Q2 2023

INTERIM REPORT JANUARY 1 – JUNE 30, 2023

calliditas THERAPEUTICS

Filing for full approval of TARPEYO

Group Financial Summary

Key Figures

April 1 - June 30, 2023

- Net sales amounted to SEK 269.4 million, of which TARPEYO® net sales amounted to SEK 259.2 million, for the three months ended June 30, 2023. For the three months ended June 30, 2022 net sales amounted to SEK 64.0 million, of which TARPEYO net sales amounted to SEK 63.6 million.
- Operating loss amounted to SEK 75.2 million and SEK 209.8 million for the three months ended June 30, 2023 and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 1.71 and SEK 3.62 for the three months ended June 30, 2023 and 2022, respectively.
- Cash amounted to SEK 866.2 million and SEK 846.8 million as of June 30, 2023 and 2022, respectively.

January 1 - June 30, 2023

- Net sales amounted to SEK 460.7 million, of which TARPEYO net sales amounted to SEK 444.9 million, for the six months ended June 30, 2023. For the six months ended June 30, 2022 net sales amounted to SEK 113.8 million, of which TARPEYO net sales amounted to SEK 81.6 million.
- Operating loss amounted to SEK 255.2 million and SEK 418.2 million for the six months ended June 30, 2023 and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 5.21 and SEK 7.57 for the six months ended June 30, 2023 and 2022, respectively.

Investor Presentation August 17, 2023 14:30 CET

Audio cast with teleconference, Q2 2023.
Web cast: https://ir.financialhearings.com/calliditas-therapeutics-q2-2023
Tele Conference: SWE +46 (8) 525 07 003, US +1 774 450 99 00, UK +44 7073 5048

Significant Events in Q2 2023, in Summary

In June 2023, Calliditas had two oral presentations and two abstracts reflecting top line data and analyses from the NefIgArd Phase 3 Study, evaluating Nefecon® (TARPEYO (budesonide) delayed release capsules/Kinpeygo®) in patients with IgA nephropathy (IgAN), at the European Renal Association (ERA) Congress in Milan, Italy.

In June 2023, Calliditas announced the submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) seeking full approval of TARPEYO (budesonide) delayed release capsules (developed under the project name Nefecon) for the entire study population evaluated in the Phase 3 NefIgArd study. The sNDA submission was based on the full data set from the Phase 3 NefIgArd clinical trial, a randomized, double-blind, multicenter study which assessed the efficacy and safety of Nefecon dosed at 16 mg once daily versus placebo on a background of optimized RASi therapy in adult patients with primary IgAN.

The trial met its primary endpoint of kidney function, with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in estimated glomerular filtration rate (eGFR) over the two-year period of 9 months of treatment with Nefecon or placebo and 15 months of follow-up off drug.

Key Takeaways

- Late breaking data from the Phase 3 NefIgArd study presented at the ERA EDTA Conference in June, 2023.
- sNDA submitted to the FDA in June, 2023 for full approval in the entire study population of NefIgArd.
- In August Calliditas Therapeutics announced full results from the NefIgArd Phase 3 trial published in The Lancet.

Updated 2023 Outlook

For 2023, Calliditas expects revenue growth in the US where:

Net sales from TARPEYO are estimated to be USD 100-120 million for the year ending December 31, 2023.

CEO STATEMENT

sNDA submitted to the FDA for full approval

In June we submitted a supplemental New Drug Application (sNDA) to the FDA for full approval of TARPEYO® for patients with primary IgAN, based on the data from our Phase 3 clinical trial, NefIgArd. This global, randomized, placebo controlled, double- blinded study successfully met its primary endpoint, demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in average estimated glomerular filtration rate (eGFR) over the two-year period of 9-months of treatment with Nefecon® or placebo and 15-months of follow-up off drug. There was statistically significant impact on microhematuria and the 2-year total slope, using the Vonesh method*, showed an improvement of approximately 3.0ml/min/year, which is significantly higher than the assumed minimum level of ~1.3ml/min/year that is often quoted as the bar the FDA looks for in terms of establishing clinical benefit. There was also a durable suppression of proteinuria, which lasted not only during the 9 months of treatment but also over the 15 months of observation off drug. These results were observed in the entire patient population, irrespective of UPCR levels at baseline, and we believe support the thesis that this drug is disease modifying, with a potential to significantly delay the need for dialysis or transplantation.

The data from the trial were first shared in late breaking presentations at the ERA EDTA conference, which took place 15 – 18th of June in Milan and where we had two oral presentations and two posters. The presentations were very well received by the nephrology community and there was a lot of buzz in several subsequent presentations where the data was mentioned or discussed. We have also had the opportunity to conduct some Advisory Board meetings in the US, where we have shared the recent clinical data under confidentiality and received feedback from practicing nephrologists. This has been extremely encouraging and the feedback has been consistent related to TARPEYO being perceived as a disease modifying treatment with an attractive risk / benefit profile, which is expected to become part of standard of care. We can't wait to share the data with the broader nephrology community in the US and ultimately offer physicians a medication that may significantly delay patient time to dialysis.

