Q1 2023

INTERIM REPORT JANUARY 1ST – MARCH 31ST 2023

calliditas THERAPEUTICS

Strong eGFR Data from Positive NefIgArd Phase 3 Trial Readout

Financial Summary For the Group

Key Figures

January 1 - March 31 2023

- Net sales amounted to SEK 191.4 million, of which TARPEYO® net sales amounted to SEK 185.7 million, for the three months ended March 31, 2023. For the three months ended March 31, 2022 net sales amounted to SEK 49.7 million, of which TARPEYO net sales amounted to SEK 18.0 million.
- Operating loss amounted to SEK 180.1 million and SEK 208.4 million for the three months ended March 31, 2023 and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 3.49 and SEK 3.95 for the three months ended March 31, 2023 and 2022, respectively.
- Cash amounted to SEK 1,013.6 million and SEK 825.4 million as of March 31, 2023 and 2022, respectively.

Investor Presentation May 16, 2023 14:30 CET

Audio cast with teleconference, Q1 2023.

Webcast: https://ir.financialhearings.com/calliditas-therapeutics-q1-2023

Teleconference: https://conference.financialhearings.com/teleconference/?id=200781

Significant Events in Q1 2023, in Summary

In February 2023, Calliditas announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom granted Conditional Marketing Authorization (CMA) for Kinpeygo® for the treatment of primary immunoglobulin A (IgA) nephropathy in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram. Kinpeygo became the first and only approved treatment for IgAN in the UK.

In March 2023, Calliditas announced positive topline results from the global, randomized, double-blind, placebo-controlled Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon (TARPEYO®/Kinpeygo® (budesonide) delayed release capsules) versus placebo in patients with primary IgA nephropathy. The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in kidney function measured by estimated glomerular filtration rate (eGFR) over the two-year period of 9-months of treatment and 15-months of follow-up off drug.

Key Takeaways:

- In March the global NefIgArd Phase 3 trial successfully met its primary endpoint, estimated glomerular filtration rate (eGFR) with a p value < 0.0001. Also, supportive 2-year total slope analyses were statistically significant and clinically meaningful reflecting a sustained treatment benefit. The eGFR benefit was observed across the entire study population, irrespective of urine protein-to-creatinine ratio (UPCR) baseline, which the company believes supports a regulatory filing with the FDA, planned for July 2023, for full approval in the study population.
- In the first quarter of 2023, a record level of 408 new enrollments were generated, reflecting a growth of over 30% from Q4, 2022.
- The growth in unique prescribing nephrologists was also the highest to date with 276 new prescribers in Q1, resulting in a total of 918 unique prescribers since launch.

2023 Outlook Unchanged

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

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

Strong Phase 3 results support disease modification in IgAN

In March we announced that the global NefIgArd Phase 3 trial successfully met its primary endpoint, estimated glomerular filtration rate (eGFR), with a p value < 0.0001. Achieving this clinically relevant endpoint of kidney filtration capability represents a crowning achievement after well over a decade of pioneering work in IgA nephropathy. Nefecon, commercially available in the US and Europe under the brand name TARPEYO® and Kinpeygo® respectively, indeed seems to be disease modifying, having shown both immediate and enduring kidney protective capability, with the treatment effect remaining intact even after 15 months off drug. In addition, the trial showed a significant proteinuria (UPCR) reduction of 34% versus optimized and stable standard of care at 9 months, and importantly also demonstrated that the proteinuria reduction was durable with similar levels recorded even after patients were off drug for 15 months. These benefits and the durability of treatment were observed across the entire study population, irrespective of UPCR levels.

» We are planning to file for full approval of the entire study population with the FDA in July, which would enable a regulatory decision in the first half of 2024.«

This highly differentiated approach, of targeting the origin of the disease with a locally active treatment that focuses on the production of secretory galactose-deficient IgA1, has generated what we believe is groundbreaking data showing a truly unique and impressive impact on eGFR. We are confident this data will not only impact clinical practice but also provide hope for the thousands of patients for whom there has been no appropriate medication to address their continued progression towards end stage renal disease.

We are planning to file for full approval of the entire study population with the FDA in July, which would then enable a regulatory decision in the first half of 2024. The exact timing of this decision is dependent on whether the process would be conducted under priority or standard review. We are also expecting our European partner, STADA, to file for full approval in Europe in the second half of 2023. We plan to share clinical data from the Phase 3 trial during the year at conferences such as ERA/EDTA, where we have two oral presentations and an abstract accepted, as well as at IIGANN and ASN later in the year. We look forward to sharing our data with nephrologists and to working with KOLs to explore and understand the appropriate use of TARPEYO in a clinical setting based on the kidney results observed.

In the US, we reported a record of 408 enrollments for the quarter, reflecting a weak January but a strong March. As the published interim data continues to become better known and understood throughout the broader nephrology community, we expect this trend of increased enrollments to continue over the year and to build towards our revenue guidance of USD 120-150 million for 2023. We are hearing more patient success stories from the field and, for the overall patient population, we have observed a varying duration of therapy, including that the majority of patients who have completed 9 months of treatment remain on drug. We believe that this reflects the attractive risk/reward profile of TARPEYO when used appropriately in clinical practice.

Total Q1 revenues were SEK 191.4 million, of which net revenues from TARPEYO amounted to SEK 185.7 million (USD 17.8 million). The growth in unique prescribing nephrologists was the highest to date with 276 new prescribers in Q1. We continue to be immensely proud to be able to support the patient community with a drug which we believe has been proven to be disease modifying, thereby providing an ability to significantly delay the need for patients to undergo dialysis treatment. Our cash position remains strong with SEK 1,013.6 million on the balance sheet, which we believe will be sufficient to take us to profitability. The positive clinical data from the full NefIgArd trial may provide additional momentum to uptake during the year as the data becomes better known and understood by nephrologists, though any commercial promotion would only be possible following a regulatory approval and updated label, which we would expect to take place in 2024.

We are still on track to report out biomarker data from the setanaxib head and neck cancer trial around mid-year 2023 as previously disclosed. We are also excited to start our trial in Alport syndrome, a renal orphan disease for which there is no FDA or EMA approved drug today and where there is a substantial unmet medical need. Our expectation is that the trial would start in the second half of 2023 and would enroll around 20 patients. We continue to explore additional renal indications for which we believe that setanaxib may have a beneficial effect based on its mode of action.

We look forward to continuing our commercial, regulatory and clinical work throughout this year and beyond, and are excited about what we believe we can achieve in the remainder of 2023.

