of the prior year.

Cash flow from/(used in) financing activities amounted to SEK 282.6 million and (SEK 41.3 million) for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, cash flow from financing activities amounted to SEK 576.0 million and SEK 435.2 million, respectively. The increase in cash flow from financing activities for the three months and year ended December 31, 2022, compared to the corresponding periods of the prior year, was primarily due to the USD 25 million each draw down of tranche 2 and 3 of the Kreos loan facility in June and December 2022, respectively.

Net increase/(decrease) in cash amounted to SEK 511.2 million and (SEK 207.9 million) for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, net increase/(decrease) in cash amounted to SEK 259.5 million and (SEK 50.8 million), respectively. Cash amounted to SEK 1,249.1 million and SEK 955.5 million as of December 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 766.3 million and SEK 1,008.3 million as of December 31, 2022 and 2021, respectively. The number of registered and subscribed but not registered shares amounted to 59,580,087 and 52,341,584 as of December 31, 2022 and 2021, respectively. The increase in number of shares between the periods was derived from a new share issue in April and May 2022 of 856,586 shares related to the Warrant Program 2018/2022, a new share issue in December 2022 of 422,500 shares related to the Warrant Program 2019/2022, a new share issue of 51,399 shares related to the Board LTIP 2019 program and a new issue of 5,908,018 shares held as treasury shares for future potential delivery of shares under the company's at-the-market program.

Issuance and Repurchase of Treasury Shares

For the year ended December 31, 2022, Calliditas resolved to carry out an issue of 5,908,018 C-shares at a subscription price of SEK 0.04 per share and to subsequently immediately repurchased the 5,908,018 newly issued C-shares for SEK 0.04 per share and subsequently was converted into ordinary shares in accordance with the company's articles of association and held as treasury shares. The purpose of the issue and repurchase is to secure future potential delivery of shares under the company's at-the-market program. The share issue has increased the share capital by SEK 0.2 million. See Note 10 for additional information.

Changes in Contingent Consideration

Contingent consideration amounted to SEK 75.9 million and SEK 54.4 million as of December 31, 2022 and 2021, respectively. The increase of SEK 21.5 million was primarily derived from the assumptions regarding the probability of success in the clinical trials and related currency effect.

Personnel

The number of employees were 102 and 66 employees as of December 31, 2022 and 2021, respectively. The total number of full-time equivalent (FTE), including consultants, were 178 and 86 as of December 31, 2022 and 2021, respectively. The average number of employees were 100 and 66 employees for the three months ended December 31, 2022 and 2021, respectively and 86 and 56 employees for the year ended December 31, 2022 and 2021, respectively.

FINANCIAL OVERVIEW

Incentive Programs

For the three months ended December 31, 2022, there have been no allocation of options. For more information on incentive programs, see Note 11.

2023 Outlook

In 2022, the first year of commercialization of TARPEYO in the U.S. net sales were USD 36.8 million. For 2023, Calliditas expects accelerated revenue growth in the U.S. where:

Net sales from TARPEYO are estimated to be USD 120-150 million for the year ending December 31, 2023, (corresponding to approx. SEK 1,214-1,518 million, using a SEK/USD average exchange rate of 10.12).

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 297.1 million and SEK 31.2 million for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, net sales amounted to SEK 549.0 million and SEK 229.3 million, respectively. The increase for the three months and year ended December 31, 2022 was primarily derived from an outlicensing transaction to Viatris and sales of TARPEYO compared to the corresponding periods of the prior year. Operating profit/(loss) amounted to SEK 86.7 million and (SEK 154.0 million) for the three months ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022 and 2021, operating loss amounted to SEK 215.4 million and SEK 355.7 million, respectively. The improvement of the operating profit/(loss) for both periods was primarily derived from the increase in revenues compared to the corresponding periods of the prior year. Non-current financial assets amounted to SEK 887.5 million and SEK 552.9 million as of December 31, 2022 and 2021, respectively. The increase of SEK 334.6 million was primarily derived from intercompany transactions.

