

Q2 2022

INTERIM REPORT JANUARY 1ST – JUNE 30TH 2022

European approval for Kinpeygo®

Financial Summary For the Group

Key Figures

April 1 - June 30, 2022

- » Net sales amounted to SEK 64.0 million, whereof TARPEYO® net sales amounted to SEK 63.6 million, for the three months ended June 30, 2022. No net sales were recognized for the three months ended June 30, 2021.
- » Operating loss amounted to SEK 209.8 million and SEK 159.4 million for the three months ended June 30, 2022 and 2021, respectively.
- » Loss per share before and after dilution amounted to SEK 3.62 and SEK 3.22 for the three months ended June 30, 2022 and 2021, respectively.
- » Cash amounted to SEK 846.8 million and SEK 709.3 million as of June 30, 2022 and 2021, respectively.

January 1 - June 30, 2022

- » Net sales amounted to SEK 113.8 million, whereof TARPEYO® net sales amounted to SEK 81.6 million, for the six months ended June 30, 2022. No net sales were recognized for the six months ended June 30, 2021.
- » Operating loss amounted to SEK 418.2 million and SEK 310.2 million for the six months ended June 30, 2022 and 2021, respectively.
- » Loss per share before and after dilution amounted to SEK 7.57 and SEK 5.84 for the six months ended June 30, 2022 and 2021, respectively.

Investor Presentation August 18, 2022 14:30 CET

Audio cast with teleconference, Q2 2022

Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q2-2022>

Teleconference: SE: +46856642692 UK: +443333009260 US: +16467224904

Significant Events in Q2 2022, in Summary

In May 2022, Calliditas announced that the first patient has 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 IgA nephropathy.

In May 2022, the Annual General Meeting of Calliditas was held and, among other things, the meeting decided 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, pursuant to which Calliditas may, at its option, sell American Depositary Shares ("ADSs") in the United States.

Significant Events After the Reporting Period

In July 2022, Calliditas announced that the European Commission (EC) granted conditional marketing authorization 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. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in the European Economic Area (EEA). Kinpeygo will be marketed in the EEA exclusively by STADA Arzneimittel AG.

European approval for Kinpeygo®



On May 19th, the European Medicines Agency (EMA) announced that it had adopted a positive opinion regarding the application for conditional approval of Kinpeygo® for the treatment of IgA nephropathy, and on July 15th the European Commission issued the market authorization for Kinpeygo in Europe.

This is the first time that any drug has achieved approval for this rare disease in Europe and we are delighted that we can contribute a piece of the puzzle in the broader effort to

improve care for patients with orphan diseases. We have now initiated the transfer of our market authorization to our partner, STADA, and look forward to seeing Kinpeygo being launched in Europe. Having now received approval in both the US and Europe we are looking forward to the regulatory process in China, where our partner, Everest Medicines, plans to file for approval with the NMPA in the second half of this year.

In the US we continue to have significant success in our early commercial efforts. Net revenues from TARPEYO® grew by well over 250% when compared to Q1, resulting in net revenues of SEK 64 million (\$6.6m) from TARPEYO for Q2. This reflects the continued strong interest from nephrologists, with unique prescribers growing from 111 in Q1 to 314 prescribers during Q2 with enrolments growing significantly from 134 in Q1 to 315 in Q2. This is a testament both to the unmet medical need perceived by nephrologists for this patient group as well as significant interest from prescribers generated due to the strong proteinuria and eGFR data associated with our product.

The US operation continues to grow as we add complementary resources in key areas. The multidisciplinary team continues to reach out to physicians across multiple channels in support of our commercial activities and positive momentum continues to build in the market. We believe the combination of the significant proteinuria reduction vs ACE / ARB therapy at 9 months (-31%) and the continued significant decline in proteinuria observed 3 months after withdrawal of the treatment (-52%) that we observed in the Phase 3 trial reflect the differentiated mechanism of action of TARPEYO. Its design, which specifically targets the origin of the disease, continues to drive strong interest from both patients and nephrologists, who seem especially impressed by the impact on eGFR during the 9 months of treatment. In order to fully support this growing interest, we

decided post this period's end to expand our US sales force to encompass a total of 60 sales executives, with recruitment of an additional 20 sales executives expected in Q3 and who will become fully operational in Q4. We are truly excited about this development which further builds on TARPEYO's initial commercial success and our commitment to ensure that TARPEYO continues to be readily available for appropriate patients with IgA nephropathy.

The second quarter also saw the dosing of the first patient in our Phase 2 study in head and neck cancer, studying the efficacy and safety of the lead candidate from our proprietary NOX platform, setanaxib. There is significant interest in cancer associated fibroblasts (CAFs) from a variety of industry participants and we look forward to hopefully sharing biomarker data with you before the end of the year.

In Q2 we also revisited the existing credit line with Kreos regarding the final \$25 million tranche under the \$75 million non-dilutive loan facility we put in place mid 2021. As a result, we do not have any specific operational requirements and are thus able to draw down the last tranche at any time before the end of December, 2022. In addition, we expect to receive €12.5m (approximately SEK 130 million) in milestone payments related to the approval and commercial launch of Kinpeygo in Europe from STADA during the second half of 2022.

We are thrilled to be another step closer to bringing the first approved medication in IgAN to patients around the world and look forward to continuing to expand access for patients with an unmet medical need for the rest of the year and beyond.

Renée Aguiar-Lucander, CEO

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 the first 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.

