
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: November 14, 2022

(Commission File No. 001-39308)

CALLIDITAS THERAPEUTICS AB

(Translation of registrant's name into English)

Kungsbron 1, D5

SE-111 22

Stockholm, Sweden

(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

Company Announcement and Interim Report

On November 14, 2022, the Company announced its unaudited results for the nine months ended September 30, 2022, which are further described in the Company's Interim Report Q3 2022 and press release, copies of which are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated by reference herein.

The information contained in this Form 6-K, including Exhibits 99.1 and 99.2, is hereby incorporated by reference into the registrant's Registration Statement on Form F-3 (File No. 333-265881).

EXHIBIT INDEX

Exhibit	Description
99.1	Interim Report Q3 2022
99.2	Press release dated November 14, 2022

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CALLIDITAS THERAPEUTICS AB

Date: November 14, 2022

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

Q3 2022

INTERIM REPORT JANUARY 1ST – SEPTEMBER 30TH 2022

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Conditional Marketing Authorization in Europe Granted for Kinpeygo[®]

Financial Summary For the Group

Key Figures

July 1 - September 30, 2022

- » Net sales amounted to SEK 260.1 million, whereof TARPEYO[®] net sales amounted to SEK 123.4 million, for the three months ended September 30, 2022. For the three months ended September 30, 2021 net sales amounted to SEK 198.2 million and no TARPEYO net sales were recognized.
- » Operating profit/(loss) amounted to (SEK 36.2 million) and SEK 7.9 million for the three months ended September 30, 2022 and 2021, respectively.
- » Earnings/(loss) per share before and after dilution amounted to (SEK 0.17) and SEK 0.21 for the three months ended September 30, 2022 and 2021, respectively.
- » Cash amounted to SEK 736.2 million and SEK 1,163.8 million as of September 30, 2022 and 2021, respectively.

January 1 - September 30, 2022

- » Net sales amounted to SEK 373.8 million, whereof TARPEYO net sales amounted to SEK 205.0 million, for the nine months ended September 30, 2022. For the nine months ended September 30, 2021 net sales amounted to SEK 198.2 million and no TARPEYO net sales were recognized.
- » Operating loss amounted to SEK 454.4 million and SEK 302.3 million for the nine months ended September 30, 2022 and 2021, respectively.
- » Loss per share before and after dilution amounted to SEK 7.72 and SEK 5.53 for the nine months ended September 30, 2022 and 2021, respectively.

Significant Events in Q3 2022 in Summary

In July 2022, Calliditas announced that the European Commission granted a Conditional Marketing Authorization for Kinpeygo for the treatment of IgA nephropathy (IgAN) in adults at risk of rapid disease progression (protein-to-creatinine ratio (UPCR) ≥ 1.5 g/gram). Kinpeygo is a novel oral treatment product and became the first and only approved treatment for IgAN. Kinpeygo will be marketed in the European Economic Area by Calliditas and its partner, STADA Arzneimittel AG. Subsequently, in September 2022, Calliditas received its Conditional Market Authorization for Kinpeygo to be marketed in additional European countries to follow.

Investor Presentation November 14, 2022 14:00 CET

Audio cast with teleconference, Q3 2022

Webcast: <https://ir.financialhearings.com/calliditas-therapeutics-q3-2022>

Teleconference: SE: +46850558350 UK: +443333009265 US: +16467224956



European Launch and Approval

On July 15th the European Commission issued the conditional marketing authorization for Kinpeygo, which marked the first time that any drug has achieved approval for this rare disease in EU.

We immediately started the process of transferring the market authorization to our European partner, STADA Arzneimittel AG, in order to enable a launch in Europe as quickly as possible. STADA is initially launching the product in Germany, with other European countries to follow over time. With approval and commercial efforts now ongoing in both the US and Europe, we are looking forward to the regulatory process in China, where our partner, Everest Medicines, expects to receive NDA acceptance notice from NMPA this quarter. We are excited to support Everest as they work with regulators in China, who are expected to reach a decision regarding a potential approval in the second half of next year. If Nefecon is approved, this would be the first and only approved medication for the by Everest estimated 5m biopsy-proven IgAN patients in China.

In the US, we continue to build on our early commercial success. Net sales from TARPEYO grew by 94% when compared to Q2, resulting in net sales from TARPEYO of SEK 123.4 million (\$12.1m) for Q3. There is a growing number of nephrologists choosing to prescribe TARPEYO, with 166 new prescribers added in Q3, bringing total unique prescribers to 480 at the end of the quarter. We continue to see a continuous build of interest which mirrors the natural cadence of nephrology visits, which aligns with our expectations regarding this fairly silent, progressive disease. We expect to achieve net sales from TARPEYO for the year of between \$35 – 40m, which aligns with our internal plans for 2022. We also expect to see significant continued growth in 2023 as nephrologists become more familiar with the clinical data, access becomes more streamlined, and as topline data from the Part B of the NeflgArd trial becomes available.

As we continued to work on disease state education and built on our interactions with nephrologists, we became increasingly aware of the need to provide the broader community with a peer-reviewed overview of Part A of the NeflgArd data. We were therefore delighted to be able to have the Part A data published in *Kidney International* in October, 2022, as regulators also posted their review assessments. This data set, showing increasing reduction of proteinuria across the entire patient population during the 9 months on drug as well as significant continued reduction of proteinuria across the entire study population in the following 3 months when no drug was administered, showing a highly differentiated profile. The significance of this data was further confirmed by countless interactions at the American Society of Nephrology (ASN) Kidney Week in early November, where we had the opportunity to engage not only with KOLs but with the broader nephrology community treating IgAN patients. It was fantastic to see the high level of interest and excitement following the publication of our data and we were greatly encouraged by all of our interactions at ASN related to the interest in TARPEYO. The continued strong decline of proteinuria combined with the ability to immediately, as well as over the entire 12 month time period observed in Part A, virtually stabilize estimated glomerular filtration rate (eGFR) in patients with rapid disease progression was particularly interesting for physicians, since it provides early support for the

ability of TARPEYO/Kinpeygo to be disease-modifying. We are looking forward to the read out of Part B of the NeflgArd trial in H1 of 2023 in order to report out the clinical data on patients' underlying kidney function.

Once patients have concluded the NeflgArd trial, we will roll over into the Open Label Extension (OLE) trial, with all patients receiving the active drug. The OLE trial remains blinded as to whether patients are receiving placebo in the Phase 3 trial. Inclusion criteria for the OLE trial: proteinuria levels have to be at least 30 ml/min. By the end of the OLE trial, we had chosen to screen for OLE. Out of the 100 patients included, the predominant reason for exclusion was low eGFR levels. Though exciting, no conclusions can be drawn from this blinded study, but it potentially opens up a new approach of targeting the origin of IgAN. The safety profile in the OLE trial was observed in the Phase 3 NeflgArd trial. We will follow this patient population and look forward to the Phase 3 trial once the Phase 3 trial has been fully completed.