Auditor's review

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

Stockholm, February 23, 2023

Renée Aguiar-Lucander
CEO

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended December 31,		Year Ended December 31,	
		2022	2021	2022	2021
Net sales	4	429,042	31,180	802,879	229,347
Cost of sales		(7,879)	-	(15,201)	-
Gross profit		421,163	31,180	787,678	229,347
Research and development expenses		(102,239)	(100,291)	(414,749)	(357,485)
Marketing and selling expenses	13	(191,887)	(70,638)	(515,190)	(179,603)
Administrative expenses	13	(81,028)	(81,072)	(259,469)	(210,630)
Other operating income		696	965	2,862	259
Other operating expenses		(14,210)	(2,277)	(23,074)	(6,344)
Operating profit/(loss)		32,495	(222,133)	(421,943)	(524,456)
Net financial income/(expenses)		(22,428)	3,666	12,526	11,083
Profit/(loss) before income tax		10,066	(218,467)	(409,417)	(513,373)
Income tax		(13,747)	(199)	(2,851)	3,836
Loss for the period		(3,681)	(218,666)	(412,268)	(509,537)
Attributable to:					
Equity holders of the Parent Company		(3,681)	(219,170)	(412,268)	(500,293)
Non-controlling interests		-	503	-	(9,244)
		(3,681)	(218,666)	(412,268)	(509,537)
Loss per share before/after dilution (SEK)		(0.07)	(4.19)	(7.78)	(9.84)

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Loss for the period	(3,681)	(218,666)	(412,268)	(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	1,661	(25,030)	36,287	(20,111)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods	1,661	(25,030)	36,287	(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	387	232	2,763	1,993
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods	387	232	2,763	1,993
Other comprehensive income/(loss) for the period	2,047	(24,798)	39,050	(18,118)
Total comprehensive income/(loss) for the period	(1,634)	(243,464)	(373,218)	(527,655)
Attributable to:				
Equity holders of the Parent Company	(1,634)	(243,971)	(373,218)	(519,190)
Non-controlling interests	-	507	-	(8,466)
	(1,634)	(243,464)	(373,218)	(527,655)

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	December 31,	
		2022	2021
ASSETS			
Non-current assets			
Intangible assets	6,13	483,841	399,418
Equipment		7,468	6,309
Right-of-use assets		24,452	33,300
Non-current financial assets		11,210	3,915
Deferred tax assets		13,799	4,196
Total non-current assets		540,770	447,138
Current assets			
Inventories		3,647	889
Accounts receivable		78,703	-
Other current receivables		10,018	11,343
Prepaid expenses and accrued income		70,741	45,032
Cash		1,249,094	955,507
Total current assets		1,412,204	1,012,772
TOTAL ASSETS		1,952,973	1,459,910
EQUITY AND LIABILITIES			
Equity			
Share capital		2,383	2,094
Additional paid-in-capital		2,590,890	2,459,741
Retained earnings, including net loss for the period		(1,827,010)	(1,453,554)
Equity attributable to equity holders of the Parent Company		766,264	1,008,281
Non-controlling interests		-	-
Total equity	9,10,11	766,264	1,008,281
Non-current liabilities			
Provisions	11	12,675	17,712
Contingent consideration		75,880	54,399
Deferred tax liabilities	7,13	39,752	30,856
Non-current interest-bearing liabilities	12	713,030	189,164
Lease liabilities		15,792	24,052
Other non-current liabilities		4,350	-
Total non-current liabilities		861,479	316,183
Current liabilities			
Accounts payable		160,404	67,971
Other current liabilities		28,381	13,922
Accrued expenses and deferred revenue		136,446	53,553
Total current liabilities		325,231	135,446
TOTAL EQUITY AND LIABILITIES		1,952,973	1,459,910

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Year Ended December 31,	
	2022	2021
Opening balance equity attributable to equity holders of the Parent Company	1,008,281	1,210,491
Loss for the period	(412,268)	(500,293)
Other comprehensive income/(loss)	39,050	(18,897)
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	(373,218)	(519,190)
Transactions with owners:		
New share issue	-	324,000
Costs attributable to new share issue	-	(20,909)
Issuance of treasury shares	236	-
Repurchase of treasury shares	(236)	-
Exercise of warrants	95,121	-
Share-based payments	36,080	23,567
Purchase of non-controlling interests	-	(9,678)
Total transactions with owners	131,201	316,980
Closing balance equity attributable to equity holders of the Parent Company	766,264	1,008,281
Opening balance equity attributable to non-controlling interests	-	45,809
Total comprehensive loss for the period	-	(8,466)
Contribution from non-controlling interests	-	2,282
Purchase of non-controlling interests	-	(39,625)
Closing balance equity attributable to non-controlling interests	-	-
Closing balance equity	766,264	1,008,281