In the US, we reported another quarter of record enrollments of 422, and 232 new prescribers, reflecting the continued growth of the TARPEYO franchise. Total Q2 revenues were SEK 269 million, out of which net revenues from TARPEYO amounted to SEK 259 million (USD 24.7m). We have seen very positive development both in terms of enrolments as well as revenue growth from the TARPEYO franchise this year, but due to challenges primarily relating to market access friction and the reduced market opportunity related to accelerated approval with a more limited label, we have revised our guidance for 2023 to USD 100 – 120m of net TARPEYO revenues. We believe that, if granted, a full approval with access to the entire study population will provide significant benefits in 2024 and we are excited about continuing to build an even stronger franchise on the basis of the effect on kidney function. The operating loss for the quarter was significantly reduced to SEK 75m (USD 7.2m) and our cash position remains strong with SEK 866m on the balance sheet, which we believe will be sufficient to take us to profitability.

The publication in The Lancet this week of the positive clinical data from the first ever successful full Phase 3 study in IgA nephropathy will mark the beginning of peer-to-peer scientific dialogue with physicians, offering opportunities to educate the nephrology community about the results of the trial and discuss appropriate treatment paradigms.

In the post quarter period we also reported clinical and biomarker data from our Phase 2 setanaxib head and neck cancer trial. We were very excited to see that 6 out the 7 patients who were progression-free at the time of readout were in the treatment arm, and we look forward to reading out the full trial in 1H 2024. This also marked an opportunity for us to conduct a transcriptomic analysis, which clearly identified the hepatic and IPF related fibrosis pathways as core pathways impacted by the drug. Based on recently reported biomarker data, as well as other factors including regulatory feedback, we have decided to revise the design of the TRANSFORM trial, our clinical study in PBC, to enable us to read out Phase 2b data in 1H 2024. This will allow us to review the optimal endpoint of a potential Phase 3 study, as well as to explore alternative or complementary indications and potential partnerships within the broader area of fibrotic disease.

We continue to make progress on our preparations for the study of setanixib in Alport syndrome, and the investigator led study in IPF. We also 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 through the rest of this year and beyond as we await regulatory decisions both in China and in the US - we remain excited about the future!

Renée Aguiar-Lucander, CEO

*Linear spline mixed-effect method for slope-based endpoints in clinical trials of chronic kidney disease

Filing for Full Approval of TARPEYO

In June 2023, Calliditas submitted a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) seeking full approval of TARPEYO® (budesonide) delayed release capsules for the entire study population from the Phase 3 NefIgArd study. TARPEYO is currently approved in the US under accelerated approval to reduce proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g.

The sNDA submission is based on the full data set from the Phase 3 NefIgArd clinical trial, a randomized, double-blind, multicenter study which assessed the efficacy and safety of TARPEYO (developed under the project name Nefecon®) dosed at 16 mg once daily versus placebo on a background of optimized RASi therapy in adult patients with primary IgAN. 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 over placebo (p value < 0.0001) in kidney function, as measured by estimated glomerular filtration rate (eGFR) over the two-year period of 9 months of treatment with TARPEYO or placebo and 15 months of follow-up off drug. The eGFR benefit was observed across the entire study population, irrespective of urine protein-to-creatinine ratio (UPCR) baseline, which supports the regulatory filing for full approval in the study population.

Calliditas initially filed for accelerated approval with the FDA in March 2021. The accelerated approval pathway allows drugs targeting serious conditions that fill an unmet medical need to be approved based on a surrogate endpoint. The surrogate endpoint in the NefIgArd trial was reduction of proteinuria versus placebo, an endpoint supported by a meta-analysis of clinical studies carried out by Inker et al. The FDA granted accelerated approval for TARPEYO in December 2021, and it was launched in the US on January 28, 2022.

"The eGFR treatment benefit observed across the entire study population, irrespective of UPCR levels, provides further evidence that targeting IgAN at its source can offer patients a treatment that holds the promise of being disease-modifying.
We are pleased to be able to provide the FDA with the full results of our Phase 3 study, and we look forward to interactions with the FDA regarding full approval of TARPEYO."

Renée Aguiar-Lucander, CEO

1 *Inker LA, Mondal H, Greene T, et al. Early Change in Urine Protein as a Surrogate End Point in Studies of IgA Nephropathy: An Individual-Patient Meta-analysis. Am J Kidney Dis. 2016;68(3):392-401. doi:10.1053/j.ajkd.2016.02.042*

The NeflgArd Phase 3 Trial: Design

NeflgArd 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] The sNDA submission to the FDA was based on the data from this trial, with Calliditas filing for full approval on the basis of the strong eGFR and UPCR data readout.