Following a good start of our setanaxib trial, we observed a slower rate of site activations compared to our previous cancer study. Biomarker data readout from the TRANSFORM study is expected in the second half of 2024. This revised timing is still subject to change as per our revised expectations. We believe that hospitals and clinics catching up on their staffing levels will enable us to improve our site activations. We remain encouraged by the excitement of investigators and the growing interest in setanaxib specifically, across the industry. We will continue to update you on the continued progress in our Q4 report, when we will also provide guidance on product sales for 2023.

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 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.

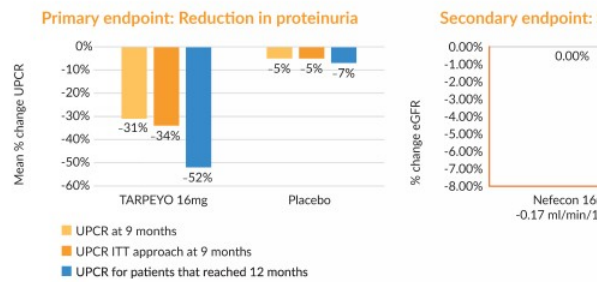
The galactose-deficient spot at the hinge region of the IgA antibodies is immunogenic when found in the circulation. It therefore generates an autoimmune response, attracting autoantibodies in the form of IgG or IgA which form pathogenic immune complexes that deposit in the glomeruli, the kidney's filtration 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 with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes first-pass metabolism, resulting in limited systemic exposure. It was designed as a delayed-release capsule with an enteric coating so that it remains intact until it reaches the ileum. The capsule contains beads coated with various polymers and budesonide designed to target the highest concentration of Peyer's patches, with the intention of having a direct effect on the gut.

Data

Calliditas' regulatory filings with the FDA and European Medicines Agency (EMA) are based on positive data from Part A of the NeflgArd pivotal Phase 3 study, which was completed in November 2020. Patients taking Nefecon showed a statistically significant reduction in proteinuria from baseline vs 5% in the placebo cohort at 9 months; in the population, the reduction at 9 months of treated patients was 34%. Further 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 treatment arm over 9 months compared to a 0.17 ml/min/1.73m² decline in the placebo arm. The study demonstrated that Nefecon was well-tolerated. This data has now been published in a peer-reviewed article in *Kidney International*.¹



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.



Approval in EU

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

Kinpeygo will be marketed in the European Economic Area (EEA) exclusively AG with whom Calliditas entered into a license agreement in July 2021. The register and commercialize Kinpeygo in the European Economic Area (EEA) n zeland and the UK was valued at a total of EUR 97.5 million, plus royalties. In agreement, Calliditas received an initial upfront payment of EUR 20 million u received additional EUR 12.5 million for conditional marketing authorization tion. Calliditas is further entitled to up to an additional EUR 65 million in futu pre-defined regulatory and commercialization milestones. STADA is also due on net sales expressed as a percentage between the low twenties and the lo

Following the transfer of the conditional marketing authorisation, STADA la Germany, with additional European countries to follow. In Germany it is est per 100,000 develop IgAN each year.

Greater China, Singapore and South Korea

Calliditas also has a commercial partner in China and Singapore, having ente agreement to develop and commercialize NEFECON for IgAN in those marl Medicines in 2019. Calliditas received an initial upfront payment of USD 15 as well as future payments linked to development, regulatory and commerci to an additional USD 106 million, plus royalties. In March 2022, this agreem include South Korea. Everest Medicines will look to file with regulators in CI 2022, with a view to target potential approval in the second half of 2023.

Building on a Successful Commercial Launch

In our third quarter of sales of TARPEYO®, the commercial team has built on the successful strides made since our first sale in late January. We continue to engage with healthcare providers (HCPs), payers and patients and remain encouraged by their enthusiasm for our product.

Our specialty sales team has continued to build on the strong results in the first half of the year, recording net sales for the third quarter of USD 12.1 million (SEK 123.4 million). An expansion of our sales force was decided in June and conducted during the third quarter, as we brought our sales team up to 60 specialty sales representatives. We expect that the impact of the expansion should be reflected to some degree in Q4, but predominantly in early 2023 as these representatives begin bolstering our reach and frequency of contact to our target audience.

Since the launch of TARPEYO in late January to the end of September, there have been a total of 730 patient enrollments, with enrollments in Q3 amounting to 281, reflecting a strong September month after the summer period of July and August. In terms of new prescribers, Q3 continued to see broad interest from nephrologists with unique prescribers at the end of September amounting to 480, reflecting an increase of 166 new prescribers during the third quarter. In addition to our sales force expansion, we expect continued growth based on our extensive interactions and large presence at Kidney Week/ASN as well as the publication of the data from the NeflgArd trial.

The process of achieving 85-90% reimbursement coverage for TARPEYO is now almost complete, with the channel mix still containing approximately 70-75% commercial insured patients. The majority of the remaining 25-30% are government subsidized insured patients, which include Medicare and Medicaid. Enrolled patients whose process has reached a conclusion continued to have an impressive reimbursement approval rate of more than 80%. While the average time for prescription fill is already less than 30 days for those prescriptions which have been successfully concluded, the commercial team continues to focus to improve this rate to 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 ensure uptake of TARPEYO. Awareness of TARPEYO remains high with unaided and aided awareness greater than 70% and 80%, respectively. 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 and we look forward to launching several additional educational initiatives over the next several months.

All patients are guided through the enrollment and procurement process with patient services program, TARPEYO Touchpoints™, which assists physicians a designated Rare Pod Team – including nurses, pharmacists, and a fulfillment a. This quarter, the TARPEYO Touchpoints team was expanded, adding additional support the increasing numbers of patients being part of the program, with t to provide high engagement and service for every patient.

Calliditas remains engaged with the IgA nephropathy patient audience via our efforts and outreach. In July, Calliditas was a lead sponsor at the IGA Nephro SPARK 2022 symposium, continuing our long-standing support of the found educate, support and engage the IgAN patient and caregiver community. Also we launched an unbranded patient ambassador program and went live with a video featuring former NFL player Donald Jones and leading KOL Dr Gerald. We work closely with IgAN patient ambassadors to raise awareness of this disease on patients and caregivers via multiple channels, including TV and radio networks.



Our medical affairs team has continued to ensure we have a presence at all major congresses, with the annual American Society of Nephrology kidney week in the most important of the year. During the past quarter, our Chief Medical Officer participated on a key panel discussion alongside the FDA's Deputy Director of Regulatory & Nephrology, Aliza Thompson, at the Annual Rare & Genetic Kidney Disease Management conference. Calliditas' medical affairs team has continued to partner with regional and local meetings to engage in peer-to-peer group and individual education.

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.