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating activities				
Operating profit/(loss)	32,495	(222,133)	(421,943)	(524,456)
Adjustment for non-cash-items	30,916	42,540	61,260	66,676
Interest received	3,551	102	3,553	102
Interest paid	(11,576)	(4,896)	(35,252)	(5,432)
Income taxes paid	(2,675)	(2,479)	(7,392)	(3,949)
Cash flow from/(used in) operating activities before changes in working capital	52,712	(186,865)	(399,774)	(467,058)
Cash flow from/(used in) changes in working capital	177,318	25,611	88,420	5,470
Cash flow from/(used in) operating activities	230,029	(161,254)	(311,354)	(461,588)
Cash flow used in investing activities	(1,466)	(5,337)	(5,144)	(24,340)
Cash flow used in investing activities	(1,466)	(5,337)	(5,144)	(24,340)
New share issue	-	-	-	324,000
Costs attributable to new share issue	-	-	-	(20,909)
Issuance of treasury shares	-	-	236	-
Repurchase of treasury shares	-	-	(236)	-
Exercise of warrants	31,476	-	95,121	-
Purchase of non-controlling interests	-	(39,020)	-	(49,303)
Contribution from non-controlling interests	-	-	-	2,282
New borrowings	255,282	-	491,745	199,524
Costs attributable to new loans	(1,260)	-	(1,260)	(14,857)
Repayment of lease liabilities	(2,861)	(2,269)	(9,615)	(5,575)
Cash flow from/(used in) financing activities	282,638	(41,289)	575,990	435,162
Net increase/(decrease) in cash	511,201	(207,880)	259,493	(50,766)
Cash at the beginning of the period	736,161	1,163,818	955,507	996,304
Net foreign exchange gains/(loss) on cash	1,732	(431)	34,094	9,969
Cash at the end of the period	1,249,094	955,507	1,249,094	955,507

FINANCIAL STATEMENTS

Condensed Parent Company Statements of Income

(SEK in thousands)	Notes	Three Months Ended December 31,		Year Ended December 31,	
		2022	2021	2022	2021
Net sales	4	297,144	31,180	548,977	229,347
Cost of sales		(7,820)	-	(15,141)	-
Gross profit		289,324	31,180	533,836	229,347
Research and development expenses		(97,724)	(65,319)	(384,453)	(275,950)
Marketing and selling expenses		(113,499)	(59,015)	(310,372)	(151,125)
Administrative expenses		(61,252)	(92,322)	(212,971)	(226,349)
Other operating income		72,236	31,524	165,698	70,234
Other operating expenses		(2,388)	-	(7,101)	(1,874)
Operating profit/(loss)		86,696	(153,951)	(215,364)	(355,718)
Net financial income/(expenses)		(6,525)	(7,128)	6,816	1,312
Profit/(loss) before income tax		80,172	(161,080)	(208,548)	(354,405)
Income tax		-	-	-	-
Profit/(loss) for the period		80,172	(161,080)	(208,548)	(354,405)

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Profit/(loss) for the period	80,172	(161,080)	(208,548)	(354,405)
Other comprehensive income/(loss)	-	-	-	-
Total comprehensive income/(loss)	80,172	(161,080)	(208,548)	(354,405)

FINANCIAL STATEMENTS

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	December 31,	
		2022	2021
ASSETS			
Non-current assets			
Intangible assets	6	32,132	32,132
Equipment		567	514
Non-current financial assets		887,456	552,924
Total non-current assets		920,154	585,570
Current assets			
Inventories		3,647	889
Accounts receivable		6,877	-
Other current receivables		122,213	5,699
Prepaid expenses and accrued income		61,092	41,825
Cash		1,059,655	894,455
Total current assets		1,253,485	942,868
TOTAL ASSETS		2,173,639	1,528,439
SHAREHOLDERS' EQUITY AND LIABILITIES			
<i>Restricted Shareholders' equity</i>			
Share capital		2,383	2,094
Statutory reserve		3,092	3,092
Total restricted Shareholders' equity		5,475	5,186
<i>Non-restricted shareholders' equity</i>			
Share premium reserve		2,521,419	2,420,698
Retained earnings		(1,187,391)	(863,175)
Net loss for the period		(208,548)	(354,405)
Total non-restricted shareholders' equity		1,125,480	1,203,117
Total shareholders' equity	9,11	1,130,956	1,208,303
Non-current liabilities			
Provisions	11	9,512	9,075
Non-current interest-bearing liabilities	12	713,030	189,164
Other non-current liabilities		4,455	105
Total non-current liabilities		726,997	198,344
Current liabilities			
Accounts payable		100,469	51,711
Other current liabilities		141,750	33,466
Accrued expenses and deferred revenue		73,468	36,615
Total current liabilities		315,686	121,792
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		2,173,639	1,528,439

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") 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 year ended December 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 February 23, 2023.

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 pages 28-29.

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 risks, such as a failure to demonstrate efficacy or a favorable risk/benefit profile, 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 commercialized product, which has been approved under accelerated approval in the U.S. under the brand name TARPEYO and has received conditional marketing authorization in the EU and the UK under the brand name Kinpeygo. 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. Today this varies in different geographies, and future developments cannot be predicted with reasonable assurance.