NeflgArd is a pivotal, global Phase 3 trial consisting of two readouts. 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 measure of kidney function. These data were published in Kidney International in October 2022. Calliditas' initial regulatory filings with the FDA and European Medicines Agency (EMA) were based on positive data from the interim readout of the NeflgArd pivotal Phase 3 study, which read out topline data in November 2020.

The full Phase 3 NeflgArd trial consisted of a total of 364 patients, including the 200 patients in the interim analysis and included a 15-month post-treatment observational period for all study participants to confirm long-term renal protection. The endpoint of the full 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.

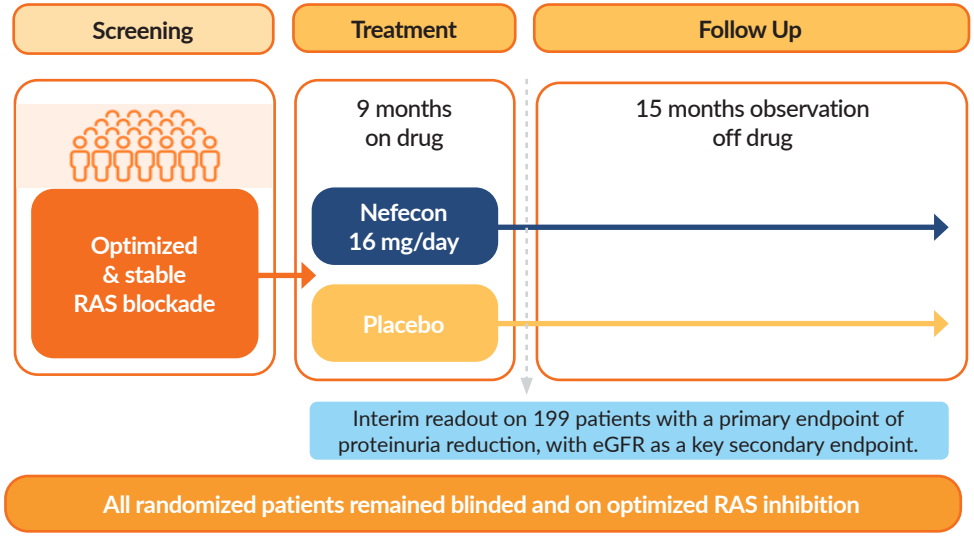
Base inclusion criteria:

- 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 NeflgArd trial evaluated targeted-release formulation of budesonide for the treatment of primary https://doi.org/10.1016/j.kint.2022.09.017*

The full NeflgArd trial read out positive topline data in March 2023, meeting its primary endpoint of kidney function by demonstrating a statistically significant benefit in eGFR of Nefecon over placebo after 9 months of treatment and 15 months of follow-up off drug.

NeflgArd: A two-part, global, randomized, placebo-controlled study



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

The NeflgArd Phase 3 Trial: Topline Readout

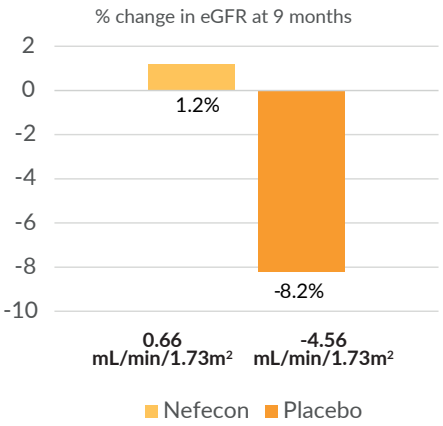
eGFR Data:

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).

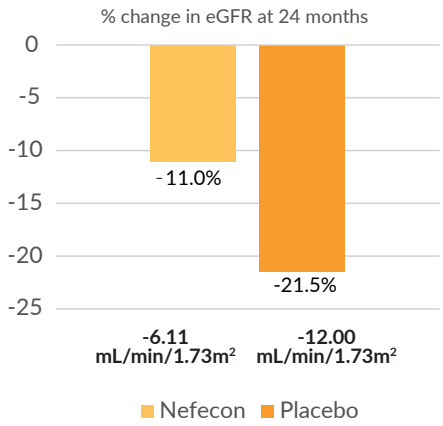
In placebo-treated patients, after 9 months there was a decline in eGFR of 8.2%, corresponding to a loss of 4.56 mL/min/1.73 m^2. Meanwhile, in Nefecon-treated patients, eGFR increased by 1.2% versus baseline, reflecting a slight increase in eGFR of 0.66 mL/min/1.73 m^2.

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, dosing with 16mg Nefecon in 364 patients resulted in 50% less loss of kidney function, as measured by eGFR, vs placebo at 24 months after a treatment of only 9 months.