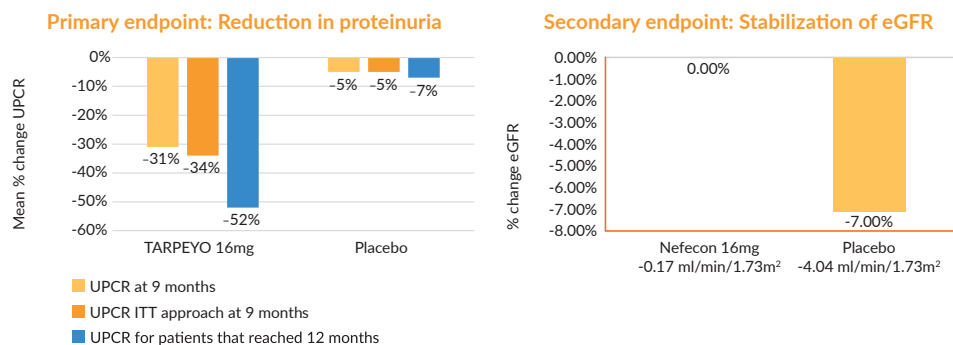
The galactose-deficient spot at the hinge region of the IgA antibodies is immunogenic when found in the circulation. It therefore generates an autoimmune response, attracting autoantibodies in the form of IgG or IgA and form pathogenic immune complexes that deposit in the glomeruli, the kidney's filtration 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.

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. 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 NefIgArd 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.



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 and only 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.



TARPEYO™
(budesonide) delayed release capsules • 4 mg

Approval in Europe

In July 2022, the product was granted conditional marketing authorization by the European Commission under the brand name 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. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in the European Economic Area (EEA).

Kinpeygo will be marketed in the EEA exclusively by STADA Arzneimittel AG with whom Calliditas entered into a license agreement in July 2021. The deal with STADA to register and commercialize Kinpeygo in the European Economic Area (EEA) member states, Switzerland and the UK was valued at a total of EUR 97.5 million, plus royalties. Under the terms of the agreement, Calliditas received an initial upfront payment of EUR 20 million upon signing and is entitled to up to an additional EUR 77.5 million in future payments linked to pre-de-fined 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.

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, as well as future payments linked to development, regulatory and commercialization milestones up to an additional USD 106 million, plus royalties. In March 2022, this agreement was expanded to include South Korea. Everest Medicines will look to file with regulators in China in 2H 2022, with a view to target potential approval in 2023.

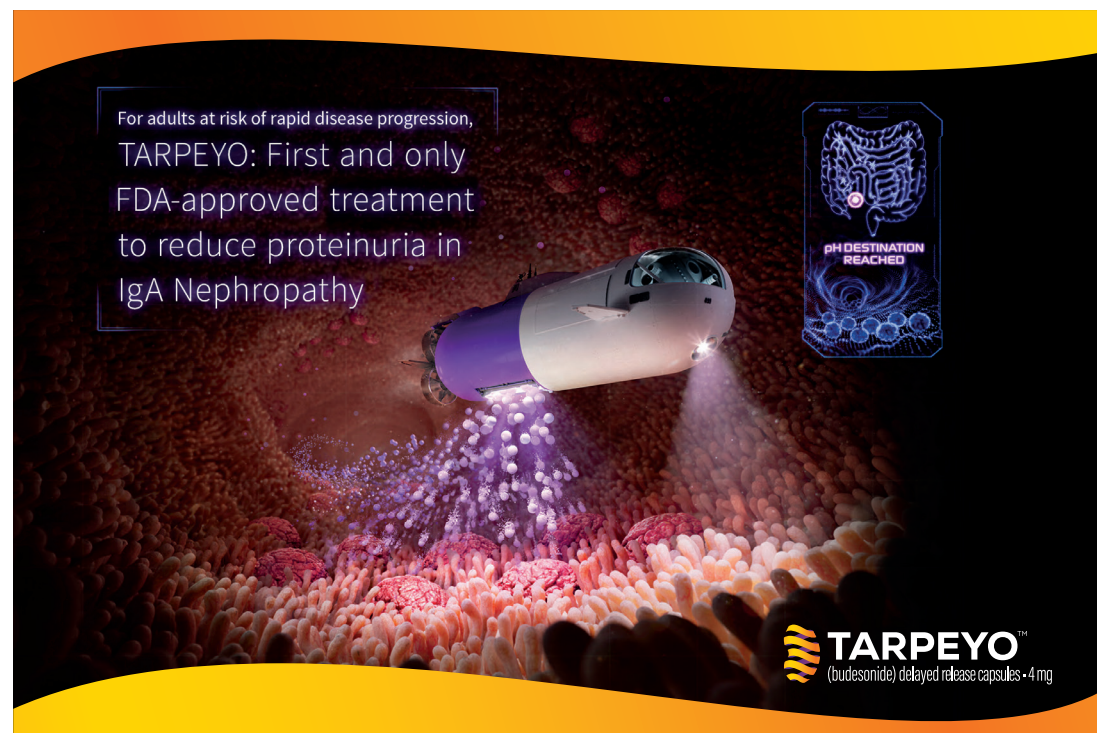
Building on a Successful Commercial Launch

In our second and first full quarter of sales of TARPEYO®, the commercial team has continued to build on the foundation established in Q1 subsequent to TARPEYO's approval. The enthusiasm for TARPEYO from physicians and patients has been encouraging, we are pleased with the progress that has been made to date, and we remain confident in our ability to continue our growth, this year and beyond.

Since TARPEYO's launch in late January, there have been a total of 450 patient enrollments, with 235% more enrollments in Q2 compared to Q1. All patients are guided through the enrollment and procurement process with the support of our patient services program, TARPEYO Touchpoints™, which has been assisting physicians and patients via a designated Rare Pod Team – including nurses, pharmacists, and a fulfillment and distribution team.

The Calliditas market access team continues to engage with payers and focus on the key targeted payers that cover most American lives. While the review process for coverage and formulary placement is on-going it typically takes six to nine months. When we look at coverage, as reported by Breakaway Partners, a Komodo Health Company, well over 80% of US lives are covered for TARPEYO.

Following the required FDA review related to accelerated approved medications, we launched our branded campaign during Q2. The multimedia campaign focuses on the unique mechanism of action of TARPEYO and the efficacy and safety results achieved in the clinic. Supported by our medical affairs education and marketing campaign, the adoption of TARPEYO by physicians has been quick and after only 5 months of promotion awareness of our drug is high, with unaided awareness at 70% and aided awareness at 80%. A total of 314 prescribers to date have prescribed TARPEYO for their patients, reflecting a broad interest in the drug.