Renée Aguiar-Lucander, CEO

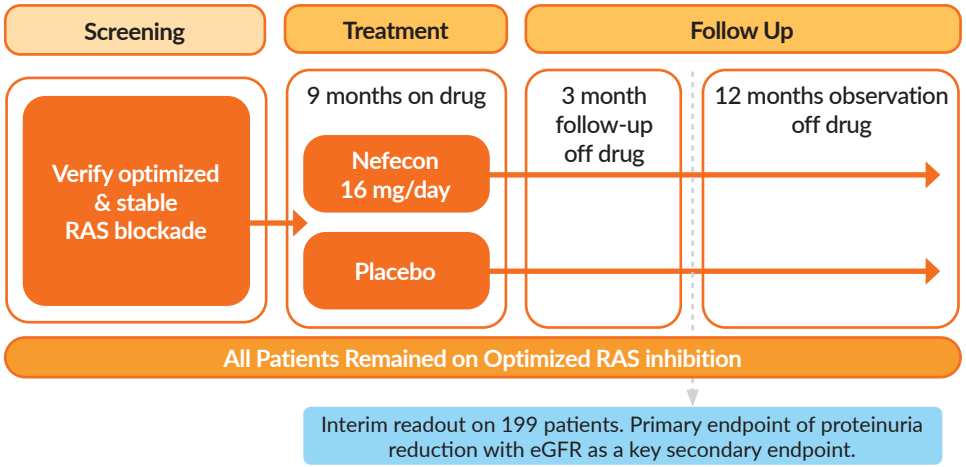
The NefIgArd Phase 3 Trial

In March 2023, Calliditas read out topline data from the pivotal Phase 3 NefIgArd trial, which met its primary endpoint by demonstrating a highly statistically significant benefit in estimated glomerular filtration rate (eGFR). NefIgArd is the first Phase 3 trial specifically designed for IgA nephropathy to show a statistically significant and clinically relevant kidney protective effect as measured by eGFR.[1]

NefIgArd Trial Design

Calliditas' regulatory filings with the FDA and European Medicines Agency (EMA) were based on positive data from the interim readout of the NefIgArd pivotal Phase 3 study, which read out topline data in November 2020. NefIgArd is a pivotal, global Phase 3 trial consisting of two read-outs. An interim readout provided data on the efficacy and safety of Nefecon in 199 patients. The primary endpoint was the effect of Nefecon on urine protein-to-creatinine ratio (UPCR, otherwise known as proteinuria) over 9 months compared to placebo, and a key secondary endpoint was change in estimated glomerular filtration rate (eGFR), a true measure of kidney function. These data were published in Kidney International in October 2022, and can be accessed here.

The full Phase 3 NefIgArd trial, meanwhile, included a post-market approval observational period to confirm long-term renal protection. The endpoint of the Phase 3 trial assessed the difference in kidney function between treated and placebo patients, as measured by eGFR, over a two-year period from the start of dosing of each patient. The 364-patient population of the Phase 3 trial included a further 165 patients enrolled in addition to the 199 patients from the interim readout. The full NefIgArd trial read out positive topline data in March 2023, meeting its primary endpoint by demonstrating a highly statistically significant benefit in eGFR of Nefecon over placebo after 9-months of treatment and 15-months of follow-up off drug.



Baseline Characteristics

	Full Patient Population (N=364)
Age (years) (Median, [range])	43 [20, 73]
Sex (n, % male)	240 (66%)
Race (n, % White)	275 (76%)
(n, % Asian)	83 (23%)
Systolic BP/Diastolic BP (Median)	125/79
UPCR (g/gram) (Median)	1.26
eGFR CKD-EPI (mL/min/1.73 m²) (Median)	55.5

Base inclusion criteria:

- Biopsy proven IgAN; >1 gram of proteinuria; >35 eGFR <90 mL/min
- Patients were required to have well-controlled blood pressure of <140/90 mmHg to enter into the study, to ensure no BP confounding effects on proteinuria reduction
- No immunosuppressive drugs were permitted during the study; changes to anti-hypertensive medications were discouraged

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

The NeflgArd Phase 3 Trial: Topline Readout

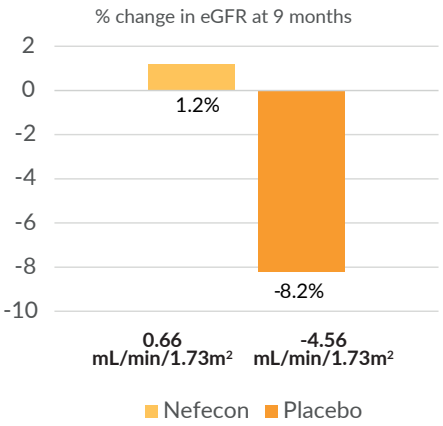
eGFR Data:

The primary endpoint of the Phase 3 trial was a time-weighted average of eGFR observed at each time point over two years. The primary endpoint was met, and over the two-year period of treatment and observation, the mean decline in eGFR was 2.47 mL/min/1.73 m^2 for patients who received Nefecon compared with 7.52 mL/min/1.73 m^2 for patients who received placebo, a result that was highly statistically significant. On average, over the two-year period, there was therefore a 5.05 mL/min/1.73 m^2 eGFR treatment benefit in favor of Nefecon compared to placebo ($p<0.0001$).

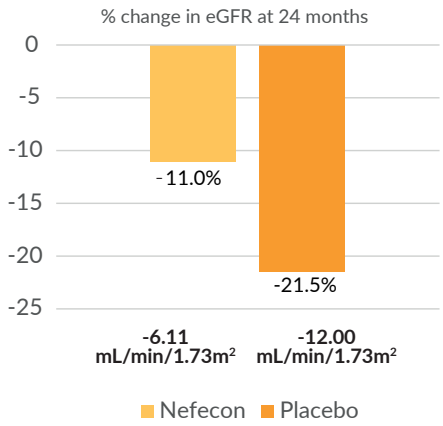
In placebo-treated patients, after 9 months there was a decline in eGFR of 8.2%, corresponding to a loss of 4.56 mL/min/1.73 m^2. Meanwhile, in Nefecon-treated patients, eGFR was stable compared to baseline at 9 months, increasing by, reflecting a slight increase in eGFR of 0.66 mL/min/1.73 m^2.

At 24 months, after 9 months of treatment and 15 months of observation, the eGFR decline for placebo-treated patients was 21.5%, corresponding to a loss of 12 mL/min/1.73 m^2. For those patients dosed with Nefecon the eGFR decline was 11%, corresponding to a 6 mL/min/1.73 m^2 decline in eGFR. Therefore, 9 months of dosing with 16mg Nefecon in 364 patients resulted in 50% less loss of kidney function vs placebo at 24 months after a treatment of only 9 months.

Impact on eGFR at 9 months



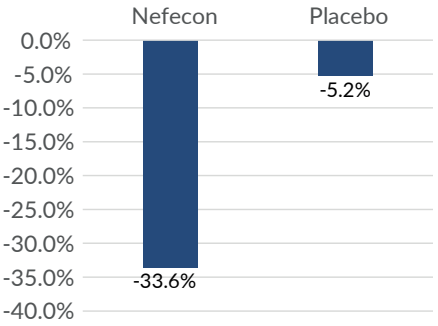
Impact on eGFR at 24 months



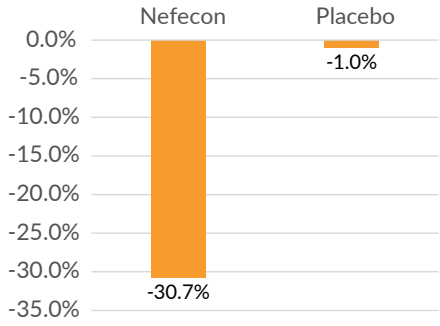
Proteinuria Data:

There was a cumulative improvement in proteinuria in patients treated with Nefecon versus placebo during the 9-month treatment period, which continued to significantly improve at 12 months. At month 24, proteinuria levels in patients who had received Nefecon were still at a reduced level, similar to that observed at the 9-month time point, reflecting the durability of the proteinuria reduction of a 9 month course of treatment.