Impact on eGFR at 9 months



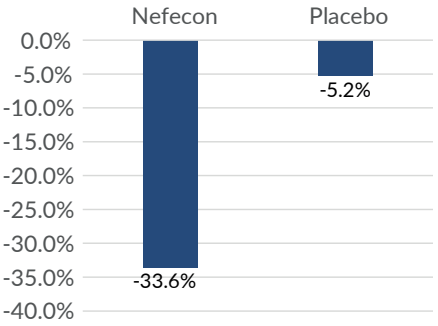
Impact on eGFR at 24 months



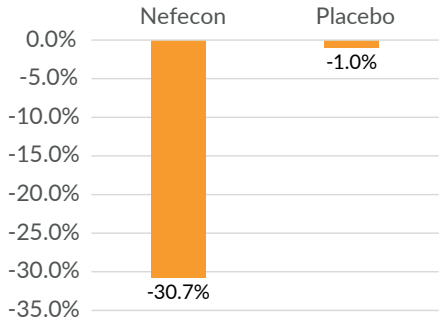
Proteinuria Data:

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.

Publication in a Peer-Reviewed Journal:

In August 2023 Calliditas announced the publication of this data in *The Lancet*.

Data Presentations at ERA-EDTA Congress

Following the trial readout of the NefIgArd study in March, Calliditas' late-breaking data presentations were selected for the 60th European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Congress, which took place in Milan in June.

Oral Presentation:
Long-term renal benefit over 2 years with Nefecon® verified: The NefIgArd Phase 3 full trial results

Professor Richard Lafayette presented the primary data from the final analysis of NefIgArd, comprising 9 months of treatment and 15 months of follow-up. The presentation included a detailed overview of the patient population characteristics, and an analysis of the eGFR benefit in the overall patient population and subgroups; UPCR benefit was also presented.

Oral Presentation:
Nefecon Treatment Likely Modulates Downstream Pathways of Kidney Inflammation and Fibrosis in IgA Nephropathy

Karen Molyneux, PhD, of the University of Leicester, presented her research into Nefecon's effect on processes previously shown to be important in the pathogenesis of kidney injury in IgAN. Her gene ontology analysis of urine samples from 18 patients from each of the placebo and 16 mg/day arms of the NEFIGAN trial, collected at start and end of treatment, revealed that treatment with 16 mg of Nefecon led to a significant enrichment of multiple downstream pathways of kidney inflammation and fibrosis.

ePoster:
Hematuria reduction in patients with IgAN following Nefecon treatment: A secondary analysis of the full 2-year NefIgArd Phase 3 trial results

This poster from Professor Richard Lafayette presented further details on a secondary efficacy endpoint in the NefIgArd trial, the presence of microhematuria (blood in the urine). Hematuria is a common clinical manifestation of IgAN, and changes in hematuria can be measured as part of the evaluation of the efficacy of IgAN treatments. In the NefIgArd trial, at randomization the proportion of patients with microhematuria was similar in the Nefecon and placebo groups. The proportion of patients with microhematuria in the Nefecon group decreased from 66.5% at baseline to 40.5% during follow-up, compared with a decrease from 67.8% to 61.2% in the placebo group at the same time points. This secondary analysis shows that after 9 months of Nefecon 16 mg/day treatment, a clinically relevant and durable reduction in microhematuria was seen, providing further evidence for the disease-modifying effect of Nefecon.

ePoster:
Durable proteinuria reduction over 2 years with Nefecon treatment: A secondary analysis of the full NefIgArd Phase 3 trial results

This poster from Professor Richard Lafayette presented further details on changes in UPCR observed in the NefIgArd trial. At 24 months, UPCR was reduced by 30.7% from baseline in the Nefecon group compared with 1% in the placebo group (comparative reductions at the end of the 9-month treatment period were 33.6% and 5.2%, respectively). The pre-defined secondary analysis of durability of proteinuria reduction showed that both UPCR and UACR (urine albumin-to-creatinine ratio) were significantly reduced over 12–24 months in the Nefecon group compared with placebo. These secondary analyses demonstrated that after 9 months of Nefecon 16 mg/day treatment, a clinically relevant reduction in proteinuria was seen in patients with primary IgAN. This effect was durable, being maintained throughout the 15-month off-drug observation period. These results lend further support to the clinical benefit of Nefecon, as well as provide further evidence of a disease-modifying effect.