Our medical affairs team has been active at the big symposia and congresses, such as the National Kidney Foundation's yearly Spring Clinical Meetings educational event. We also continue to work with patient advocacy groups and were thrilled to continue to lend our support to the IgA Nephropathy Foundation as it worked towards hosting its yearly symposium, SPARK 2022, in July.

Our specialty sales team has continued to build on the strong results in Q1, recording net sales for the second quarter of USD 6.6 million (SEK 64 million), more than tripling net sales compared to Q1. We are now, in light of the broad and strong demand, planning to expand our sales force with the aim of further bolstering our reach and frequency of contact, empowering our sales team to support the demand from the physician audience and increase the individual frequency of meetings and of face-to-face interactions.

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 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.

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.

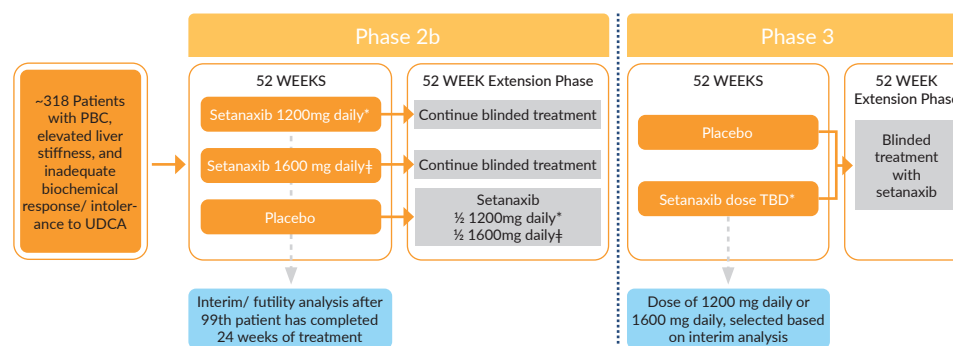
Setanaxib in Primary Biliary Cholangitis

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 EMA-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 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 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 Q2 or Q3 2023, and will determine which dose of setanaxib will be used for the Phase 3 part of the study. 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

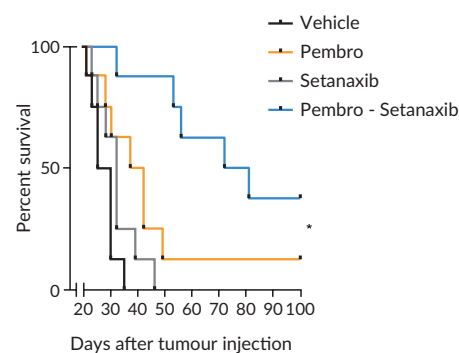
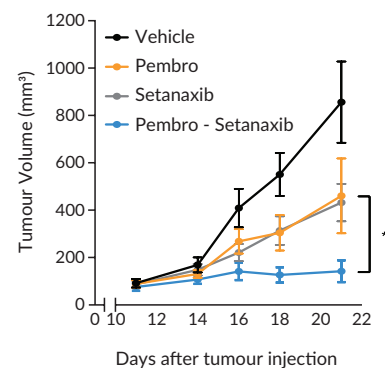
Setanaxib in Squamous Cell Carcinoma of the Head & Neck

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%).

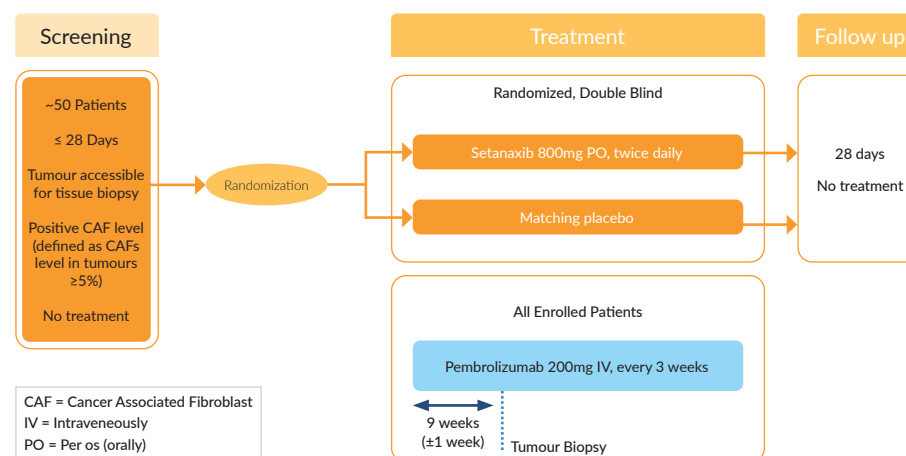
Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:

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



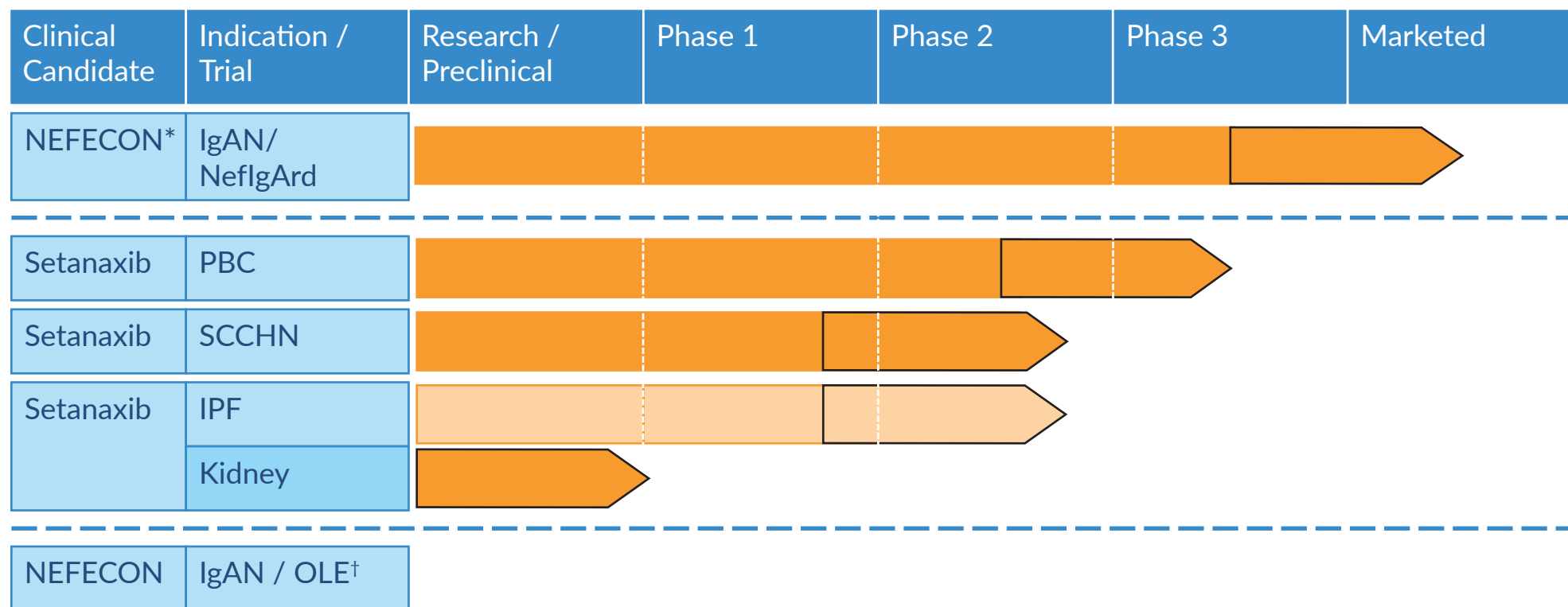
Proof-of-concept study in head and neck cancer