The pandemic may negatively impact our trials 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 trials. 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 holds accounts receivables in USD and cash in USD and EUR to meet future expected costs in USD and EUR in connection with commercialization of TARPEYO in the U.S. 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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Type of goods or services				
Product sales	168,881	-	375,515	-
Outlicensing of product	257,873	27,085	421,689	225,252
Royalty income	2,287	-	2,287	-
Performance of certain regulatory services	-	4,095	3,387	4,095
Total	429,042	31,180	802,879	229,347
Geographical markets				
USA	167,258	-	372,247	-
Europe	3,911	4,095	143,955	201,878
Asia	257,874	27,085	286,677	27,469
Total	429,042	31,180	802,879	229,347

The Group's revenues for the three months and year ended December 31, 2022, primarily originates from net sales of TARPEYO in the U.S. and milestones from our partnerships in Europe, China and Japan. Net sales from TARPEYO amounted to SEK 167.3 million for the three months ended December 31, 2022, and SEK 372.2 million for the year ended December 31, 2022. Milestones and royalties from our partnerships amounted to SEK 260.2 million for the three months ended December 31, 2022, and SEK 427.4 million for the year ended December 31, 2022.

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 pharmacy 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 accounted for 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. As of December 31, 2022, the total liability for expected returns and rebates amounts to SEK 24.3 million. In addition, there are no other performance obligations.

Revenue attributable to outlicensing Nefecon consisted of the agreement with STADA for Europe, the expansion of Everest Medicines to South Korea and the agreement with Viartis for Japan. Revenue for outlicensing 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 the parties were 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.

Note 5 - Related-Party Transactions

During the reporting period, no significant related-party transactions have occurred. For information about incentive programs please see Note 11.

Note 6 - Intangible Assets

(SEK in thousands)	December 31,	
	2022	2021
Cost at opening balance	427,393	418,825
Acquisition license	-	16,066
Exchange difference on translation	84,423	(7,498)
Cost at closing balance	511,816	427,393
Accumulated impairment at closing balance	(27,975)	(27,975)
Net book value	483,841	399,418

Intangible assets consist of licenses and similar rights of SEK 438.0 million and goodwill of SEK 45.8 million as of December 31, 2022. 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.

Note 7 - Deferred Tax Liabilities

(SEK in thousands)	December 31,	
	2022	2021
Cost at opening balance	30,857	37,454
Tax loss carried forward	-	(5,065)
Exchange difference on translation	8,896	(1,532)
Cost at closing balance	39,753	30,856

Tax loss carried forward of SEK 17.0 million have been offset against deferred tax liabilities in the statement of financial position as of December 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, other non-current liabilities, lease liabilities, accounts payable and other current liabilities, all of which except contingent consideration, are recognized at amortized cost. The carrying amount is an approximation of the fair value. Contingent consideration are recognized at fair value, measured at Level 3 of the IFRS value hierarchy.

Note 9 - Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	December 31,	
	2022	2021
Total registered shares at the beginning of the period	52,341,584	49,941,584
New issue of shares during the period	7,231,003	2,400,000
Shares subscribed but not registered during the period	7,500	-
Total registered and subscribed but not registered shares at the end of the period	59,580,087	52,341,584
Shares		
Ordinary shares	59,580,087	52,341,584
Total	59,580,087	52,341,584
- of which shares are held by Calliditas	5,908,018	-
Total registered and subscribed but not registered shares at the end of the period, net of shares held by Calliditas	53,672,069	52,341,584
Share capital at the end of the period	2,383	2,094
Equity attributable to equity holders of the Parent Company	766,264	1,008,281
Non-controlling interests	-	-
Equity at the end of the period	766,264	1,008,281

(SEK in thousands, except per share amounts and number of shares)	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Loss per share before/after dilution, SEK	(0.07)	(4.19)	(7.78)	(9.84)
Weighted-average number of ordinary shares outstanding for the period, before/after dilution	53,259,179	52,341,584	53,022,550	50,829,255

Reserves for translation from foreign operations amounted to SEK 9.3 million and (SEK 27.0 million) which are included in retained earnings in equity as of December 31, 2022 and 2021, respectively.

As of December 31, 2022, there was an on-going issue of 7,500 shares under registration related to the exercise under the Warrant Program 2019/2022. These shares have been included in the weighted-average number of shares outstanding for the period.