Nefecon's Mechanism of Action

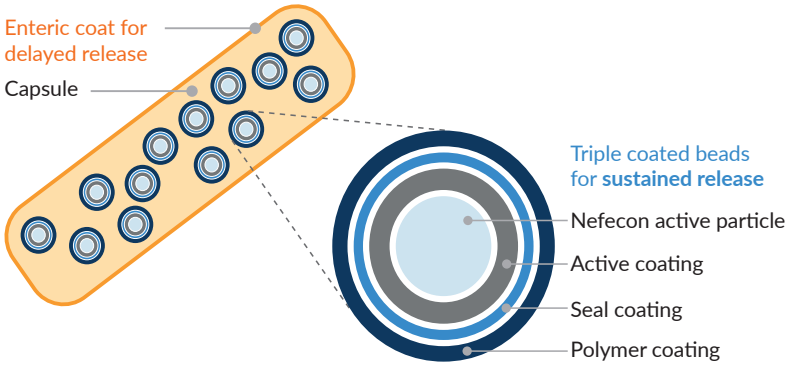
Nefecon® was the first-ever medication approved by the FDA and European Commission for IgAN, and the only treatment specifically designed to target the origin of IgA nephropathy (IgAN) with a view to be disease-modifying.

IgAN Disease Background

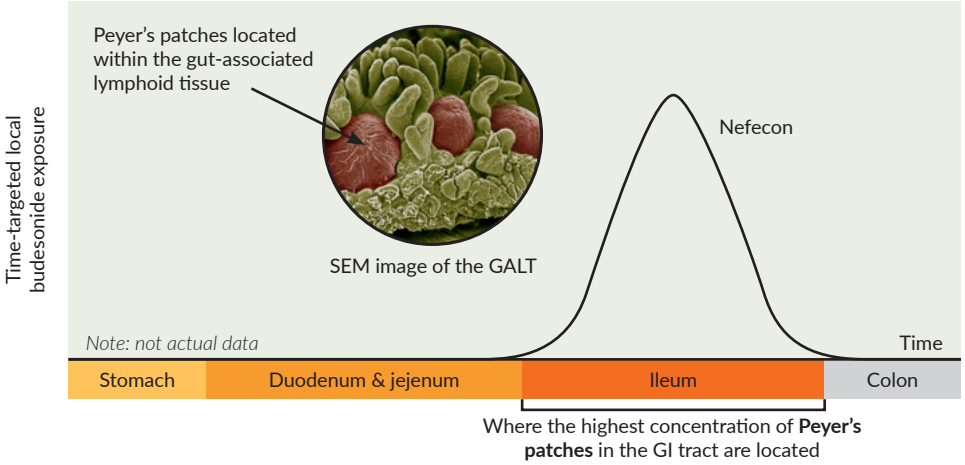
IgAN is a serious progressive disease, in which up to 50% of patients end up at risk of developing end-stage renal disease (ESRD) within ten to twenty years. Although IgAN manifests in the kidney, the evidence indicates that it is a disease that starts in the distal part of the intestine, specifically 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 a kidney transplant.

Nefecon 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.



Continued Growth of TARPEYO

During the second quarter of 2023, the Calliditas commercial team continued to expand the TARPEYO® franchise, further reinforcing the position of TARPEYO as a transformative treatment option for IgA Nephropathy (IgAN).

The ERA-EDTA presentation of key data from the Phase 3 trial including the long term kidney protective effect of the drug marked the first time the results from the full Phase 3 study population were shared with the scientific community. The presentation was received with great enthusiasm by nephrologists and there was a real buzz around the data presented. Another critical milestone this quarter was submitting the sNDA to the FDA seeking full approval for patients with primary IgAN for TARPEYO.

Net sales of TARPEYO in the US for Q2 were USD 24.7 million (SEK 259.2 million), a 39% increase over Q1 and 275% increase over the same quarter in 2022. In addition, our specialty sales force generated another record quarter of 422 enrollments, contributing to a total of 831 enrollments year-to-date. This reflects over 180% growth over the first half of 2022, which underscores the continued adoption and growing recognition of TARPEYO's clinical value among healthcare providers. Furthermore, an additional 232 new prescribers were added during the quarter.

In the second quarter, over 90% of the patients enrolled in TARPEYO Touchpoints during the quarter, excluding those still waiting for a final insurance decision, received TARPEYO. The channel mix of new patients on therapy are predominantly on commercial plans, approximately 65%, with the majority of the remaining 35% on government-subsidized plans. Compared to the first quarter, we saw a 14% improvement in the average time-to-fill, reflecting our continuous investment in supporting providers and patients in accessing TARPEYO.

Our medical and commercial teams had a robust presence at major nephrology conferences, such as the National Kidney Foundation (NKF) and ERA-EDTA Congress. During the NKF conference, we presented and discussed the clinical benefits of TARPEYO and its role in treating IgAN. This information was shared across promotional product theaters and CME programs focused on IgAN disease, which furthered the education of nephrologists. The ERA-EDTA conference proved instrumental in Calliditas' scientific exchange efforts, with NefIgArd pivotal data receiving recognition as a late-breaking presentation by Richard Lafayette.