Calliditas is 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 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 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 approval in EU 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 – June 30, 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) ≥ 1.5 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 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 Medicines 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).
- In May 2022, Calliditas announced that the first patient has 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 immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (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.

Significant Events After the Reporting Period

- In July 2022, Calliditas announced that the European Commission (EC) granted conditional marketing authorization 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. 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) exclusively by STADA Arzneimittel AG.

Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Net sales	64,047	-	113,781	-	229,347
Research and development expenses	(96,290)	(75,020)	(209,633)	(165,097)	(357,485)
Research and development expenses/Total operating expenses in %	35%	47%	40%	53%	47%
Operating loss	(209,844)	(159,398)	(418,210)	(310,179)	(524,456)
Loss before income tax for the period	(192,090)	(165,212)	(403,525)	(301,386)	(513,373)
Loss per share before and after dilution	(3.62)	(3.22)	(7.57)	(5.84)	(9.84)
Cash flow used in operating activities	(225,234)	(132,910)	(416,658)	(267,089)	(461,588)

(SEK in thousands, except per share amount or as otherwise indicated)	June 30,		December 31,
	2022	2021	2021
Total registered shares at the end of the period	59,106,188	49,941,584	52,341,584
Equity attributable to equity holders of the Parent Company at the end of the period	721,094	931,206	1,008,281
Equity ratio at the end of the period in %	49%	78%	69%
Cash at the end of the period	846,799	709,306	955,507

January – June 2022

Revenue

Net sales amounted to SEK 64.0 million for the three months ended June 30, 2022 and for the six months ended June 30, 2022 net sales amounted to SEK 113.8 million. No net sales were recognized during the three and six months ended June 30, 2021, respectively. Net sales for the three and six months ended June 30, 2022 primarily originates from net sales of TARPEYO in the U.S., which amounted to SEK 63.6 million for the three months ended June 30, 2022 and SEK 81.6 million for the six months ended June 30, 2022. Further for the six months ended June 30, 2022, net sales also consisted of the milestone fee from Everest Medicines for the extension of the license agreement for South Korea which amounted to SEK 28.8 million. For additional information see Note 4.

Total Operating Expenses

Total operating expenses amounted to SEK 271.5 million and SEK 159.4 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, total operating expenses amounted to SEK 529.0 million and SEK 310.2 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 96.3 million and SEK 75.0 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, research and development expenses amounted to SEK 209.6 million and SEK 165.1 million, respectively. The increase of SEK 21.3 million for the three months ended June 30, 2022 and SEK 44.5 million for the six months ended June 30, 2022 was primarily due to the setanaxib trials and the development of setanaxib compared to the corresponding periods of the prior year.

Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 113.3 million and SEK 58.4 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, marketing and selling expenses amounted to SEK 207.2 million and SEK 77.8 million, respectively. The increase of SEK 54.9 million for the three months ended June 30, 2022 and SEK 129.4 million for the six months ended June 30, 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.

Administrative Expenses

Administrative expenses amounted to SEK 58.9 million and SEK 26.0 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, administrative expenses amounted to SEK 107.4 million and SEK 65.4 million, respectively. The increase of SEK 32.9 million for the three months ended June 30, 2022 and SEK 42.0 million for the six months ended June 30, 2022 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

Other operating income amounted to SEK 0.3 million and SEK 0.4 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, other operating income amounted to SEK 1.1 million and SEK 0.4 million, respectively. Other operating expenses amounted to SEK 3.4 million and SEK 0.4 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, other operating expenses amounted to SEK 5.9 million and SEK 2.3 million, respectively. The increase in other operating expenses for the three and six months ended June 30, 2022, was primarily related to a more disadvantageous exchange rate development on operating liabilities compared to the corresponding periods of the prior year.

Net Financial Income and Expenses

Net financial income/(expenses) amounted to SEK 17.8 million and (SEK 5.8 million) for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, net financial income amounted to SEK 14.7 million and SEK 8.8 million, respectively. The increase of SEK 23.6 million for the three months ended June 30, 2022 and SEK 5.9 million for the six months ended June 30, 2022 was primarily derived by currency effect related to intercompany loan and unrealized foreign currency transaction gains on cash accounts.

Tax

Income tax expenses, in all material respects, primarily relates to the U.S. subsidiaries of Calliditas Therapeutics. Deferred tax assets of SEK 5.3 million related to Calliditas Therapeutics Suisse have been recognized in the six months ended June 30, 2022, due to future temporary differences that such losses can be used to offset. 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.