Note 10 - Transactions in Treasury Shares

Since 2020, Calliditas has had ordinary shares, in the form of American Depositary Shares ("ADSs"), listed in the United States on The Nasdaq Global Select Market. Calliditas has now implemented and launched an At-The-Market program ("ATM Program"). The purpose of the ATM Program is to efficiently and cost-effectively raise capital, if necessary, in the U.S. market and to ensure delivery of shares to be sold under the company's ATM Program.

For the year ended December 31, 2022, 5,908,018 series C shares were issued, which were repurchased and converted to ordinary shares by Calliditas. These transactions are in accordance with the granting mandate. For the year ended December 31, 2022, no shares were sold in the ATM Program. The total number of issued shares as of December 31, 2022, is presented in Note 9.

Note 11 - Incentive Programs

	Options Outstanding	Share Awards Outstanding	Total Outstanding as of December 31, 2022
Incentive Programs			
Board LTIP 2020	-	29,928	29,928
Board LTIP 2021	-	24,244	24,244
Board LTIP 2022	-	40,706	40,706
ESOP 2020	1,371,666	-	1,371,666
ESOP 2021	1,479,500	-	1,479,500
ESOP 2022	1,101,000	-	1,101,000
Total Outstanding as of December 31, 2022	3,952,166	94,878	4,047,044

	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

Board LTIP 2020:

This is a performance-based long-term incentive program for Calliditas Board members. A total of 29,928 share awards have been granted under the program. 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 24,244 share awards have been granted under the program. 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.

Board LTIP 2022:

This is a performance-based long-term incentive program for Calliditas Board members. A total of 40,706 share awards have been granted under the program. The share awards are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2022 Annual General Meeting to July 1, 2025.

ESOP Programs

Calliditas implements option programs for employees and key consultants in Calliditas. The options are 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 each issue, been valued according to the Black & Scholes valuation model.

Note 12 - Non-current interest-bearing liabilities

(SEK in thousands)	December 31,	
	2022	2021
Opening balance	189,164	-
New borrowings	491,745	199,524
Transaction costs	(1,260)	(14,858)
Interest expense	4,874	2,145
Exchange difference on translation	28,507	2,353
Closing balance	713,030	189,164

In July 2021, Calliditas signed a loan agreement of up to the euro equivalent of USD 75 million with Kreos Capital. The loan facility is divided into three tranches of USD 25 million each. Draw down of the first USD 25 million tranche was made in 2021. Draw down of the second tranche of USD 25 million was made in June 2022 and draw down of the third and final USD 25 million tranche was made December 2022. The interest rate on the loan is 9% per annum with a maturity to December 2025, which is recognized in Net financial income/(expenses). The loan has no financial covenants.

Note 13 - 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.

(SEK in thousands)	Year Ended December 31,		
	2021	Re-classification	2021
Net sales	229,347	-	229,347
<i>Operating expenses</i>			
Research and development expenses	(357,485)	-	(357,485)
Marketing and selling expenses	-	(179,603)	(179,603)
Administrative expenses	(390,232)	179,603	(210,629)
Other operating income/expenses	(6,085)	-	(6,085)
Operating loss	(524,456)	-	(524,456)
Net financial income/(expenses)	11,083	-	11,083
Loss before income tax	(513,373)	-	(513,373)
Income tax	3,836	-	3,836
Loss for the period	(509,537)	-	(509,537)

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 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 December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Research and development expenses/Total operating expenses in %				
Research and development expenses	(102,239)	(100,291)	(414,749)	(357,485)
Marketing and selling expenses	(191,887)	(70,638)	(515,190)	(179,603)
Administrative expenses	(81,028)	(81,072)	(259,469)	(210,630)
Other operating income/(expenses), net	(13,514)	(1,312)	(20,212)	(6,085)
Total operating expenses	(388,668)	(253,313)	(1,209,621)	(753,803)
Research and development expenses/Total operating expenses in %	26%	40%	34%	47%

(SEK in thousands or otherwise indicated)	December 31,	
	2022	2021
Equity ratio at the end of the period in %		
Total shareholders' equity at the end of the period	766,264	1,008,281
Total assets at the end of the period	1,952,973	1,459,910
Equity ratio at the end of the period in %	39%	69%

Financial Calendar

Annual Report 2022	April 26, 2023
Interim Report for the period January 1- March 31, 2023	May 16, 2023
Annual General Meeting 2023	May 17, 2023
Interim Report for the period January 1- June 30, 2023	August 17, 2023
Interim Report for the period January 1- September 30, 2023	November 16, 2023

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 Year-End 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, revenue and other financial projections, 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 Year-End 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 Year-End Report, including, without limitation, any related to Calliditas' business, operations, commercialization of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines for development and potential approvals, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts, 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 Year-End 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 Year-End 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.