This marked the scientific community's first encounter with these critical findings, capturing the interest level of nephrologists around the globe. Additionally, abstracts with valuable data on proteinuria and hematuria were presented from the full NefIgArd study population, which further demonstrated the uniqueness and benefits of TARPEYO in the treatment of IgAN. Discussions at ERA-EDTA centered around the evolving IgAN treatment landscape and the importance of immuno-modulatory therapies to suppress pathogenic IgA production and control glomerular inflammation, highlighting Nefecon's pivotal role in the treatment paradigm.

In addition to driving scientific exchange, patient education and engaging with advocacy groups continue to be at the core of our efforts in the US. We work closely with key partners such as the IgAN Foundation, NKF, the American Kidney Fund, and Nephcure to raise awareness about rare diseases and support patients.

During Q2 we engaged with numerous patient advocacy groups and patients, providing them with valuable information about IgA Nephropathy and TARPEYO. Our commitment to empowering patients is exemplified through updates to our IgAN Connect website, featuring additional valuable resources, including patient stories and blog posts by three inspiring patient advocates. Collaboratively with advocacy groups, we seek to provide patients with credible, up-to-date information and answers to some of their queries. We strive to stand as a trusted resource for the IgAN and TARPEYO patient community, facilitating informed dialogues between patients and their healthcare providers.

Our team is fully committed to advancing TARPEYO's commercial and medical initiatives and eagerly anticipates engaging with nephrologists at the upcoming IIgANN and ASN national conferences. Our goal is to educate the nephrology community on how TARPEYO can benefit IgAN patients by providing a disease-modifying approach to the disease.

Our Commercial Partnerships

Europe

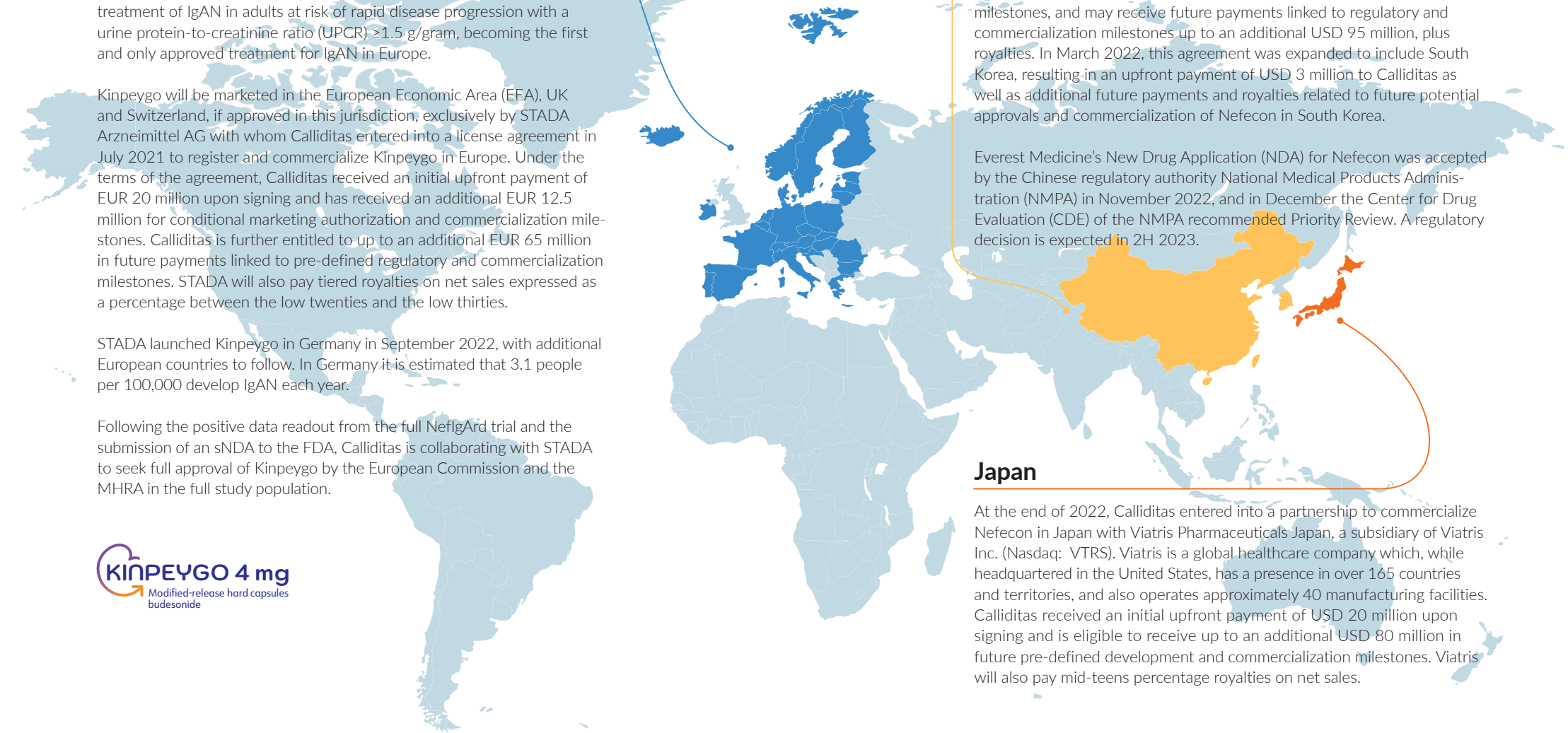
Nefecon® was granted conditional marketing authorization (CMA) by the European Commission in July 2022, and subsequently by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom in February 2023, under the brand name Kinpeygo® for the treatment of IgAN in adults at risk 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.