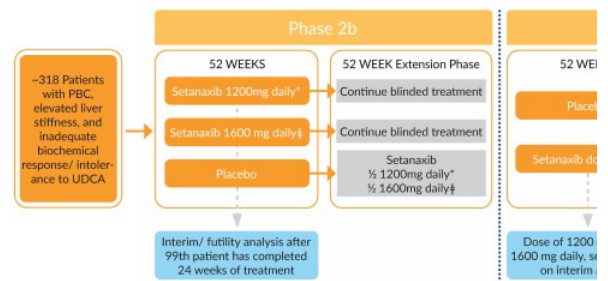
Setanaxib in Primary Biliary Cholangitis

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 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, adaptive Phase 2b/3 design. Calliditas announced that the first patient was recruited to the TRANSFORM study on 15th February 2022.

Setanaxib will be administered to approximately 318 patients with PBC and intolerance or inadequate response to UDCA in a global trial across 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). Based on 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 randomised patient has completed the Week 24 visit, which is expected in the first half of 2024, and will determine which dose of setanaxib will be used for the Phase 3 part of the trial. In August 2021, Calliditas received FDA Fast Track Designation for setanaxib in the treatment of 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

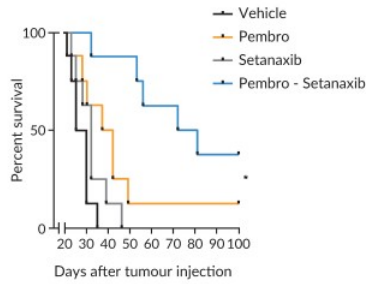
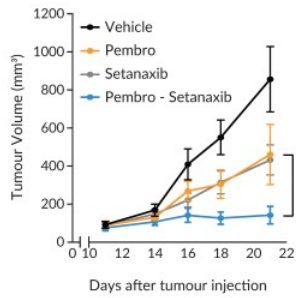
Setanaxib in Squamous Cell Carcinoma of the Head & Neck

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%).

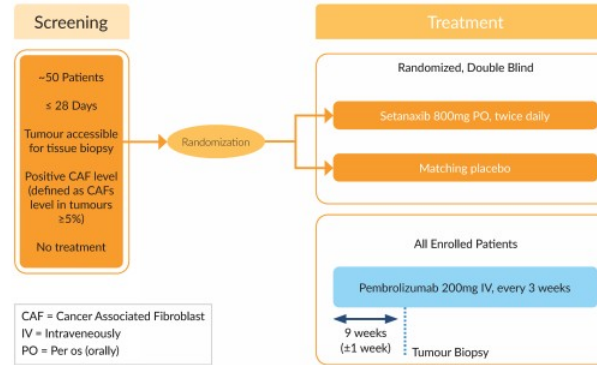
Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:

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



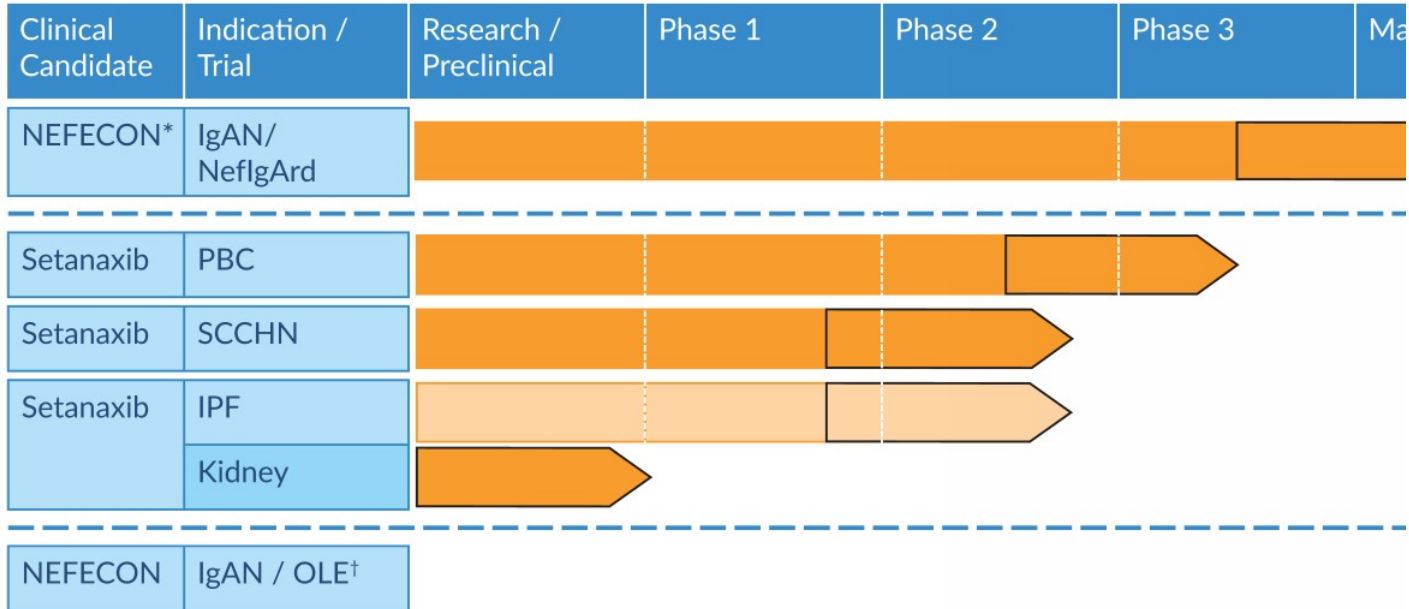
Proof-of-concept study in head and neck cancer

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.



The study will likely involve approximately 50 patients. The first patient was Q2 2022, with an interim biomarker readout expected in 1H 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 ≥ 1.5g/g. Approved under conditional marketing authorisation 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 – September 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 in the first half of 2024, subject to recruitment rate. 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 a proof-of-concept Phase 2 study in patients with squamous cell carcinoma (SCCHN) with the NOX 1 and 4 inhibitor, setanaxib.
- In May 2022, Calliditas announced that the Committee for Medicinal Products (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion on the granting of a conditional marketing authorisation for Kinpeygo for the treatment of 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. At the AGM, things, the AGM resolved on the election of Henrik Stenqvist and Elisabeth Stenqvist as Directors and the establishment of a U.S. At-the-Market framework of 5,908,019 shares, pursuant to which Calliditas may, at its option, sell up to 5,908,019 Shares ("ADSs") in the United States at market price, from time to time, in connection with transactions on The Nasdaq Global Select Market.
- In July 2022, Calliditas announced that the European Commission (EC) granted marketing authorization for Kinpeygo for the treatment of IgA nephropathy in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio ≥ 1.5 g/gram. Kinpeygo is an orphan medicinal product and became the first and only orphan medicinal product for IgAN in EU. Kinpeygo will be marketed in the European Economic Area by STADA Arzneimittel AG. Subsequently, in September 2022, Calliditas received marketing authorization for Kinpeygo to its European commercial partner, STADA Arzneimittel AG, which will initially launch in Germany, with additional European countries to follow.

Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net sales	260,056	198,167	373,837	198,167
Research and development expenses	(102,877)	(92,098)	(312,510)	(257,194)
Research and development expenses/Total operating expenses in %	35%	48%	38%	51%
Operating profit/(loss)	(36,227)	7,856	(454,438)	(302,323)
Profit/(loss) before income tax for the period	(15,958)	6,480	(419,483)	(294,906)
Earnings/(loss) per share before dilution (SEK)	(0.17)	0.21	(7.72)	(5.53)
Earnings/(loss) per share after dilution (SEK)	(0.17)	0.21	(7.72)	(5.53)
Cash flow used in operating activities	(124,725)	(33,245)	(541,383)	(300,334)

(SEK in thousands, except per share amount or as otherwise indicated)	September 30,	
	2022	2021
Total registered shares, including shares held by Calliditas, at the end of the period	59,157,587	52,341,587
Equity attributable to equity holders of the Parent Company at the end of the period	725,936	1,255,041
Equity ratio at the end of the period in %	48%	73%
Cash at the end of the period	736,161	1,163,811

January – September 2022

Revenue

Net sales amounted to SEK 260.1 million for the three months ended September 30, 2022, and for the nine months ended September 30, 2022, net sales amounted to SEK 373.8 million. For the three and nine months ended September 30, 2021, net sales amounted to SEK 198.2 million, respectively. Net sales for the three and nine months ended September 30, 2022, primarily originates from net sales of TARPEYO in the U.S., which amounted to SEK 123.4 million for the three months ended September 30, 2022, and SEK 205.0 million for the nine months ended September 30, 2022. Further, for the three and nine months ended September 30, 2022, net sales also consisted of SEK 135.0 million in milestone fees from STADA for the conditional approval and commercialization of Kinpeygo in Europe. In addition, for the nine months ended September 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.

Cost of Goods Sold

Cost of goods sold amounted to SEK 4.3 million for the three months ended September 30, 2022, and for the nine months ended September 30, 2022, cost of goods sold amounted to SEK 7.3 million. For the three and nine months ended September 30, 2021, no cost of goods sold were recognized.

Total Operating Expenses

Total operating expenses amounted to SEK 292.0 million and SEK 190.3 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, total operating expenses amounted to SEK 821.0 million and SEK 500.5 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 102.9 million and SEK 92.1 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, research and development expenses amounted to SEK 312.5 million and SEK 257.2 million, respectively. The increase of SEK 10.8 million for the three months ended September 30, 2022, and SEK 55.3 million for the nine months ended September 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 116.1 million and SEK 31.3 million for the three months ended September 30, 2022 and 2021, respectively. For the three months ended September 30, 2022 and 2021, marketing and selling expenses amounted to SEK 109.0 million and SEK 109.0 million, respectively. The increase of SEK 84.9 million for the three months ended September 30, 2022, and SEK 214.3 million for the nine months ended September 30, 2022, was primarily related to the costs for sales and marketing of TARPEYO in the U.S. for the sales force compared to the corresponding periods of the prior year.

Administrative Expenses

Administrative expenses amounted to SEK 71.0 million and SEK 64.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, administrative expenses amounted to SEK 178.4 million and SEK 48.8 million, respectively. The increase of SEK 6.8 million for the three months ended September 30, 2022, and SEK 48.8 million for the nine months ended September 30, 2022, was primarily related to 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 1.9 million) and (SEK 4.8 million) for the three months ended September 30, 2022 and 2021, respectively. For the three months ended September 30, 2022 and 2021, other operating income/(expenses), net amounted to (SEK 1.9 million) and (SEK 4.8 million), respectively. The increase for the nine months ended September 30, 2022, was primarily related to a more disadvantageous exchange rate development compared to the corresponding period of the prior year.

Net Financial Income and Expenses

Net financial income/(expenses) amounted to SEK 20.3 million and (SEK 1.4 million) for the three months ended September 30, 2022 and 2021, respectively. For the three months ended September 30, 2022 and 2021, net financial income amounted to SEK 35.0 million and SEK 21.7 million, respectively. The increase of SEK 21.7 million for the three months ended September 30, 2022, and SEK 27.6 million for the nine months ended September 30, 2022, was primarily due to currency effect related to intercompany loan and unrealized foreign currency on cash accounts.

Tax

Total income tax/(expense) amounted to SEK 6.8 million and (SEK 0.3 million) for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, income tax amounted to SEK 10.9 million and SEK 4.0 million, respectively. The increase for the three and nine months ended September 30, 2022 were primarily explained by recognized loss carried-forward, which are expected to be utilized against future profit for the U.S. subsidiaries. The group has also recognized losses carried-forward related to the Swiss subsidiary, which there are temporary differences that such taxable losses can be used to offset. The Group's tax losses carried-forward have otherwise not been recognized as deferred tax assets.

Result for the Period

For the three months ended September 30, 2022 and 2021, loss for the period amounted to SEK 9.1 million and SEK 6.2 million, and the corresponding earnings/(loss) per share before and after dilution amounted to (SEK 0.17) and SEK 0.21, respectively. For the nine months ended September 30, 2022 and 2021, loss for the period amounted to SEK 408.6 million and SEK 290.9 million, and the corresponding loss per share before and after dilution amounted to SEK 7.72 and SEK 5.53, respectively.

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 124.7 million and SEK 33.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, cash flow used in operating activities amounted to SEK 541.4 million and SEK 300.3 million, respectively. The increase in cash flow used in operating activities for the three and nine months ended September 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 0.9 million and SEK 0.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, cash flow used in investing activities amounted to SEK 3.7 million and SEK 19.0 million, respectively. The decrease in cash flow used in investing activities for the nine months ended September 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 2.6 million) and SEK 486.8 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, cash flow from financing activities amounted to SEK 293.4 million and SEK 476.5 million, respectively. The decrease in cash flow from financing activities for the three and nine months ended September 30, 2022, compared to the corresponding periods of the prior year, was primarily due to a new share issue of net SEK 304.0 million in the third quarter of 2021.

Net increase/(decrease) in cash amounted to (SEK 128.2 million) and SEK 4 three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, net increase/(decrease) in cash amounted to (SEK 157.1 million) and SEK 157.1 million, respectively. Cash amounted to SEK 736.2 million as of September 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 1,255.0 million as of September 30, 2022 and 2021, respectively. The shares amounted to 59,157,587 and 52,341,584 as of September 30, 2022 and 2021, respectively. The increase in number of shares between the periods was derived from the issuance of 5,908,018 C-shares in April and May 2022 of 856,586 shares related to the Warrant Program 2 and 5,051,432 shares related to the Board LTIP 2019 program and a new issue of 51,399 shares held as treasury shares for future potential delivery of shares under the at-the-market program.

Issuance and Repurchase of Treasury Shares

For the nine months ended September 30, 2022, Calliditas resolved to carry out the issuance of 5,908,018 C-shares at a subscription price of SEK 0.04 per share and to subsequently repurchase the 5,908,018 newly issued C-shares for SEK 0.04 per share and convert them into ordinary shares in accordance with the company's articles of association. The purpose of the issue and repurchase is to secure future treasury shares under the company's at-the-market program. The share issue has increased treasury shares by SEK 0.2 million. See Note 10 for additional information.