Proteinuria (UPCR) at 9 months



Proteinuria (UPCR) at 24 months



Safety Profile:

Nefecon was generally well tolerated, and the adverse event profile was similar to that reported at the time of the interim results. The majority of the treatment emergent adverse events (TEAEs) were mild or moderate severity. The most commonly reported TEAEs observed with an increased frequency compared to placebo were peripheral oedema, hypertension, muscle spasms, and acne. Objective measures of mean weight and BP showed non-clinically relevant, fully reversible changes, and TEAEs led to discontinuation of study drug in fewer than 10% of Nefecon-treated patients.

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 (EC) in July 2022, was the first ever approved medication for IgAN and the only treatment specifically designed to target the origin of the autoimmune kidney disease IgA nephropathy (IgAN) with a view to be disease modifying.

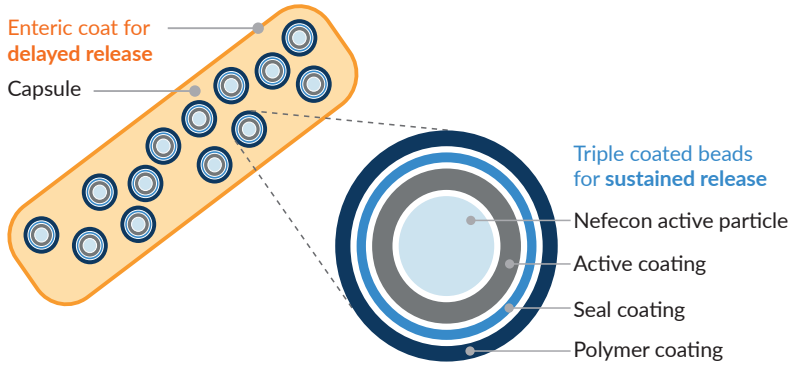
IgAN is a serious progressive disease, in which up to 50% of patients end up at risk of developing end-stage renal disease (ESRD) within ten to twenty years. This product, which was developed under the name Nefecon, is approved under the brand name TARPEYO® in the United States and under the brand name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

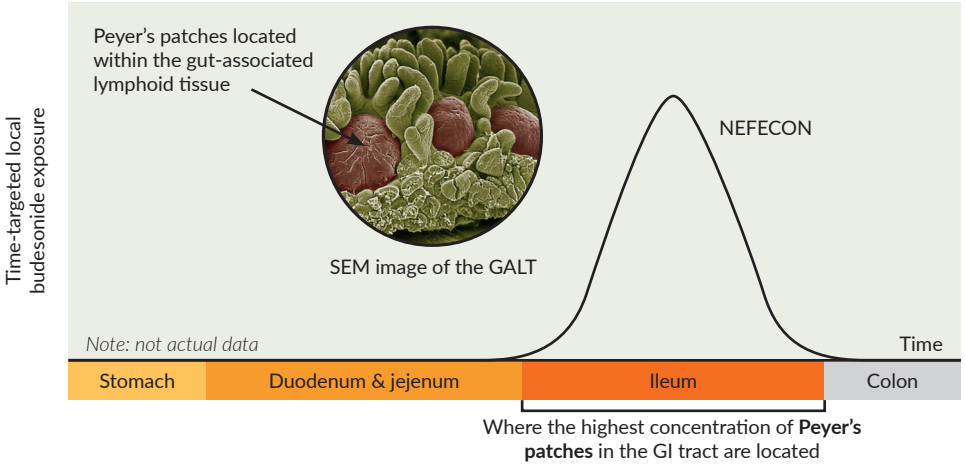
Disease Background

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 poly-meric 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.

Calliditas' lead product is an oral, delayed release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism, resulting in limited systemic exposure. It was designed as a 4 mg delayed release capsule with an enteric coating so that it remains intact until it reaches the ileum. Each capsule contains beads coated with various polymers and budesonide designed to target the area with the highest concentration of Peyer's patches, with the intention of having a disease-modifying effect.





A quarter of record TARPEYO enrollments

In the first quarter of 2023, our commercial team continued to interact with nephrologists to build on the successful first year of launch. We are encouraged by the patient and physician enthusiasm for our product and by the progress we have made in our work to bring the first approved medication to patients with IgA nephropathy.

In the first quarter of 2023, our specialty sales force generated a record level of 408 new enrollments, reflecting a growth of over 30% from Q4, 2022. Q1 also saw a record quarter of new prescribing physicians, with 276 new prescribers. Net sales of TARPEYO were USD 17.8 million (SEK 185.7 million), reflecting a weak January offset by a record month in March. The expanded commercial sales team continued to gain access to key nephrologists with an increase in reach and frequency, while patients continued to be guided through the enrollment and procurement process with the support of our patient services program, TARPEYO Touchpoints™. This white glove service program assists physicians and patients via a dedicated Rare Pod Team – including Care Navigators, nurses, pharmacists, and a fulfilment and distribution team. This quarter, we further expanded the TARPEYO Touchpoints Care Team with an additional nurse and Care Navigator due to the increased patient load.

In the first quarter, 85% of the patients enrolled in TARPEYO Touchpoints, excluding those that are waiting for an insurance decision, received TARPEYO. The channel mix of patients on therapy to date remains primarily commercial plans, approximately 70%, with the majority of the remaining 30% on government subsidized plans. The commercial team continues to focus on improving the average time-to-fill rate to exceed industry standards. Regarding duration of therapy, though variable, as we see more patients completing 9 months on treatment we observe that a majority of these patients remain on therapy beyond 9 months, which we believe reflects the risk/reward profile of the product. This quarter we also expanded our Field Reimbursement Managers team, as planned, to complement TARPEYO Touchpoints and to keep pace with increased patient enrollments.

Market research conducted with nephrologists demonstrated the effectiveness of our educational and promotional programs. The awareness of TARPEYO has continuously increased and is now greater than 90%. Close to 80% of nephrologists stated that IgAN is an autoimmune disease and requires an immunomodulating treatment and the majority of nephrologists agreed that targeting Peyer's patches, a major source of Gd-IgA1, is an important treatment goal for IgAN.

Educating healthcare providers and patients on the clinical value of TARPEYO continues to be an important strategic priority for 2023. Throughout the quarter, our commercial team continued to engage KOLs in peer-to-peer programs and initiatives to provide education on IgAN and TARPEYO. Our medical team also launched IgA Nexus (iganexus.com), an educational site developed in collaboration with nephrology and immunology experts who are focused on advancing peer-to-peer scientific education in IgA nephropathy.

The first quarter was filled with opportunities to discuss TARPEYO with nephrologists at local and regional congresses, such as the Southwest Nephrology & Cardiology Conference, the Renal Physicians Association (RPA), the Mayo Clinic, and others. We look forward to continuing these conversations with nephrologists at the ERA/EDTA congress in June, which will also afford us the opportunity to discuss additional data accepted for presentations from the NefIgArd Phase 3 trial.

Finally, we have continued to engage with the IgAN patient community and advocacy organizations and support IgAN patients, who are at the core of our commercial activities. Calliditas continued to provide both patient education on disease awareness and brand-specific education about TARPEYO through the IgANConnect platform, and we have also educated on TARPEYO through personal interactions such as a live presentation to patients. In January, we partnered with the American Association of Kidney Patients (AAKP) to hold the first TARPEYO patient educational webinar with Dr. Jonathan Barratt, who discussed IgAN disease and what to expect when on TARPEYO. We also drove connections within the community through our celebrations of Kidney Awareness Month in March. This quarter we started an IgAN ambassador program to conduct patient-to-patient education and drive disease awareness. We look forward to continuing our work with IgAN patients as we strive to address their unmet medical needs.