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.

Following the positive data readout from the full NefIgArd trial and the submission of an sNDA to the FDA, Calliditas is collaborating with STADA to seek full approval of Kinpeygo by the European Commission and the MHRA in the full study population.

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

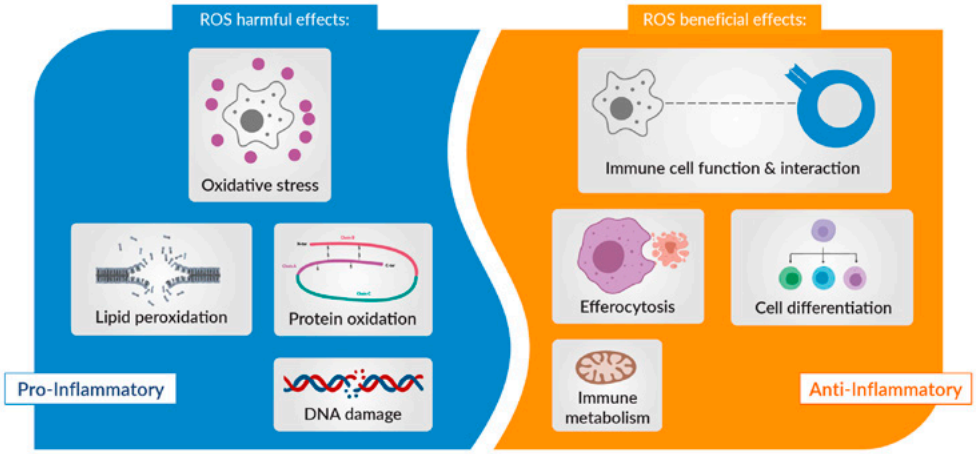
Calliditas' pipeline contains development programs based on a first-in-class, novel NOX inhibitor platform. Calliditas is presently running trials with lead compound setanaxib in Squamous Cell Carcinoma of the Head & Neck (SCCHN), which read out interim data in July, as well as in Primary Biliary Cholangitis (PBC). We also plan to launch 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 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. When a cell is injured, excess NOX activity is triggered and redox homeostasis becomes unbalanced, leading to activation of pro-fibrogenic pathways. Cancer-associated fibroblasts in the tumor microenvironment also express NOX enzymes, which can result in tumours with low immunological activity and relative resistance to the effects of immuno-oncologic agents, such as checkpoint inhibitors.

Setanaxib, which is the first NOX inhibitor to reach the clinical trial stage, inhibits NOX1 and NOX4, enzymes that are implicated in inflammation and fibrosis pathways, and represent a high-potential therapeutic target.

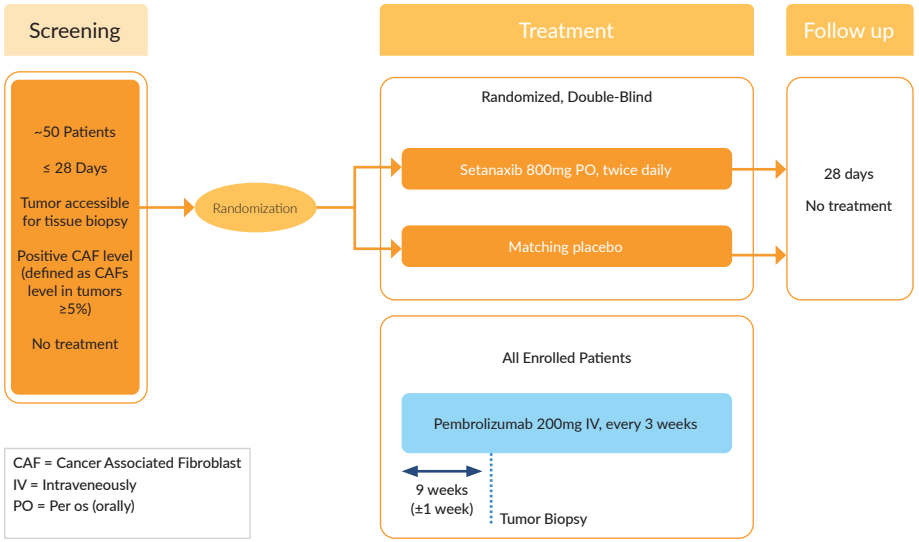


Pipeline: Head and Neck Cancer

Setanaxib in Squamous Cell Carcinoma of the Head & Neck

Calliditas is evaluating setanaxib in head and neck cancer, building on promising in vivo preclinical data that suggests that setanaxib could significantly enhance the effects of immune-oncology therapies. We are conducting a double-blind, randomized, placebo-controlled, proof-of-concept Phase 2 study, which is investigating the effect of setanaxib 800mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks, in at least 50 patients with relapsed or metastatic SCCHN and tumors with moderate or high levels of cancer-associated fibroblasts.