Personnel

The number of employees were 98 and 65 employees as of September 30, 2022 and 2021, respectively. The total number of full-time equivalent (FTE), including consultants, amounted to 81 as of September 30, 2022 and 2021, respectively. The average number of employees for the three months ended September 30, 2022 and 2021 were 62 and 51 employees for the nine months ended September 30, 2022 and 2021, respectively.

Incentive Programs

For the three months ended September 30, 2022, an allocation of 1,101,000 shares was granted for the ESOP 2022 program. For more information on incentive programs, see Note 10.

FINANCIAL OVERVIEW

2022 Outlook

In 2021, the FDA granted accelerated approval for TARPEYO in the U.S. During the beginning of 2022, commercialization began in the U.S. and as a result, Calliditas expects accelerated revenue growth in the U.S. market and:

Net sales from TARPEYO from the U.S. are estimated to be USD 35-40 million for the year ending December 31, 2022, (corresponding to approx. 347-397 MSEK, using Riksbanken SEK/USD average exchange rate for the period January-September 2022 of 9.92).

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 219.6 million and SEK 198.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, net sales amounted to SEK 251.8 million and SEK 198.2 million, respectively. The increase for the three and nine months ended September 30, 2022 was primarily derived from sales of TARPEYO compared to the corresponding periods of the prior year. Operating profit/(loss) amounted to (SEK 47.4 million) and SEK 49.8 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, operating loss amounted to SEK 302.1 million and SEK 201.8 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 247.8 million to SEK 800.7 million as of September 30, 2022, compared to December 31, 2021, which was primarily derived from intercompany transactions.

Stockholm, November 14, 2022

Renée Aguiar-Lucander
CEO

Review report

Calliditas Therapeutics AB, corporate identity number 556659-9766

Introduction

We have reviewed the condensed interim report for Calliditas Therapeutics AB as at September 30, 2022 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

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

Conclusion

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

Stockholm 14 November 2022

Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended September 30,		Nine Months Ended September 30,	
		2022	2021	2022	2021
Net sales	4	260,056	198,167	373,837	198,167
Cost of goods sold		(4,322)	-	(7,322)	
Gross profit		255,734	198,167	366,515	198,167
Research and development expenses		(102,877)	(92,098)	(312,510)	(257,194)
Marketing and selling expenses	13	(116,135)	(31,171)	(323,303)	(108,965)
Administrative expenses	13	(71,003)	(64,200)	(178,441)	(129,558)
Other operating income		1,065	2,153	2,166	2,534
Other operating expenses		(3,011)	(4,994)	(8,864)	(7,309)
Operating profit/(loss)		(36,227)	7,856	(454,438)	(302,323)
Net financial income/(expenses)		20,269	(1,375)	34,955	7,417
Profit/(loss) before income tax		(15,958)	6,480	(419,483)	(294,906)
Income tax		6,848	(321)	10,896	4,031
Profit/(loss) for the period		(9,111)	6,159	(408,587)	(290,871)
Attributable to:					
Equity holders of the Parent Company		(9,111)	10,573	(408,587)	(281,123)
Non-controlling interests		-	(4,414)	-	(9,748)
		(9,111)	6,159	(408,587)	(290,871)
Earnings/(loss) per share before dilution (SEK)		(0.17)	0.21	(7.72)	(5.53)
Earnings/(loss) per share after dilution (SEK)		(0.17)	0.21	(7.72)	(5.53)

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Profit/(loss) for the period	(9,111)	6,159	(408,587)	(290,871)
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	4,558	2,639	34,626	4,915
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods	4,558	2,639	34,626	4,915
<i>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:</i>				
Remeasurement gain on defined benefit plans	(94)	236	2,377	1,765
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods	(94)	236	2,377	1,765
Other comprehensive income/(loss) for the period	4,464	2,875	37,003	6,680
Total comprehensive income/(loss) for the period	(4,647)	9,034	(371,584)	(284,191)
Attributable to:				
Equity holders of the Parent Company	(4,647)	13,113	(371,584)	(275,219)
Non-controlling interests	-	(4,079)	-	(8,973)
	(4,647)	9,034	(371,584)	(284,191)

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	September 30,	
		2022	2021
ASSETS			
Non-current assets			
Intangible assets	6.13	487,348	441,457
Equipment		7,700	1,197
Right-of-use assets		28,161	20,084
Non-current financial assets		6,909	3,947
Deferred tax assets		14,889	2,601
Total non-current assets		545,007	469,276
Current assets			
Inventories		582	
Accounts receivable		176,832	
Other current receivables		10,347	55,477
Prepaid expenses and accrued income		49,175	36,867
Cash		736,161	1,163,811
Total current assets		973,099	1,256,155
TOTAL ASSETS		1,518,106	1,725,431
EQUITY AND LIABILITIES			
Equity			
Share capital		2,366	2,097
Additional paid-in-capital		2,548,946	2,451,977
Retained earnings, including net loss for the period		(1,825,376)	(1,199,026)
Equity attributable to equity holders of the Parent Company		725,936	1,255,048
Non-controlling interests		-	27,957
Total equity	9,10,11	725,936	1,283,005
Non-current liabilities			
Provisions	11	8,030	14,207
Contingent consideration		62,365	52,977
Deferred tax liabilities	7.13	34,338	33,317
Non-current interest-bearing liabilities	12	448,129	187,427
Lease liabilities		19,188	14,447
Total non-current liabilities		572,049	302,375
Current liabilities			
Accounts payable		95,763	74,857
Other current liabilities		14,796	10,647
Accrued expenses and deferred revenue		109,561	54,577
Total current liabilities		220,120	140,071
TOTAL EQUITY AND LIABILITIES		1,518,106	1,725,431

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Nine Months Ended September 30,	
	2022	2021
Opening balance equity attributable to equity holders of the Parent Company	1,008,281	1,210,497
Loss for the period	(408,587)	(281,123)
Other comprehensive income/(loss)	37,003	5,901
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	(371,584)	(275,219)
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	63,644	-
Share-based payments	25,595	15,801
Purchase of non-controlling interests	-	871
Total transactions with owners	89,239	319,771
Closing balance equity attributable to equity holders of the Parent Company	725,936	1,255,049
Opening balance equity attributable to non-controlling interests	-	45,801
Total comprehensive loss for the period	-	(8,973)
Contribution from non-controlling interests	-	2,281
Purchase of non-controlling interests	-	(11,162)
Closing balance equity attributable to non-controlling interests	-	27,951
Closing balance equity	725,936	1,283,000