Our Commercial Partnerships

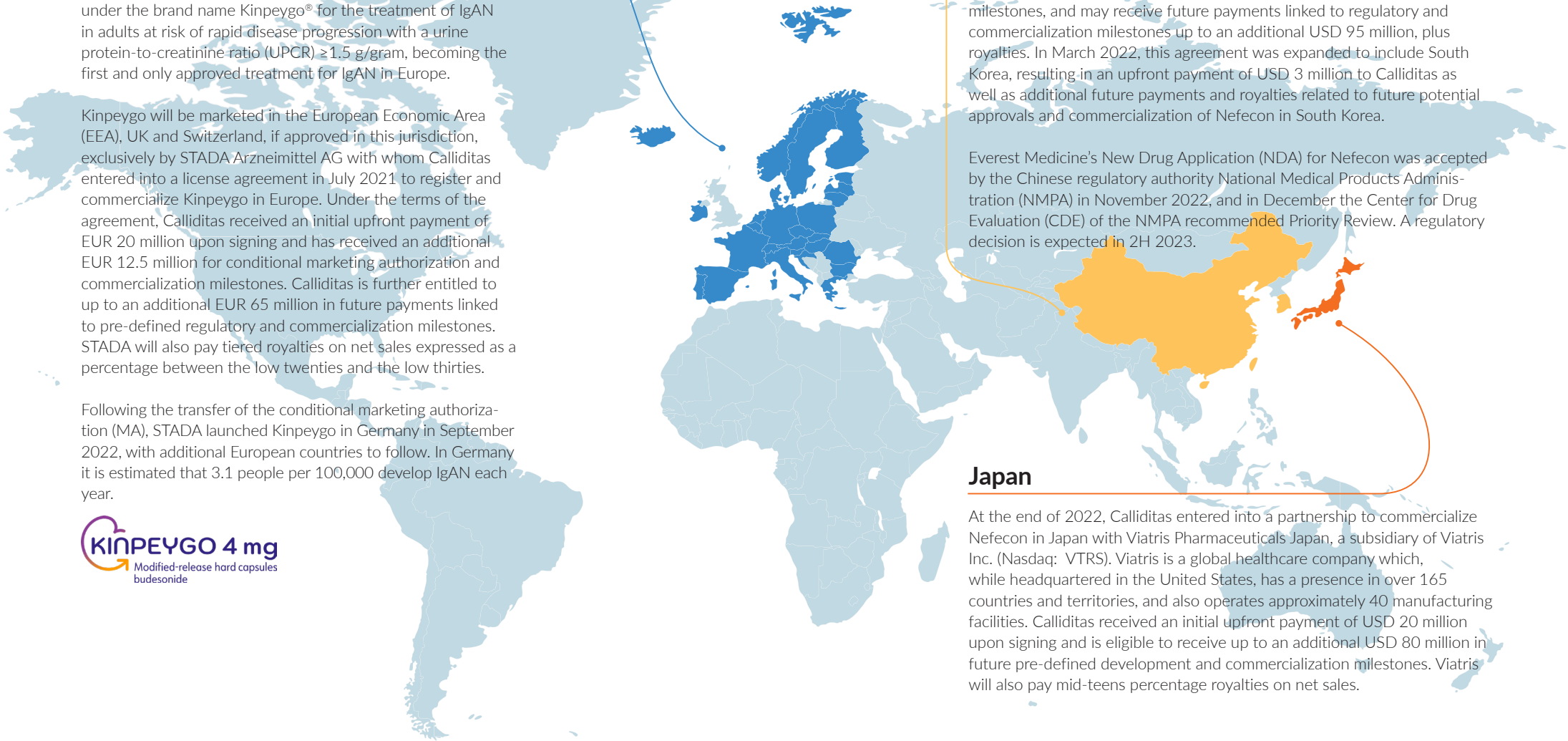
Europe

Nefecon was granted conditional marketing authorization (CMA) by the European Commission in July 2022, and subsequently by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom in February 2023, under the brand name Kinpeygo® for the treatment of IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram, becoming the first and only approved treatment for IgAN in Europe.

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

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

KINPEYGO 4 mg
Modified-release hard capsules
budesonide



Greater China

Calliditas entered into a license agreement to develop and commercialize Nefecon for IgAN in China and Singapore with Everest Medicines (HKEX 1952.HK) in 2019. Calliditas received an initial upfront payment of USD 15 million upon signing, and has received USD 13 million in additional milestones, and may receive future payments linked to regulatory and commercialization milestones up to an additional USD 95 million, plus royalties. In March 2022, this agreement was expanded to include South Korea, resulting in an upfront payment of USD 3 million to Calliditas as well as additional future payments and royalties related to future potential approvals and commercialization of Nefecon in South Korea.

Everest Medicine's New Drug Application (NDA) for Nefecon was accepted by the Chinese regulatory authority National Medical Products Administration (NMPA) in November 2022, and in December the Center for Drug Evaluation (CDE) of the NMPA recommended Priority Review. A regulatory decision is expected in 2H 2023.

Japan

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

Pipeline: NOX Inhibitor Platform

Calliditas' pipeline contains development programs based on a first-in-class, novel NOX inhibitor platform. The lead compound setanaxib is the first NOX inhibitor to reach the clinical trial stage and is a selective NOX 1 and NOX 4 inhibitor. Calliditas is presently running trials with setanaxib in Primary Biliary Cholangitis (PBC) and in Squamous Cell Carcinoma of the Head & Neck (SCCHN), and is planning to start a clinical trial in Alport syndrome in the second half of 2023.

NOX Enzymes

NOX enzyme inhibitors are a set of promising novel experimental drugs in a new therapeutic class, recognized by the WHO since 2019 when it approved "naxib" as a new stem. Nicotinamide adenine dinucleotide phosphate (NADPH) oxidases, otherwise known as NOX enzymes, are the only known enzymes that are solely dedicated to produce reactive oxygen species (ROS) as their primary and sole function. They are transmembrane enzymes that transfer electrons from NADPH in the cytoplasm across the cell membrane, which results in the formation of ROS.

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

Setanaxib in Primary Biliary Cholangitis

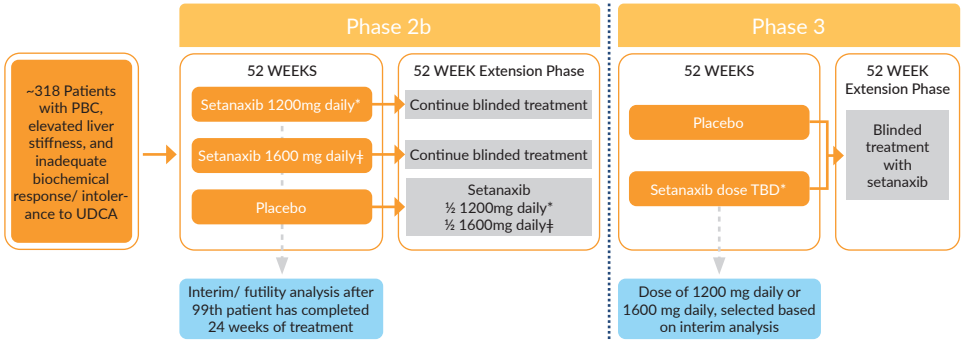
PBC is a progressive and chronic autoimmune disease of the liver that causes a cycle of immune injury to biliary epithelial cells, resulting in cholestasis and fibrosis. It is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 140,000 patients in the US, where the annual incidence ranges from 0.3 to 5.8 cases per 100,000.