FINANCIAL OVERVIEW

Result for the Period

For the three months ended June 30, 2022 and 2021, loss for the period amounted to SEK 192.4 million and SEK 164.2 million, and the corresponding loss per share before and after dilution amounted to SEK 3.62 and SEK 3.22, respectively. For the six months ended June 30, 2022 and 2021, loss for the period amounted to SEK 399.5 million and SEK 297.0 million, and the corresponding loss per share before and after dilution amounted to SEK 7.57 and SEK 5.84, respectively.

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 225.2 million and SEK 132.9 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, cash flow used in operating activities amounted to SEK 416.7 million and SEK 267.1 million, respectively. The increase in cash flow used in operating activities for the three and six months ended June 30, 2022, were 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 compared to the corresponding periods of the prior year.

Cash flow used in investing activities amounted to SEK 0.1 million and SEK 18.6 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, cash flow used in investing activities amounted to SEK 2.8 million and SEK 18.8 million, respectively. The decrease in cash flow used in investing activities for the three and six months ended June 30, 2022 were mainly derived from a EUR 1.5 million milestone payment for the Budenofalk license, which occurred the corresponding periods of the prior year.

Cash flow from/(used in) financing activities amounted to SEK 235.9 million and (SEK 0.7 million) for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, cash flow from/(used in) financing activities amounted to SEK 295.9 million and (SEK 10.3 million), respectively. The increase in cash flow from financing activities for the three and six months ended June 30, 2022, compared to the corresponding periods of the prior year, was primarily due to the draw down of the second tranche of the Kreos loan facility of SEK 236.5 million. Further for the six month period, the increase in cash flow from financing activities was also derived from the payments related to the exercise of warrant program 2018/2022.

Net increase/(decrease) in cash amounted to SEK 10.5 million and (SEK 152.2 million) for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, net decrease in cash amounted to SEK 123.5 million and SEK 296.2 million, respectively. Cash amounted to SEK 846.8 million and SEK 709.3 million as of June 30, 2022 and 2021, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 721.1 million and SEK 931.2 million as of June 30, 2022 and 2021, respectively. The number of registered shares amounted to 59,106,188 and 49,941,584 as of June 30, 2022 and 2021, respectively. The increase in number of shares between the periods was derived from a new share issue in August 2021 of 2.4 million shares, a new share issue in April and May 2022 of 856,586 shares related to the Warrant Program 2018/2022 and a new issue of 5,908,018 C-shares, which subsequently immediately was repurchased and, after the end of the period, converted to common shares.

Issuance and Repurchase of Treasury Shares

For the three months ended June 30, 2022, Calliditas resolved to carry out a new 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, after the end of the period, 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 new share issue has increased the share capital by SEK 0.2 million. See Note 10 for additional information.

Personnel

The number of employees were 85 and 54 employees as of June 30, 2022 and 2021, respectively. The total number of full-time equivalent (FTE), including consultants, were 137 and 61 as of June 30, 2022 and 2021, respectively. The average number of employees were 81 and 44 employees for the three months ended June 30, 2022 and 2021, respectively and 76 and 40 employees for the six months ended June 30, 2022 and 2021, respectively.

Incentive Programs

For the three months ended June 30, 2022, an allocation of 40,706 share awards have been granted for the Board LTIP 2022 program. For more information on incentive programs, see Note 11.

FINANCIAL OVERVIEW

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 0.4 million for the three months ended June 30, 2022 and for the six months ended June 30, 2022 net sales amounted to SEK 32.2 million. No net sales were recognized for the three and six months ended June 30, 2021, respectively. The increase was primarily derived from the extension of the Everest Medicines agreement to South Korea by SEK 28.8 million. Operating loss amounted to SEK 152.1 million and SEK 123.6 million for the three months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, operating loss amounted to SEK 254.7 and SEK 251.5 million, respectively. The decrease for both periods was primarily derived from larger organization compared to the corresponding periods of the prior year. Non-current financial assets have increased by SEK 190.2 million to SEK 743.2 million as of June 30, 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.

Declaration by the Board of Directors

The Board of Directors and CEO declare that the interim report for the six months ended June 30, 2022 gives a fair view of the business development, financial position and result of operation of the Parent Company and the Group and describes significant risks and uncertainties that the Parent Company and its subsidiaries are facing.

Stockholm, August 18, 2022

Board of Directors

Elmar Schnee
Chairman of the board

Henrik Stenqvist
Board member

Diane Parks
Board member

Hilde Furberg
Board member

Molly Henderson
Board member

Elisabeth Björk
Board member

Renée Aguiar-Lucander
CEO

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
		2022	2021	2022	2021	2021
Net sales	4	64,047	-	113,781	-	229,347
Cost of goods sold		(2,385)	-	(2,999)	-	-
Gross profit		61,662	-	110,781	-	229,347
Research and development expenses		(96,290)	(75,020)	(209,633)	(165,097)	(357,485)
Marketing and selling expenses	13	(113,272)	(58,368)	(207,169)	(77,794)	(179,603)
Administrative expenses	13	(58,907)	(26,004)	(107,438)	(65,357)	(210,630)
Other operating income		336	383	1,101	383	259
Other operating expenses		(3,374)	(390)	(5,853)	(2,315)	(6,344)
Operating loss		(209,844)	(159,398)	(418,210)	(310,179)	(524,456)
Net financial income/(expenses)		17,754	(5,814)	14,686	8,793	11,083
Loss before income tax		(192,090)	(165,212)	(403,525)	(301,386)	(513,373)
Income tax		(339)	1,054	4,048	4,356	3,836
Loss for the period		(192,429)	(164,157)	(399,477)	(297,030)	(509,537)
Attributable to:						
Equity holders of the Parent Company		(192,429)	(160,825)	(399,477)	(291,696)	(500,293)
Non-controlling interests		-	(3,332)	-	(5,334)	(9,244)
		(192,429)	(164,157)	(399,477)	(297,030)	(509,537)
Loss per share before and after dilution (SEK)		(3.62)	(3.22)	(7.57)	(5.84)	(9.84)