FINANCIAL STATEMENTS

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating activities				
Operating profit/(loss)	(36,227)	7,856	(454,438)	(302,323)
Adjustment for non-cash-items	11,173	8,912	30,344	24,134
Interest received	-	-	2	-
Interest paid	(12,830)	(327)	(23,676)	(536)
Income taxes paid	(1,788)	(477)	(4,718)	(1,470)
Cash flow used in operating activities before changes in working capital	(39,672)	15,963	(452,485)	(280,193)
Cash flow from/(used in) changes in working capital	(85,053)	(49,208)	(88,898)	(20,141)
Cash flow used in operating activities	(124,725)	(33,245)	(541,383)	(300,334)
Cash flow used in investing activities	(888)	(236)	(3,678)	(19,003)
Cash flow used in investing activities	(888)	(236)	(3,678)	(19,003)
New share issue	-	324,000	-	324,000
Costs attributable to new share issue	-	(19,927)	-	(20,909)
Issuance of treasury shares	-	-	236	-
Repurchase of treasury shares	-	-	(236)	-
Exercise of warrants	-	-	63,644	-
Purchase of non-controlling interests	-	-	-	(10,283)
Contribution from non-controlling interests	-	-	-	2,284
New borrowings	-	199,524	236,462	199,524
Costs attributable to new loans	-	(14,857)	-	(14,857)
Repayment of lease liabilities	(2,569)	(1,944)	(6,754)	(3,305)
Cash flow from/(used in) financing activities	(2,569)	486,795	293,353	476,451
Net increase/(decrease) in cash	(128,183)	453,315	(251,708)	157,111
Cash at the beginning of the period	846,799	709,306	955,507	996,304
Net foreign exchange gains/(loss) on cash	17,545	1,198	32,362	10,400
Cash at the end of the period	736,161	1,163,818	736,161	1,163,814

FINANCIAL STATEMENTS

Condensed Parent Company Statements of Income

(SEK in thousands)	Notes	Three Months Ended September 30,		Nine Months Ended September 30,	
		2022	2021	2022	2021
Net sales	4	219,642	198,167	251,833	198,167
Cost of goods sold		(4,322)	-	(7,322)	-
Gross profit		215,320	198,167	244,511	198,167
Research and development expenses		(94,340)	(79,258)	(286,729)	(210,631)
Marketing and selling expenses		(134,066)	(23,539)	(196,873)	(92,110)
Administrative expenses		(57,378)	(68,217)	(151,720)	(134,027)
Other operating income		24,650	26,362	93,462	41,031
Other operating expenses		(1,564)	(3,746)	(4,712)	(4,199)
Operating profit/(loss)		(47,377)	49,769	(302,061)	(201,766)
Net financial income/(expenses)		7,500	(865)	13,341	8,441
Profit/(loss) before income tax		(39,877)	48,903	(288,720)	(193,326)
Income tax		-	-	-	-
Profit/(loss) for the period		(39,877)	48,903	(288,720)	(193,326)

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Profit/(loss) for the period	(39,877)	48,903	(288,720)	(193,326)
Other comprehensive income/(loss)	-	-	-	-
Total comprehensive income/(loss)	(39,877)	48,903	(288,720)	(193,326)

FINANCIAL STATEMENTS

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	September 30,	
		2022	2021
ASSETS			
Non-current assets			
Intangible assets	6	32,132	32,13
Equipment		623	
Non-current financial assets		800,703	399,51
Total non-current assets		833,457	431,64
Current assets			
Inventories		582	
Accounts receivable		111,288	
Other current receivables		100,826	84,85
Prepaid expenses and accrued income		27,410	34,98
Cash		632,236	1,131,55
Total current assets		872,342	1,251,39
TOTAL ASSETS		1,705,800	1,683,03
SHAREHOLDERS' EQUITY AND LIABILITIES			
Restricted Shareholders' equity			
Share capital		2,366	2,09
Statutory reserve		3,092	3,09
Total restricted Shareholders' equity		5,458	5,18
Non-restricted shareholders' equity			
Share premium reserve		2,487,126	2,420,69
Retained earnings		(1,195,042)	(870,937)
Net loss for the period		(288,720)	(193,32)
Total non-restricted shareholders' equity		1,003,365	1,356,43
Total shareholders' equity	9,11	1,008,823	1,361,62
Non-current liabilities			
Provisions	11	4,209	5,02
Non-current interest-bearing liabilities	12	448,129	187,42
Other non-current liabilities		105	10
Total non-current liabilities		452,443	192,55
Current liabilities			
Accounts payable		44,217	70,38
Other current liabilities		139,699	21,37
Accrued expenses and deferred revenue		60,617	37,10
Total current liabilities		244,534	128,86
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,705,800	1,683,03

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 nine months ended September 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 November 14, 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 31-32.

Note 3 - Risks and Uncertainties in the Group and the Parent Operational Risks

Research and drug development up to approved registration is subject to a capital-intensive process. The majority of all initiated projects will never reach registration due to the technological risk such as the risk for insufficient efficacy, in or manufacturing problems. Competing pharmaceuticals can capture market faster, or if competing research projects achieve better product profile of the product portfolio may be lower than expected. The operations may be 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 name TARPEYO, which has been approved for marketing in the U.S under an accelerated approval under the brand name Kinpeygo, which has received conditional marketing authorisation and may undermine renewal of the current conditional marketing authorisation, commercialization

will not go according to plan or that the uptake of prescribing physicians will be lower than planned or that the drug will not have sufficient effect or show unwanted side effects may affect the sales negatively.

COVID-19

The COVID-19 virus has rapidly spread from an initial event and infections globally. Calliditas has clinical trial sites based in areas currently affected by COVID-19. Calliditas has not yet experienced any major disturbances in the trials. The extent of the coronavirus impacts the operations and the trials, or any planned trials for 2022 will depend on the type, degree and duration of the various restrictions put in place to prevent the spread of the virus or treat those affected. This today varies in different geographies, and cannot be predicted with reasonable assurance.

The pandemic may negatively impact our trials as a result of disruptions, supply chain, and inability of patients to access the trial sites and provide sample collections in the supply chain, which could result in delays and impact on the data. The impact of the coronavirus outbreak for Calliditas have been limited so far. The spread of the coronavirus globally, may negatively impact our operations, and could also negatively affect the operations of key governmental agencies, such as the EMA, which may delay the development of our product candidates, or could impact our suppliers to deliver components or raw materials on a timely basis, which 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 September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Type of goods or services					
Product sales	125,045	-	206,634	-	-
Outlicensing of product	135,012	198,167	163,816	198,167	225,252
Performance of certain regulatory services	-	-	3,387	-	4,095
Total	260,056	198,167	373,837	198,167	229,347
Geographical markets					
USA	123,400	-	204,989	-	-
Europe	136,656	198,167	140,044	198,167	201,878
Asia	-	-	28,804	-	27,469
Total	260,056	198,167	373,837	198,167	229,347

The Group's revenues for the three and nine months ended September 30, 2022, consist of net sales of TARPEYO in the U.S. and milestone fees from STAD approval and commercialization in Europe. Further for the nine months ended September 30, 2022, net sales also consisted of the milestone fee from Everest Medicines pursuant to the license agreement for South Korea.