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

However, despite these treatment options, there is still an unmet medical need among PBC patients, in particular when it comes to important quality of life outcomes.

Calliditas has initiated a pivotal 52-week, randomized, placebo-controlled, double-blind, trial with an adaptive Phase 2b/3 design.

Setanaxib will be administered to approximately 318 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to UDCA in a global trial conducted at up to 150 investigational centers. The primary endpoint is ALP reduction, with key secondary endpoints including change in liver stiffness, and effect on pruritus (itching) and fatigue. An interim analysis is planned to be conducted once the 99th randomized patient has completed the week 24 visit, which is expected in H1 2024, subject to recruitment, which continues to be challenging.



*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

In August 2021, Calliditas received FDA Fast Track Designation for setanaxib in PBC.

Pipeline: NOX Inhibitor Platform

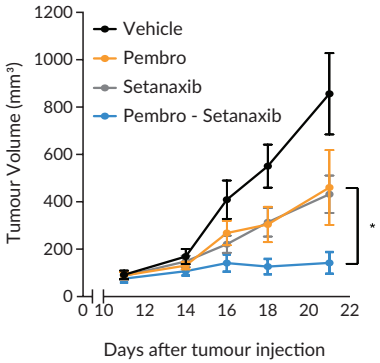
Setanaxib in Squamous Cell Carcinoma of the Head & Neck

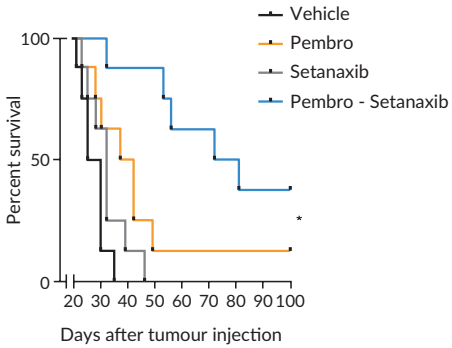
Calliditas also intends to evaluate setanaxib in head and neck cancer, building on promising in vivo preclinical data that suggests that setanaxib could function as an adjunct therapy to immune-oncology therapies. The response to immuno-oncology therapies can be affected by the tumor microenvironment, in particular by the numbers of tumor-infiltrating lymphocytes (TILs) and cancer-associated fibroblasts (CAFs) in the tumor. A relationship between 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 tumors, 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 tumor model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:

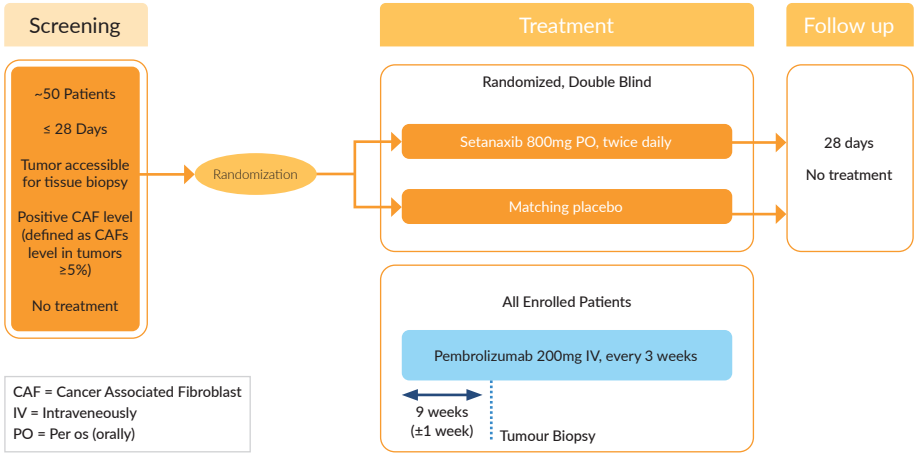
- Improved penetration of TILs into the centre of the tumor
- Slowing of tumor growth and improved survival





Proof-of-concept study in head and neck cancer

Calliditas is conducting a double-blind, randomized, placebo-controlled, proof-of-concept Phase 2 study, which will investigate the effect of setanaxib 800mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks, in approximately 50 patients with relapsed or metastatic SCCHN and tumors with moderate or high levels of CAFs. A tumor biopsy will be taken prior to randomization and again after approximately 9 weeks of treatment. Treatment will continue until unacceptable toxicity or disease progression, in keeping with standard practice for oncology trials.



An interim analysis is targeted for mid 2023, subject to recruitment rate, and final data readout is expected in 2024.

Alport syndrome

Based on significant and supportive pre-clinical work, Calliditas has decided to launch a randomized, placebo controlled clinical trial in Alport syndrome involving around 20 patients. We would expect the study to be initiated in 2H of 2023 and on the basis of the data readout, which would reflect overall safety as well as impact on proteinuria, we would decide on a full regulatory program.

Our Pipeline

Rights	Commercial region	Upcoming milestones
calliditas THERAPEUTICS	United States	File for regulatory approval in the US – around July 2023
STADA	European Economic Area, UK, Switzerland	Support STADA EMA filing in 2023
EVEREST MEDICINES	China, Hong Kong, Macau, Taiwan, Singapore, South Korea	NDA accepted and FTD received in China. Decision expected in 2H 2023
VIATRIS	Japan	
calliditas THERAPEUTICS	Global	Interim Analysis: 1H 2024 (subject to recruitment)
calliditas THERAPEUTICS	Global	Interim Data Readout: Mid 2023 (subject to recruitment)
calliditas THERAPEUTICS	Global	
calliditas THERAPEUTICS	Global	Trial launch in 2H 2023

* Approved in the United States under accelerated approval, under the brand name TARPEYO® (budesonide) delayed release capsules to reduce the levels of protein in the urine (proteinuria) in adults with primary IgA nephropathy who are at high risk of rapid disease progression, generally urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g and granted conditional marketing authorization by the European Commission, under the brand name Kinpeygo® for the treatment of primary IgA nephropathy in adults at risk of rapid disease progression with a (UPCR) ≥1.5 g/g.

Significant Events

Significant Events During the Period January 1 – March 31, 2023

- In February 2023, Calliditas announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom granted Conditional Marketing Authorization (CMA) for Kinpeygo® for the treatment of primary immunoglobulin A (IgA) nephropathy in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram. Kinpeygo became the first and only approved treatment for IgAN in the UK.

- In March 2023, Calliditas announced positive topline results from the global, randomized, double-blind, placebo-controlled Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon (TARPEYO®/Kinpeygo® (budesonide) delayed release capsules) versus placebo in patients with primary IgA nephropathy. The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in kidney function measured by estimated glomerular filtration rate (eGFR) over the two-year period of 9-months of treatment and 15-months of follow-up off drug.

Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Year Ended December 31, 2022
Net sales	191,352	49,734	802,879
Operating loss	(180,074)	(208,367)	(421,943)
Loss before income tax for the period	(208,019)	(211,434)	(409,417)
Loss per share before and after dilution (SEK)	(3.49)	(3.95)	(7.78)
Cash flow used in operating activities	(231,940)	(191,423)	(311,354)

(SEK in thousands, except per share amount or as otherwise indicated)	March 31, 2023	March 31, 2022	December 31, 2022
Total registered shares, including shares held by Calliditas, at the end of the period	59,580,087	53,172,170	59,580,087
Equity attributable to equity holders of the Parent Company at the end of the period	589,403	871,142	766,264
Equity ratio at the end of the period in %	33%	65%	39%
Cash at the end of the period	1,013,600	825,409	1,249,094

January – March 2023

Revenue

Net sales amounted to SEK 191.4 million and SEK 49.7 million for the three months ended March 31, 2023 and 2022, respectively. Net sales for the three months ended March 31, 2023, primarily originated from net sales of TARPEYO in the U.S. Net sales from TARPEYO amounted to SEK 185.7 million for the three months ended March 31, 2023. For additional information see Note 4.