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Loss for the period	(192,429)	(164,157)	(399,477)	(297,030)	(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	31,269	(3,997)	30,069	2,280	(20,111)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods	31,269	(3,997)	30,069	2,280	(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	1,177	109	2,471	1,525	1,993
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods	1,177	109	2,471	1,525	1,993
Other comprehensive income/(loss) for the period	32,445	(3,888)	32,539	3,805	(18,118)
Total comprehensive income/(loss) for the period	(159,984)	(168,046)	(366,938)	(293,225)	(527,655)
Attributable to:					
Equity holders of the Parent Company	(159,984)	(164,216)	(366,938)	(288,331)	(519,190)
Non-controlling interests	-	(3,829)	-	(4,893)	(8,466)
	(159,984)	(168,046)	(366,938)	(293,225)	(527,655)

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Financial Position

		June 30,		December 31,
(SEK in thousands)	Notes	2022	2021	2021
ASSETS				
Non-current assets				
Intangible assets	6,13	460,304	438,397	399,418
Equipment		7,034	1,078	6,309
Right-of-use assets		29,586	7,759	33,300
Non-current financial assets		5,807	3,942	3,915
Deferred tax assets		5,420	885	4,196
Total non-current assets		508,151	452,060	447,138
Current assets				
Inventories		730	-	889
Accounts receivable		38,100	-	-
Other current receivables		14,773	17,713	11,343
Prepaid expenses and accrued income		49,739	9,563	45,032
Cash		846,799	709,306	955,507
Total current assets		950,142	736,582	1,012,772
TOTAL ASSETS		1,458,293	1,188,643	1,459,910
EQUITY AND LIABILITIES				
Equity				
Share capital		2,364	1,998	2,094
Additional paid-in-capital		2,539,458	2,141,445	2,459,741
Retained earnings, including net loss for the period		(1,820,728)	(1,212,237)	(1,453,554)
Equity attributable to equity holders of the Parent Company		721,094	931,206	1,008,281
Non-controlling interests		-	32,172	-
Total equity	9,10,11	721,094	963,378	1,008,281
Non-current liabilities				
Provisions	11	8,859	15,135	17,712
Contingent consideration		59,559	51,330	54,399
Deferred tax liabilities	7,13	32,259	33,261	30,856
Non-current interest-bearing liabilities	12	437,392	-	189,164
Lease liabilities		20,635	3,478	24,052
Total non-current liabilities		558,705	103,204	316,183
Current liabilities				
Accounts payable		81,666	59,263	67,971
Other current liabilities		15,893	8,991	13,922
Accrued expenses and deferred revenue		80,935	53,806	53,553
Total current liabilities		178,494	122,060	135,446
TOTAL EQUITY AND LIABILITIES		1,458,293	1,188,643	1,459,910

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Six Months Ended June 30,		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	(399,477)	(291,696)	(500,293)
Other comprehensive income/(loss)	32,539	3,364	(18,897)
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	(366,938)	(288,331)	(519,190)
Transactions with owners:			
New share issue	-	-	324,000
Costs attributable to new share issue	-	(982)	(20,909)
Issuance of treasury shares	236	-	-
Repurchase of treasury shares	(236)	-	-
Exercise of warrants	63,644	-	-
Share-based payments	16,107	9,285	23,567
Purchase of non-controlling interests	-	743	(9,678)
Total transactions with owners	79,751	9,047	316,980
Closing balance equity attributable to equity holders of the Parent Company	721,094	931,206	1,008,281
Opening balance equity attributable to non-controlling interests	-	45,809	45,809
Total comprehensive loss for the period	-	(4,893)	(8,466)
Contribution from non-controlling interests	-	2,282	2,282
Purchase of non-controlling interests	-	(11,026)	(39,625)
Closing balance equity attributable to non-controlling interests	-	32,172	-
Closing balance equity	721,094	963,378	1,008,281

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Operating activities					
Operating loss	(209,844)	(159,398)	(418,210)	(310,179)	(524,456)
Adjustment for non-cash-items	14,104	10,217	19,171	15,224	66,676
Interest received	2	-	2	-	102
Interest paid	(5,437)	(55)	(10,846)	(209)	(5,432)
Income taxes paid	(2,930)	(993)	(2,930)	(993)	(3,949)
Cash flow used in operating activities before changes in working capital	(204,105)	(150,228)	(412,813)	(296,156)	(467,058)
Cash flow from/(used in) changes in working capital	(21,129)	17,318	(3,845)	29,067	5,470
Cash flow used in operating activities	(225,234)	(132,910)	(416,658)	(267,089)	(461,588)
Cash flow used in investing activities	(139)	(18,568)	(2,790)	(18,767)	(24,340)
Cash flow used in investing activities	(139)	(18,568)	(2,790)	(18,767)	(24,340)
New share issue	-	-	-	-	324,000
Costs attributable to new share issue	-	-	-	(982)	(20,909)
Issuance of treasury shares	236	-	236	-	-
Repurchase of treasury shares	(236)	-	(236)	-	-
Exercise of warrants	1,932	-	63,644	-	-
Purchase of non-controlling interests	-	(366)	-	(10,283)	(49,303)
Contribution from non-controlling interests	-	-	-	2,282	2,282
New borrowings	236,462	-	236,462	-	199,524
Costs attributable to new loans	-	-	-	-	(14,857)
Repayment of lease liabilities	(2,527)	(351)	(4,185)	(1,361)	(5,575)
Cash flow from/(used in) financing activities	235,867	(717)	295,922	(10,344)	435,162
Net increase/(decrease) in cash	10,494	(152,195)	(123,526)	(296,200)	(50,766)
Cash at the beginning of the period	825,408	867,346	955,507	996,304	996,304
Net foreign exchange gains/(loss) on cash	10,897	(5,845)	14,818	9,202	9,969
Cash at the end of the period	846,799	709,306	846,799	709,306	955,507