Revenue from product sales is recognized at the transaction price of goods less rebates and returns. At the time of delivery, when the control of the goods is transferred to the customer, the revenue is recognized in full, as this represents the single performance obligation for the transaction. The customer is defined as the specialty pharmaceutical who distributes the product to the end user. As the final price is related to the rebate paid to the patients' physicians, the transaction price is not known upon delivery. This is accounted for by a liability for expected returns based on estimates of the amounts earned or to be claimed on the related sales. The Group estimates the liability for expected returns of obsolete medicines through a calculation model based on historical trends. As of September 30, 2022 the total liability for expected returns is SEK 17.2 million. In addition, there are no other performance obligations.

Revenue attributable to out-licensing Nefecon consisted of the agreement with Everest Medicines and the expansion of Everest Medicines to South Korea. Revenue for out-licensing of the product candidate Nefecon is recognized at the time of signing of the agreement with the counterparty, which was at the time when the agreements with both parties were signed. The remuneration (for example, attributable to future regulatory milestones) is recognized when the milestone or royalty event occurs. There is no longer any significant uncertainty as to whether these will occur. Compensation for sales-based milestones or royalties are not recognized until the sale that triggers the milestone or royalty arises.

Calliditas has identified three performance obligations under the agreement with Everest Medicines: 1) The obligation to supply Nefecon as is at the time of signing, 2) Co-perform the regulatory process with the EMA to obtain Conditional Marketing Authorization for Nefecon. The obligation to supply Nefecon. Calliditas has completed all the performance obligations under the agreement with STADA and Everest Medicines, except the supply of Nefecon to Everest Medicines, which is performed against order.

Note 5 - Related-Party Transactions

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

Note 6 - Intangible Assets

(SEK in thousands)	September 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	87,930	6,560	(7,498)
Cost at closing balance	515,323	441,451	427,393
Accumulated amortisation and impairment at closing balance	(27,975)	-	(27,975)
Net book value	487,348	441,451	399,418

Intangible assets consist of licenses and similar rights of SEK 441.2 million and goodwill of SEK 46.1 million as of September 30, 2022. As of September 30, 2021, intangible assets consist of licenses and similar rights of SEK 402.8 million and goodwill of SEK 38.6 million.

Note 7 - Deferred Tax Liabilities

(SEK in thousands)	September 30,	
	2022	2021
Cost at opening balance	30,857	37,451
Tax loss carried forward	(5,519)	(4,835)
Exchange difference on translation	9,000	691
Cost at closing balance	34,338	33,317

Tax loss carried forward of SEK 22.9 million have been offset against deferred tax assets in the statement of financial position as of September 30, 2022 due to future tax losses can be used to offset.

Note 8 - Financial Instruments

The Group's financial assets comprise of non-current financial assets, accounts receivable and cash, which are recognized at amortized cost. The Group's financial liabilities comprise of contingent consideration, non-current interest-bearing liabilities, lease liabilities 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 considerations are recognized at fair value, measured at Level 3 of the IFRS.

Note 9 - Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	September 30,	
	2022	2021
Total registered shares at the beginning of the period	52,341,584	49,941,584
New issue of shares during the period	6,816,003	2,400,000
Total registered shares at the end of the period	59,157,587	52,341,584
Shares		
Ordinary shares	59,157,587	52,341,584
Total	59,157,587	52,341,584
- of which shares are held by Calliditas	5,908,018	
Total registered shares at the end of the period, net of shares held by Calliditas	53,249,569	52,341,584
Share capital at the end of the period	2,366	2,094
Equity attributable to equity holders of the Parent Company	725,936	1,255,041
Non-controlling interests	-	27,951
Equity at the end of the period	725,936	1,283,000

(SEK in thousands, except per share amounts and number of shares)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Earnings/(loss) per share before dilution, SEK	(0.17)	0.21	(7.72)	(5.53)
Earnings/(loss) per share after dilution, SEK	(0.17)	0.21	(7.72)	(5.53)
Weighted-average number of ordinary shares outstanding for the period, before dilution	53,247,334	51,063,323	52,942,807	50,829,251
Weighted-average number of ordinary shares outstanding for the period, after dilution	53,247,334	51,561,201	52,942,807	50,829,251

Reserves for translation from foreign operations amounted to SEK 7.6 million and (SEK 1.9 million) which are included in retained earnings in equity as of September 30, 2022 and 2021.

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 nine months ended September 30, 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. The total number of issued shares as of September 30, 2022, is presented in Note 9.

Note 11 - Incentive Programs

	Warrants Outstanding	Options Outstanding	Share Award Outstanding
Incentive Programs			
Warrant program 2019/2022	422,500	-	
Board LTIP 2020	-	-	31,371
Board LTIP 2021	-	-	26,968
Board LTIP 2022	-	-	40,706
ESOP 2020	-	1,371,666	
ESOP 2021	-	1,490,000	
ESOP 2022	-	1,101,000	
Total Outstanding as of September 30, 2022	422,500	3,962,666	99,045

	Warrants Outstanding	Options Outstanding	Share Award Outstanding
Incentive Programs			
Warrant program 2018/2022	856,586	-	
Warrant program 2019/2022	422,500	-	
Board LTIP 2019	-	-	51,391
Board LTIP 2020	-	-	31,371
Board LTIP 2021	-	-	26,968
ESOP 2020	-	1,455,000	
ESOP 2021	-	850,000	
Total Outstanding as of September 30, 2021	1,279,086	2,305,000	109,731

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, 2022.

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, 2023.

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)	September 30,	
	2022	2021
Opening balance	189,164	
New borrowings	236,584	199,524
Transaction costs	-	(14,858)
Interest expense	3,633	944
Exchange difference on translation	18,748	1,811
Closing balance	448,129	187,422

In July 2021, Calliditas signed a loan agreement of up to the euro equivalent with Kreos Capital. The loan facility is divided into three tranches of USD 25 million. 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 tranche can be made until December 31, 2022, and will be available subject to certain metrics. The interest rate on the loan is 9% per annum with a maturity to December 31, 2023. The loan is recognized at Net financial income/(expenses). The loan has no financial c

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 was thereafter finalized in 2021. The fair value of the acquisitions of Calliditas Therapeutics Suisse S.A 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)	Nine Months Ended September 30,			2021	Year Ended December	
	2021	Adjustment	Re-classification		2021	Re-classification
Net sales	198,167	-	-	198,167		229,347
<i>Operating expenses</i>						
Research and development expenses	(257,194)	-	-	(257,194)		(357,485)
Marketing and selling expenses	-	-	(108,965)	(108,965)		-
Administrative expenses	(238,522)	-	108,965	(129,557)		(390,232)
Other operating income/expenses	(4,773)	-	-	(4,773)		(6,085)
Operating loss	(302,323)	-	-	(302,323)		(524,456)
Net financial income/(expenses)	7,417	-	-	7,417		11,083
Loss before income tax	(294,906)	-	-	(294,906)		(513,373)
Income tax	11,415	(7,380)	-	4,035		3,836
Loss for the period	(283,491)	(7,380)	-	(290,871)		(509,537)