Cost of Sales

Cost of sales amounted to SEK 9.0 million and SEK 0.6 million for the three months ended March 31, 2023 and 2022, respectively.

Total Operating Expenses

Total operating expenses amounted to SEK 362.4 million and SEK 257.5 million for the three months ended March 31, 2023 and 2022, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 126.7 million and SEK 113.3 million for the three months ended March 31, 2023 and 2022, respectively. The increase of SEK 13.4 million for the period was primarily due to clinical activities for the setanaxib platform, including the ongoing setanaxib trials, compared to the corresponding period of the prior year.

Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 167.2 million and SEK 93.9 million for the three months ended March 31, 2023 and 2022, respectively. The increase of SEK 73.3 million for the period 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 period of the prior year, which was the first quarter of TARPEYO commercialization.

Administrative Expenses

Administrative expenses amounted to SEK 72.5 million and SEK 48.5 million for the three months ended March 31, 2023 and 2022, respectively. The increase of SEK 24.0 million for the period was primarily related to cost increases due to a larger organization and increased regulatory requirements compared to the corresponding period of the prior year.

Other Operating Incomes/Expenses, net

Other operating income/(expenses), net amounted to SEK 4.0 million and (SEK 1.7 million) for the three months ended March 31, 2023 and 2022, respectively. The increase for the period was primarily related to a more favourable exchange rate development on operating liabilities compared to the corresponding period of the prior year.

Net Financial Income and Expenses

Net financial income/(expenses) amounted to (SEK 27.9 million) and (SEK 3.1 million) for the three months ended March 31, 2023 and 2022, respectively. The increase of expense of SEK 24.8 million for the period was primarily derived from interest expenses from the Kreos loan and currency effect related to external and internal loans compared to the corresponding period of the prior year.

Tax

Total income tax/(expense) amounted to SEK 20.5 million and SEK 4.4 million for the three months ended March 31, 2023 and 2022, respectively. The increase for the period was primarily explained by recognized loss carried-forward, which is 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, for 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 March 31, 2023 and 2022, the loss for the period amounted to SEK 187.5 million and SEK 207.0 million, and the corresponding loss per share before and after dilution amounted to SEK 3.49 and SEK 3.95, respectively.

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 231.9 million and SEK 191.4 million for the three months ended March 31, 2023 and 2022, respectively. The increase for the period was primarily explained by the negative change in working capital compared to the corresponding period of the prior year, where payments from partner milestones were received.

Cash flow used in investing activities amounted to SEK 2.9 million and SEK 2.7 million for the three months ended March 31, 2023 and 2022, respectively.

Cash flow from/(used in) financing activities amounted to (SEK 3.0 million) and SEK 60.1 million for the three months ended March 31, 2023 and 2022, respectively. The decrease was mainly derived from the payments related to the exercise of the Warrant Program 2018/2022, which occurred in the corresponding period of the prior year.

Net decrease in cash amounted to SEK 237.8 million and SEK 134.0 million for the three months ended March 31, 2023 and 2022, respectively. Cash amounted to SEK 1,013.6 million and SEK 825.4 million as of March 31, 2023 and 2022, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 589.4 million and SEK 871.1 million as of March 31, 2023 and 2022, respectively. The number of registered shares amounted to 59,580,087 and 53,172,170 as of March 31, 2023 and 2022, respectively. The increase in number of shares between the periods was derived from a new share issue in April and May 2022 of 26,000 shares related to the Warrant Program 2018/2022, a new share issue in December 2022 of 422,500 shares related to the Warrant Program 2019/2022, a new share issue of 51,399 shares related to the Board LTIP 2019 program and a new issue of 5,908,018 shares held as treasury shares for future potential delivery of shares under the company's at-the-market program.

Issuance and Repurchase of Treasury Shares

In 2022, Calliditas resolved to carry out an issue of 5,908,018 C-shares at a subscription price of SEK 0.04 per share and subsequently immediately repurchased the 5,908,018 newly issued C-shares for SEK 0.04 per share which were then subsequently 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 was to secure future potential delivery of shares under the company's At-The-Market Program. See Note 7 for additional information.

Personnel

The number of employees were 172 and 71 employees as of March 31, 2023 and 2022, respectively. The total number of full-time equivalent (FTE), including consultants, were 181 and 131 as of March 31, 2023 and 2022, respectively. The average number of employees were 170 and 71 employees for the three months ended March 31, 2023 and 2022, respectively.

Incentive Programs

For the three months ended March 31, 2023, an allocation of 505,000 options have been granted for the ESOP 2022 Program. For more information on incentive programs, see Note 9.

2023 Outlook Unchanged

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

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

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 168.4 million and SEK 31.8 million for the three months ended March 31, 2023 and 2022, respectively. The increase for the period was primarily derived from sales of TARPEYO compared to the corresponding period of the prior year. Operating loss amounted to SEK 46.6 million and SEK 102.5 million for the three months ended March 31, 2023 and 2022, respectively. The improvement for the period was primarily derived from the increase in revenues compared to the corresponding period of the prior year. Non-current financial assets have increased by SEK 90.1 million to SEK 977.6 million as of March 31, 2023, compared to December 31, 2022, which was primarily derived from intercompany transactions.