FINANCIAL STATEMENTS

Condensed Parent Company Statements of Income

(SEK in thousands)	Notes	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
		2022	2021	2022	2021	2021
Net sales	4	420	-	32,191	-	229,347
Cost of goods sold		(2,385)	-	(2,999)	-	-
Gross profit		(1,965)	-	29,192	-	229,347
Research and development expenses		(88,708)	(59,223)	(192,389)	(131,373)	(275,950)
Marketing and selling expenses		(38,401)	(52,553)	(62,808)	(68,572)	(151,125)
Administrative expenses		(49,997)	(27,276)	(94,342)	(65,810)	(226,349)
Other operating income		28,917	14,673	68,812	14,673	70,234
Other operating expenses		(1,995)	784	(3,149)	(453)	(1,874)
Operating loss		(152,149)	(123,595)	(254,683)	(251,535)	(355,718)
Net financial income/(expenses)		9,236	(5,820)	5,841	9,306	1,312
Loss before income tax		(142,913)	(129,415)	(248,842)	(242,229)	(354,405)
Income tax		-	-	-	-	-
Loss for the period		(142,913)	(129,415)	(248,842)	(242,229)	(354,405)

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Loss for the period	(142,913)	(129,415)	(248,842)	(242,229)	(354,405)
Other comprehensive income/(loss)	-	-	-	-	-
Total comprehensive income/(loss)	(142,913)	(129,415)	(248,842)	(242,229)	(354,405)

FINANCIAL STATEMENTS

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	June 30,		December 31,
		2022	2021	2021
ASSETS				
Non-current assets				
Intangible assets	6	32,132	32,132	32,132
Equipment		679	69	514
Non-current financial assets		743,169	369,493	552,924
Total non-current assets		775,979	401,693	585,570
Current assets				
Inventories		730	-	889
Other current receivables		25,069	19,067	5,699
Prepaid expenses and accrued income		34,245	7,579	41,825
Cash		790,377	689,588	894,455
Total current assets		850,421	716,233	942,868
TOTAL ASSETS		1,626,401	1,117,926	1,528,439
SHAREHOLDERS' EQUITY AND LIABILITIES				
<i>Restricted Shareholders' equity</i>				
Share capital		2,364	1,998	2,094
Statutory reserve		3,092	3,092	3,092
Total restricted Shareholders' equity		5,456	5,090	5,186
<i>Non-restricted shareholders' equity</i>				
Share premium reserve		2,487,126	2,116,721	2,420,698
Retained earnings		(1,204,528)	(877,494)	(863,175)
Net loss for the period		(248,842)	(242,229)	(354,405)
Total non-restricted shareholders' equity		1,033,756	996,998	1,203,117
Total shareholders' equity	9,11	1,039,212	1,002,088	1,208,303
Non-current liabilities				
Provisions	11	5,149	5,946	9,075
Non-current interest-bearing liabilities	12	437,392	-	189,164
Other non-current liabilities		105	105	105
Total non-current liabilities		442,646	6,051	198,344
Current liabilities				
Accounts payable		41,346	50,462	51,711
Other current liabilities		50,334	13,636	33,466
Accrued expenses and deferred revenue		52,863	45,690	36,615
Total current liabilities		144,543	109,787	121,792
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,626,401	1,117,926	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 six months ended June 30, 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 August 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 pages 30-31.

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, which is marketed under the brand name TARPEYO, which has been approved for marketing in the U.S, and under the brand name Kinpeygo, which has been approved for marketing in EU. 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

	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
(SEK in thousands)	2022	2021	2022	2021	2021
Type of goods or services					
Product sales	63,627	-	81,590	-	-
Outlicensing of product	-	-	28,804	-	225,252
Performance of certain regulatory services	420	-	3,387	-	4,095
Total	64,047	-	113,781	-	229,347
Geographical markets					
USA	63,627	-	81,590	-	-
Europe	420	-	3,387	-	201,878
Asia	-	-	28,804	-	27,469
Total	64,047	-	113,781	-	229,347

The Group's revenues for the three and six months ended June 30, 2022 primarily originates from net sales of TARPEYO in the U.S. Further for the six months ended June 30, 2022, net sales also consisted of the milestone fee from Everest Medicines for the extension of the license agreement for South Korea.

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 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 June 30, 2022 the total liability for expected returns and rebates amounts to SEK 6.9 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 Medicines 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 has 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 11.

Note 6 - Intangible Assets

(SEK in thousands)	June 30,		December 31,
	2022	2021	2021
Cost at opening balance	427,393	418,825	418,825
Acquisition license	-	16,066	16,066
Exchange difference on translation	60,886	3,506	(7,498)
Cost at closing balance	488,279	438,397	427,393
Amortisation and impairment at closing balance	(27,975)	-	(27,975)
Net book value	460,304	438,397	399,418

Intangible assets consist of licenses and similar rights of SEK 416.9 million and goodwill of SEK 43.4 million as of June 30, 2022. As of June 30, 2021, intangible assets consist of licenses and similar rights of SEK 400.1 million and goodwill of SEK 38.3 million.

Note 7 - Deferred Tax Liabilities

(SEK in thousands)	June 30,		December 31,
	2022	2021	2021
Cost at opening balance	30,857	37,454	37,454
Tax loss carried forward	(5,291)	(4,758)	(5,065)
Exchange difference on translation	6,693	565	(1,532)
Cost at closing balance	32,259	33,261	30,857

Tax loss carried forward of SEK 21.6 million have been offset against deferred tax liabilities in the statement of financial position as of June 30, 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)	June 30,		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	6,764,604	-	2,400,000
Total registered shares at the end of the period	59,106,188	49,941,584	52,341,584
Class of shares			
Ordinary shares	53,198,170	49,941,584	52,341,584
C-shares	5,908,018	-	-
Total	59,106,188	49,941,584	52,341,584
- of which C shares held by Calliditas	5,908,018	-	-
Total registered shares at the end of the period, net of shares held by Calliditas	53,198,170	49,941,584	52,341,584
Share capital at the end of the period	2,364	1,998	2,094
Equity attributable to equity holders of the Parent Company	721,094	931,206	1,008,281
Non-controlling interests	-	32,172	-
Equity at the end of the period	721,094	963,378	1,008,281

(SEK in thousands, except per share amounts and number of shares)	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Loss per share before and after dilution, SEK	(3.62)	(3.22)	(7.57)	(5.84)	(9.84)
Weighted-average number of ordinary shares outstanding for the period, before and after dilution	53,190,170	49,941,584	52,788,020	49,941,584	50,829,255

Reserves for translation from foreign operations amounted to SEK 30.1 million and SEK 2.3 million which are included in equity as of June 30, 2022 and 2021, respectively.