NOTES

The below table describes the adjustment for the nine months ended September 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)	September 30,		2021
	2021	Adjustment	
ASSETS			
Non-current assets			
Other intangible assets	436,664	(33,821)	402,843
Goodwill	48,022	(9,414)	38,608
Other non-current assets	27,819	-	27,819
Total non-current assets	512,505	(43,235)	469,271
Current assets	1,256,159	-	1,256,159
TOTAL ASSETS	1,768,664	(43,235)	1,725,430
EQUITY AND LIABILITIES			
Equity			
Share capital	2,094	-	2,094
Additional paid in capital	2,451,979	-	2,451,979
Retained earnings, including net loss for the period	(1,192,224)	(6,802)	(1,199,026)
Equity attributable to equity holders of the Parent Company	1,261,849	(6,802)	1,255,047
Non-controlling interests	28,677	(720)	27,957
Total equity	1,290,526	(7,522)	1,283,004
Non-current liabilities			
Deferred tax liabilities	69,025	(35,713)	33,312
Other non-current liabilities	269,042	-	269,042
Total non-current liabilities	338,067	(35,713)	302,354
Current liabilities	140,072	-	140,072
TOTAL EQUITY AND LIABILITIES	1,768,664	(43,235)	1,725,430

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 adjusting the weighted average number of common share outstanding to assume conversion of all dilutive potential common shares 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 financial statements to analyse the portion of total operating 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 total assets financed by shareholders.

Reconciliations of Alternative Performance Measures

(SEK in thousands or otherwise indicated)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development expenses/Total operating expenses in %				
Research and development expenses	(102,877)	(92,098)	(312,510)	(257,194)
Marketing and selling expenses	(116,135)	(31,171)	(323,303)	(108,965)
Administrative expenses	(71,003)	(64,200)	(178,441)	(129,558)
Other operating income/expenses	(1,946)	(2,842)	(6,699)	(4,773)
Total operating expenses	(291,961)	(190,311)	(820,953)	(500,490)
Research and development expenses/Total operating expenses in %	35%	48%	38%	51%

(SEK in thousands or otherwise indicated)	September 30,	
	2022	2021
Equity ratio at the end of the period in %		
Total shareholders' equity at the end of the period	725,936	1,255,041
Total assets at the end of the period	1,518,106	1,725,430
Equity ratio at the end of the period in %	48%	73%

Financial Calendar

Year-End Report for the period January 1 - December 31, 2022

February 23, 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 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 as of the date they are made. Calliditas disclaims any obligation to publicly update statements to reflect any change in expectations or in events, conditions or circumstances, or that 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 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 the event of differences between the two, the Swedish version shall apply.

calliditas
THERAPEUTICS



Stockholm, Sweden

November 14, 2022

Interim Report Q3, 2022

Conditional Marketing Authorization in EU Granted for Kinpegyo®

“On July 15th the European Commission issued the conditional marketing authorization for Kinpegyo, which marked the first time that any drug has achieved approval for this rare disease in EU. We immediately started the process of transferring the market authorization to our European partner, STADA Arzneimittel AG, in order to enable a launch in Europe as quickly as possible. STADA is initially launching the product in Germany, with other European countries to follow over time.

With approval and commercial efforts now ongoing in both the US and Europe, we are looking forward to the regulatory process in China, where our partner, Everest Medicines, expects to receive NDA acceptance notice from NMPA this quarter. We are excited to support Everest as they work with regulators in China, who are expected to reach a decision regarding a potential approval in the second half of next year. If Nefecon is approved, this would be the first and only approved medication for the by Everest estimated 5m biopsy-proven IgAN patients in China.

In the US, we continue to build on our early commercial success. Net sales from TARPEYO grew by 94% when compared to Q2, resulting in net sales from TARPEYO of SEK 123.4 million (\$12.1m) for Q3. There is a growing number of nephrologists choosing to prescribe TARPEYO, with 166 new prescribers added in Q3, bringing total unique prescribers to 480 at the end of the quarter. We continue to see a continuous build of interest which mirrors the natural cadence of nephrology visits, which aligns with our expectations regarding this fairly silent, progressive disease. We expect to achieve net sales from TARPEYO for the year of between \$35 – 40m, which aligns with our internal plans for 2022. We also expect to see significant continued growth in 2023 as nephrologists become more familiar with the clinical data, access becomes more streamlined, and as topline data from the Part B of the NefIgArd trial becomes available.

We were delighted to be able to have the Part A data published in *Kidney International* in October, 2022, as regulators also posted their review assessments. This data set, showing increasing reduction of proteinuria across the entire patient population during the 9 months on drug as well as significant continued reduction of proteinuria across the entire study population in the following 3 months when no drug was administered, showing a highly differentiated profile. The significance of this data was further confirmed by countless interactions at the American Society of Nephrology (ASN) Kidney Week in early November, where we had the opportunity to engage not only with KOLs but with the broader nephrology community treating IgAN patients.”

CEO Renée Aguiar-Lucander

Summary of Q3 2022**July 1 - September 30**

- Net sales amounted to SEK 260.1 million, whereof TARPEYO® net sales amounted to SEK 123.4 million, for the three months ended September 30, 2022. For the three months ended September 30, 2021 net sales amounted to SEK 198.2 million and no TARPEYO net sales were recognized.
 - Operating profit/(loss) amounted to (SEK 36.2 million) and SEK 7.9 million for the three months ended September 30, 2022 and 2021, respectively.
 - Earnings/(loss) per share before and after dilution amounted to (SEK 0.17) and SEK 0.21 for the three months ended September 30, 2022 and 2021, respectively.
 - Cash amounted to SEK 736.2 million and SEK 1,163.8 million as of September 30, 2022 and 2021, respectively.
-

Significant events during Q3 2022, in summary

- 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 EU. Kinpeygo will be marketed in the European Economic Area (EEA) exclusively by STADA Arzneimittel AG. Subsequently, in September 2022, Calliditas transferred its Market Authorization for Kinpeygo to its European commercial partner, STADA Arzneimittel AG, who will initially launch in Germany, with additional European countries to follow.

Investor Presentation November 14, 2022 14:00 CET

Audio cast with teleconference, Q3 2022

Webcast: <https://ir.financialhearings.com/calliditas-therapeutics-q3-2022>

Teleconference: SE: +46850558350 UK: +443333009265 US: +16467224956

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The information in the press release is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the contact persons set out above, on November 14, 2022 at 07:00 a.m. CET.

About Calliditas

Calliditas Therapeutics is a commercial stage biopharma company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. Calliditas' lead product, developed under the name Nefecon, has been granted accelerated approval by the FDA under the trade name TARPEYO[®] and conditional marketing authorization by the European Commission under the trade name Kinpeygo[®]. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, setanaxib. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, commercialization efforts, business plans, regulatory submissions, clinical development plans, revenue and product sales projections or forecasts and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, continued and additional regulatory approvals for TARPEYO and Kinpeygo, market acceptance of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.