Auditor's Review

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

Stockholm, May 16, 2023

Renée Aguiar-Lucander
CEO

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Year Ended December 31, 2022
Net sales	4	191,352	49,734	802,879
Cost of sales		(9,028)	(614)	(15,201)
Gross profit		**182,323**	**49,119**	**787,678**
Research and development expenses		(126,653)	(113,343)	(414,749)
Marketing and selling expenses		(167,224)	(93,897)	(515,190)
Administrative expenses		(72,548)	(48,532)	(259,469)
Other operating income/(expenses), net		4,027	(1,715)	(20,212)
Operating loss		**(180,074)**	**(208,367)**	**(421,943)**
Net financial income/(expenses)		(27,944)	(3,068)	12,526
Loss before income tax		**(208,019)**	**(211,434)**	**(409,417)**
Income tax		20,494	4,387	(2,851)
Loss for the period		**(187,525)**	**(207,047)**	**(412,268)**
Attributable to:				
Equity holders of the Parent Company		(187,525)	(207,047)	(412,268)
		(187,525)	**(207,047)**	**(412,268)**
Loss per share before and after dilution (SEK)		(3.49)	(3.95)	(7.78)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Year Ended December 31, 2022
Loss for the period	(187,525)	(207,047)	(412,268)
Other comprehensive income			
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations	1,159	(1,200)	36,287
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods	**1,159**	**(1,200)**	**36,287**
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:			
Remeasurement gain/(loss) on defined benefit plans	(662)	1,294	2,763
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods	**(662)**	**1,294**	**2,763**
Other comprehensive income/(loss) for the period	**497**	**94**	**39,050**
Total comprehensive income/(loss) for the period	**(187,028)**	**(206,954)**	**(373,218)**
Attributable to:			
Equity holders of the Parent Company	(187,028)	(206,954)	(373,218)
	(187,028)	**(206,954)**	**(373,218)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	March 31, 2023	March 31, 2022	December 31, 2022
ASSETS				
Non-current assets				
Intangible assets		485,091	400,952	483,841
Equipment		8,417	6,793	7,468
Right-of-use assets		34,142	30,720	24,452
Non-current financial assets		13,390	5,842	11,210
Deferred tax assets		27,970	3,557	13,799
Total non-current assets		**569,010**	**447,862**	**540,770**
Current assets				
Inventories		12,160	1,133	3,647
Current receivables		109,551	19,293	88,721
Prepaid expenses and accrued income		84,396	50,644	70,741
Cash		1,013,600	825,409	1,249,094
Total current assets		**1,219,706**	**896,478**	**1,412,204**
TOTAL ASSETS		**1,788,716**	**1,344,340**	**1,952,973**
EQUITY AND LIABILITIES				
Equity				
Equity attributable to equity holders of the Parent Company		589,403	871,142	766,264
Total equity	*7,8,9*	**589,403**	**871,142**	**766,264**
Non-current liabilities				
Provisions	*9*	24,471	9,220	12,675
Contingent consideration	6	78,816	56,300	75,880
Deferred tax liabilities		33,728	26,112	39,752
Non-current interest-bearing liabilities		723,995	192,632	713,030
Lease liabilities		22,903	21,859	15,792
Other non-current liabilities		5,320	-	4,350
Total non-current liabilities		**889,233**	**306,123**	**861,479**
Current liabilities				
Accounts payable		108,000	100,051	160,404
Other current liabilities		33,158	14,098	28,381
Accrued expenses and deferred revenue		168,922	52,926	136,446
Total current liabilities		**310,080**	**167,075**	**325,231**
TOTAL EQUITY AND LIABILITIES		**1,788,716**	**1,344,340**	**1,952,973**

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Year Ended December 31, 2022
Opening balance equity attributable to equity holders of the Parent Company	**766,264**	**1,008,281**	**1,008,281**
Loss for the period	(187,525)	(207,047)	(412,268)
Other comprehensive income/(loss)	497	94	39,050
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	**(187,028)**	**(206,954)**	**(373,218)**
Transactions with owners:			
Issuance of treasury shares	-	-	236
Repurchase of treasury shares	-	-	(236)
Exercise of warrants	-	61,713	95,121
Share-based payments	10,167	8,103	36,080
Total transactions with owners	**10,167**	**69,815**	**131,201**
Closing balance equity attributable to equity holders of the Parent Company	**589,403**	**871,142**	**766,264**
Closing balance equity	**589,403**	**871,142**	**766,264**

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Year Ended December 31, 2022
Operating activities			
Operating loss	(180,074)	(208,367)	(421,943)
Adjustment for non-cash-items	27,141	5,067	61,260
Interest received	7	-	3,553
Interest paid	(15,460)	(5,408)	(35,252)
Income taxes paid	(1,336)	-	(7,392)
Cash flow used in operating activities before changes in working capital	**(169,722)**	**(208,708)**	**(399,774)**
Cash flow from/(used in) changes in working capital	(62,218)	17,285	88,420
Cash flow used in operating activities	**(231,940)**	**(191,423)**	**(311,354)**
Cash flow used in investing activities	**(2,913)**	**(2,651)**	**(5,144)**
Issuance of treasury shares	-	-	236
Repurchase of treasury shares	-	-	(236)
Exercise of warrants	-	61,713	95,121
New borrowings	-	-	491,745
Costs attributable to new loans	-	-	(1,260)
Repayment of lease liabilities	(2,969)	(1,658)	(9,615)
Cash flow from/(used in) financing activities	**(2,969)**	**60,054**	**575,990**
Net increase/(decrease) in cash	**(237,822)**	**(134,020)**	**259,493**
Cash at the beginning of the period	**1,249,094**	**955,507**	**955,507**
Net foreign exchange gains/(loss) on cash	2,327	3,921	34,094
Cash at the end of the period	**1,013,600**	**825,409**	**1,249,094**

Condensed Parent Company Statements of Income

(SEK in thousands)	Notes	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Year Ended December 31, 2022
Net sales		168,370	31,771	548,977
Cost of sales		(9,013)	(614)	(15,141)
Gross profit		**159,358**	**31,157**	**533,836**
Research and development expenses		(118,789)	(103,681)	(384,453)
Marketing and selling expenses		(88,671)	(24,407)	(310,372)
Administrative expenses		(59,185)	(44,344)	(212,971)
Other operating income/(expenses), net		60,653	38,741	158,597
Operating loss		**(46,635)**	**(102,534)**	**(215,364)**
Net financial income/(expenses)		(18,333)	(3,396)	6,816
Loss before income tax		**(64,968)**	**(105,929)**	**(208,548)**
Income tax		-	-	-
Loss for the period		**(64,968)**	**(105,929)**	**(208,548)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Year Ended December 31, 2022
Loss for the period	(64,968)	(105,929)	(208,548)
Other comprehensive income/(loss)	-	-	-
Total comprehensive income/(loss)	**(64,968)**	**(105,929)**	**(208,548)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	March 31, 2023	March 31, 2022	December 31, 2022
ASSETS				
Non-current assets				
Intangible assets		32,132	32,132	32,132
Equipment		511	735	567
Non-current financial assets		977,553	645,442	887,456
Total non-current assets		**1,010,195**	**678,309**	**920,154**
Current assets				
Inventories		12,160	1,133	3,647
Current receivables		211,193	16,020	129,090
Prepaid expenses and accrued income		65,046	37,622	61,092
Cash		776,220	753,407	1,059,655
Total current assets		**1,064,619**	**808,182**	**1,253,485**
TOTAL ASSETS		**2,074,814**	**1,486,491**	**2,173,639**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Total restricted equity		5,475	5,219	5,475
Total non-restricted equity		1,070,679	1,166,970	1,125,480
Total shareholders' equity	*7,9*	**1,076,155**	**1,172,189**	**1,130,956**
Non-current liabilities				
Provisions	*9*	18,769	5,128	9,512
Non-current interest-bearing liabilities		723,995	192,632	713,030
Other non-current liabilities		5,425	105	4,455
Total non-current liabilities		**748,189**	**197,865**	**726,997**
Current liabilities				
Accounts payable		53,835	67,306	100,469
Other current liabilities		93,023	18,101	141,750
Accrued expenses and deferred revenue		103,611	31,031	73,468
Total current liabilities		**250,470**	**116,438**	**315,686**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**2,074,814**	**1,486,491**	**2,173,639**

Notes to Condensed Consolidated Financial Statements

Note 1 - Description of Business

Calliditas Therapeutics AB (publ) ("Calliditas" or the "Parent Company"), with corporate registration number 556659-9766, and its subsidiaries (collectively, the "Group") conducts commercial and development activities in pharmaceuticals. These interim condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the three months ended March 31, 2023 and 2022.

Calliditas is a Swedish public limited company registered in and with its registered office in Stockholm. The registered address of the corporate headquarters is Kungsbron 1, D5, Stockholm, Sweden. Calliditas is listed at Nasdaq Stockholm in the Mid Cap segment with ticker "CALTX" and, in the form of ADSs, on the Nasdaq Global Select Market in the United States with the ticker "CALT".

These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on May 16, 2023.

This report may include forward-looking statements. Actual outcomes may deviate from what has been stated. Internal factors such as successful management of research projects, and intellectual property rights may affect future results. There are also external conditions, (e.g. the economic climate, political changes, and competing research projects) that may affect the Group's results.