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.

Calliditas has mandates to transfer treasury shares as per below:

Transfer up to 5,908,019 ordinary shares (following the reclassification from C-shares), to be effected outside Nasdaq Stockholm against payment in cash. Such transfers may be effected at a price in cash which corresponds to the market price at the time of the transfer of the Calliditas shares transferred with such deviation as the Board of Directors finds appropriate.

During the six months ended June 30, 2022, 5,908,018 series C shares were issued, which was repurchased by Calliditas and, after the end of the period, converted to ordinary shares. These transactions are in accordance with the granting mandate. The total number of issued shares as of June 30, 2022, is presented in Note 9.

Note 11 - Incentive Programs

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of June 30, 2022
Incentive Programs				
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2020	-	-	31,371	31,371
Board LTIP 2021	-	-	26,968	26,968
Board LTIP 2022	-	-	40,706	40,706
ESOP 2020	-	1,444,000	-	1,444,000
ESOP 2021	-	1,495,000	-	1,495,000
Total Outstanding as of June 30, 2022	422,500	2,939,000	99,045	3,460,545

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of June 30, 2021
Incentive Programs				
Warrant program 2018/2022	856,586	-	-	856,586
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2019	-	-	51,399	51,399
Board LTIP 2020	-	-	31,371	31,371
Board LTIP 2021	-	-	26,968	26,968
ESOP 2020	-	1,485,000	-	1,485,000
ESOP 2021	-	510,000	-	510,000
Total Outstanding as of June 30, 2021	1,279,086	1,995,000	109,738	3,383,824

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 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.

Board LTIP 2022:

This is a performance-based long-term incentive program for Calliditas Board members. A total of 40,706 share awards were granted under the program during the second quarter of 2022. 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 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 12 - Non-current interest-bearing liabilities

(SEK in thousands)	June 30,		December 31,
	2022	2021	2021
Opening balance	189,164	-	-
New borrowings	236,584	-	199,524
Transaction costs	-	-	(14,858)
Interest expense	2,393	-	2,145
Exchange difference on translation	9,251	-	2,353
Closing balance	437,392	-	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. Draw down of the third and final USD 25 million tranche can be made until December 31, 2022, and will be available subject to certain 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 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.

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)	Six Months Ended June 30,				Year Ended December 31,		
	2021	Adjustment	Re-classification	2021	2021	Re-classification	2021
Net sales	-	-	-	-	229,347	-	229,347
<i>Operating expenses</i>							
Research and development expenses	(165,097)	-	-	(165,097)	(357,485)	-	(357,485)
Marketing and selling expenses	-	-	(77,794)	(77,794)	-	(179,603)	(179,603)
Administrative expenses	(143,151)	-	77,794	(65,357)	(390,232)	179,603	(210,629)
Other operating income/expenses	(1,931)	-	-	(1,931)	(6,085)	-	(6,085)
Operating loss	(310,179)	-	-	(310,179)	(524,456)	-	(524,456)
Net financial income/(expenses)	8,793	-	-	8,793	11,083	-	11,083
Loss before income tax	(301,386)	-	-	(301,386)	(513,373)	-	(513,373)
Income tax	11,445	(7,089)	-	4,356	3,836	-	3,836
Loss for the period	(289,940)	(7,089)	-	(297,030)	(509,537)	-	(509,537)

NOTES

The below table describes the adjustment for the six months ended June 30, 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)	June 30,		2021
	2021	Adjustment	
ASSETS			
Non-current assets			
Other intangible assets	433,646	(33,569)	400,078
Goodwill	47,663	(9,344)	38,320
Other non-current assets	13,663	-	13,663
Total non-current assets	494,973	(42,912)	452,060
Current assets	736,582	-	736,582
TOTAL ASSETS	1,231,555	(42,912)	1,188,643
EQUITY AND LIABILITIES			
Equity			
Share capital	1,998	-	1,998
Additional paid in capital	2,141,445	-	2,141,445
Retained earnings, including net loss for the period	(1,205,601)	(6,636)	(1,212,237)
Equity attributable to equity holders of the Parent Company	937,842	(6,636)	931,206
Non-controlling interests	32,860	(688)	32,172
Total equity	970,702	(7,324)	963,378
Non-current liabilities			
Deferred tax liabilities	68,849	(35,588)	33,261
Other non-current liabilities	69,943	-	69,943
Total non-current liabilities	138,792	(35,588)	103,204
Current liabilities	122,060	-	122,060
TOTAL EQUITY AND LIABILITIES	1,231,555	(42,912)	1,188,643

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 June 30,		Six Months Ended June 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Research and development expenses/Total operating expenses in %					
Research and development expenses	(96,290)	(75,020)	(209,633)	(165,097)	(357,485)
Marketing and selling expenses	(113,272)	(58,368)	(207,169)	(77,794)	(179,603)
Administrative expenses	(58,907)	(26,004)	(107,438)	(65,357)	(210,630)
Other operating income/expenses	(3,038)	(6)	(4,752)	(1,931)	(6,085)
Total operating expenses	(271,506)	(159,398)	(528,992)	(310,179)	(753,803)
Research and development expenses/Total operating expenses in %	35%	47%	40%	53%	47%

(SEK in thousands or otherwise indicated)	June 30,		December 31,
	2022	2021	2021
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	721,094	931,206	1,008,281
Total assets at the end of the period	1,458,293	1,188,643	1,459,910
Equity ratio at the end of the period in %	49%	78%	69%

Financial Calendar

Interim Report for the period January 1 - September 30, 2022	November 17, 2022
Year-End Report for the period January 1 - December 31, 2022	February 23, 2023
Interim Report for the period January 1 - March 31, 2023	May 17, 2023

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Forward Looking Statements

This interim report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans, 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 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.