Note 2 - Accounting Policies

These interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting". The Parent Company applies the Swedish Financial Reporting Board recommendation RFR2, Accounting for legal entities. The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Annual Report for 2022. None of the new or amended standards and interpretations that became effective January 1, 2023, have had a significant impact on the Group's financial reporting. Significant accounting principles can be found on pages 49-54 of the Annual Report for 2022.

The ESMA (European Securities and Markets Authority) guidelines on alternative key performance ratios are applied, which means disclosure requirements regarding financial measures that are not defined in accordance with IFRS. For key ratios not defined by IFRS, see the Definitions and reconciliations of alternative performance measures on page 26.

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

Operational Risks

Research and drug development up to approved registration is subject to considerable risk and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to the technological risks, such as a failure to demonstrate efficacy or a favorable risk/benefit profile, or manufacturing problems. Competing pharmaceuticals can capture market share or reach the market faster, or if competing research projects achieve better product profiles, the future value of the product portfolio may be lower than expected. The operations may also be impacted negatively by regulatory decisions, such as lack of approvals and price changes.

Calliditas has a commercialized product, which has been approved under accelerated approval in the U.S. under the brand name TARPEYO and has received conditional marketing authorization in the EU and the UK under the brand name Kinpeygo. There is a risk that commercialization will not go according to plan or that the uptake of prescribing physicians will be worse than planned or that the drug will not have sufficient effect or show unwanted side effects, which may affect the sales negatively.

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 account 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 2022.

For more information and full disclosure regarding the operational and financial risks, reference is made to the Annual Report for 2022 and the Annual Report on Form 20-F, filed with the SEC in April 2023.

Note 4 - Revenue from Contracts with Customers

	Three Months Ended March 31,		Year Ended December 31,
(SEK in thousands)	2023	2022	2022
Type of goods or services			
Product sales	186,940	17,963	375,515
Outlicensing of product	-	28,804	421,689
Royalty revenue	4,412	-	2,287
Performance of certain regulatory services	-	2,967	3,387
Total	**191,352**	**49,734**	**802,879**
Geographical markets			
USA	185,691	17,963	372,247
Europe	5,660	2,967	143,955
Asia	-	28,804	286,677
Total	**191,352**	**49,734**	**802,879**

The Group's net sales amounted to SEK 191.4 million and SEK 49.7 million for the three months ended March 31, 2023 and 2022, respectively, which primarily originates from net sales of TARPEYO in the U.S. Net sales from TARPEYO amounted to SEK 185.7 million and SEK 18.0 million for the three months ended March 31, 2023 and 2022, respectively.

The total liability for expected returns and rebates amounts to SEK 35.2 million and SEK 1.8 million as of March 31, 2023 and 2022, respectively, which are recognized in other current liabilities and accrued expenses and deferred revenue.

Note 5 - Related-Party Transactions

During the reporting period, no significant related-party transactions have occurred.
For information about incentive programs please see Note 9.

Note 6 - Financial Instruments

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

Contingent consideration are recognized at fair value, measured at Level 3 of the IFRS value hierarchy. The contingent consideration has been computed in accordance with the present value method and the probability has been taken into account if and when the various milestones will occur. The calculations are based on a discount rate of 12.0 percent. The most significant input affecting the valuation of the contingent consideration is the Group's estimate of the probability of the milestones being reached. For the three months ended March 31, 2023 and 2022, the loss for the period amounted to SEK 1.9 million and SEK 1.3 million, respectively, which are recognized in other operating income/(expenses), net. This was attributable to the time factor. For more information see the Annual Report for 2022.

Note 7 - 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. In 2022 Calliditas has 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.

In 2022, 5,908,018 series C shares were issued, which were repurchased and converted to ordinary shares by Calliditas. These transactions are in accordance with the granting mandate. For the three months ended March 31, 2023, no shares were sold in the ATM Program. The total number of issued shares as of March 31, 2023, is presented in Note 8.

Note 8 - Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	March 31, 2023	March 31, 2022	December 31, 2022
Total registered shares at the beginning of the period	59,580,087	52,341,584	52,341,584
New issue of shares during the period	-	-	7,231,003
Shares subscribed but not registered during the period	-	830,586	7,500
Total registered and subscribed but not registered shares at the end of the period	**59,580,087**	**53,172,170**	**59,580,087**
Shares			
Ordinary shares	59,580,087	53,172,170	59,580,087
Total	**59,580,087**	**53,172,170**	**59,580,087**
- of which shares are held by Calliditas	*5,908,018*	-	*5,908,018*
Total registered and subscribed but not registered shares at the end of the period, net of shares held by Calliditas	**53,672,069**	**53,172,170**	**53,672,069**
Share capital at the end of the period	2,383	2,094	2,383
Equity attributable to equity holders of the Parent Company	589,403	871,142	766,264
Total equity at the end of the period	**589,403**	**871,142**	**766,264**

(SEK in thousands, except per share amounts and number of shares)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	Year Ended December 31, 2022
Loss per share before and after dilution, SEK	(3.49)	(3.95)	(7.78)
Weighted-average number of ordinary shares outstanding for the period, before and after dilution	53,672,069	52,381,402	53,022,550

Reserves for translation from foreign operations amounted to SEK 10.5 million and (SEK 28.2 million) which are included in retained earnings in equity as of March 31, 2023 and 2022, respectively.

Note 9 - Incentive Programs

	March 31, 2023			March 31, 2022			
	Options Outstanding	Share Awards Outstanding	Total Outstanding	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding
Incentive Programs							
Warrant program 2019/2022	-	-	-	422,500	-	-	422,500
Board LTIP 2019	-	-	-	-	-	51,399	51,399
Board LTIP 2020	-	29,928	29,928	-	-	31,371	31,371
Board LTIP 2021	-	24,244	24,244	-	-	26,968	26,968
Board LTIP 2022	-	40,706	40,706	-	-	-	-
ESOP 2020	1,364,730	-	1,364,730	-	1,444,000	-	1,444,000
ESOP 2021	1,479,500	-	1,479,500	-	1,495,000	-	1,495,000
ESOP 2022	1,548,000	-	1,548,000	-	-	-	-
Total Outstanding	**4,392,230**	**94,878**	**4,487,108**	**422,500**	**2,939,000**	**109,738**	**3,471,238**

Board LTIP 2020:

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

ESOP Programs

Calliditas implements option programs for employees and key consultants in Calliditas. The options are allotted free of charge to participants of the program. The options have a three-year vesting period calculated from the grant 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 grant date. The options have, at the time of each issue, been valued according to the Black & Scholes valuation model.

Definitions and Reconciliations of Alternative Performance Measures

Definitions of Alternative Performance Measures

Alternative Key Performance Indicator	Definitions	Reason for Inclusion
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

	March 31,		December 31,
(SEK in thousands or otherwise indicated)	2023	2022	2022
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	589,403	871,142	766,264
Total assets at the end of the period	1,788,716	1,344,340	1,952,973
Equity ratio at the end of the period in %	**33%**	**65%**	**39%**

Financial Calendar

Annual General Meeting 2023	May 30, 2023
Interim Report for the period January 1 – June 30, 2023	August 17, 2023
Interim Report for the period January 1 – September 30, 2023	November 16, 2023

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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, including 2023 revenue guidance, 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 Interim Report has been prepared in a Swedish original and has been translated into English. In case of differences between the two, the Swedish version shall apply.

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