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. Calliditas read out interim data from the study in July 2023, and expects to read out final trial data in 2024.



Further details of this study can be found at www.clinicaltrials.gov, with the reference NCT05323656.

Interim Readout: Phase 2 Proof-of-Concept Study Data

In July 2023, Calliditas read out interim data from the trial, which reflected encouraging early clinical progression-free survival (PFS) results and supports the presumed anti-fibrotic mode of action of setanaxib. The basis for the analysis consisted of a data set of 20 patients with recurrent or metastatic SCCHN, of which 16 patients had evaluable tumor size and PFS-related results. Twelve patients had tumor biopsies before and after treatment that were evaluable for the biomarker analysis, which included transcriptomic analysis and evaluated pathology markers such as SMA, Foxp3 regulatory T cells and PDL-1 CPS.

> "Based on the encouraging clinical and transcriptomic results, the data support the continuation of the trial, and provides evidence to support the presumed MOA as well as our pipeline programs."
>
> **Renée Aguiar-Lucander, CEO**

The transcriptomic analysis showed that the two top pathways impacted by the treatment were fibrosis-related signalling pathways (the Idiopathic Pulmonary Fibrosis Signaling Pathway and Hepatic Fibrosis/Hepatic Stellate Cell Activation Pathway), providing support for the presumed mode of action on activated cancer-associated fibroblasts in head and neck cancer, as well as a potential anti-fibrotic effect in Calliditas' other ongoing clinical programs.

Pathology analysis showed preliminary evidence of an increase in immunological activity within tumors of patients treated with setanaxib, with favorable changes in Foxp3and PDL-1 CPS. As SMA levels at baseline were not balanced between the groups, and tumor biopsy samples were generally small, it was not possible to draw any conclusions regarding setanaxib's impact on SMA reduction.

In terms of PFS, 7 out of the 16 evaluable patients were progression-free with either stable disease or partial response, of which 6 were in the setanaxib arm and 1 was in the placebo arm. 6 of the 7 patients were still on the study drug at the time of the data read out, with the longest period on drug being reported as 21 weeks, related to a patient in the setanaxib arm.

Pipeline: PBC and Alport Syndrome

Alport syndrome

Alport syndrome is a genetic disorder arising from the mutations in the genes that code for type 4 collagen The type 4 collagen alpha chains are primarily located in the kidneys, eyes, and cochlea, and thus the condition is characterized by kidney disease, loss of hearing, and eye abnormalities. Eventually, patients present with proteinuria, hypertension, progressive loss of kidney function (gradual decline in GFR), and end-stage renal disease (ESRD). It is estimated that approximately 30,000 to 60,000 people in the United States (US) have this disorder, and it is a significant cause of chronic kidney disease (CKD), leading to ESRD in adolescents and young adults and accounting for 1.5% to 3.0% of children on renal replacement therapies in Europe and the US.[1]

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 2023 and on the basis of the data readout, which would evaluate overall safety as well as impact on proteinuria, we would decide on a full regulatory program.

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

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

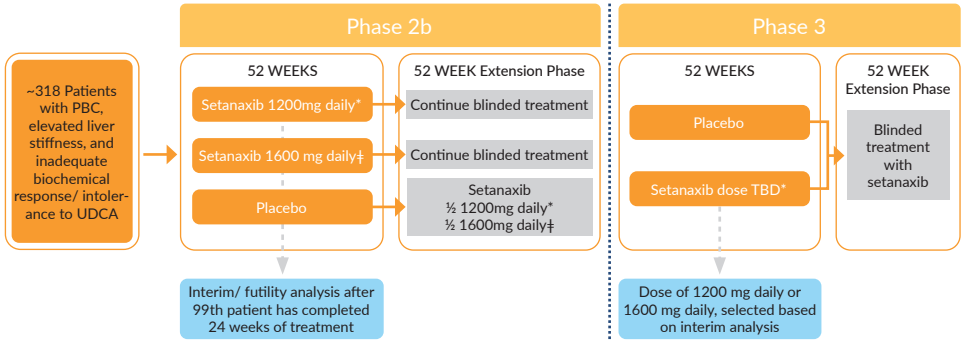
Phase 2 data from a trial with setanaxib in PBC with 111 patients demonstrated that setanaxib had a more pronounced effect on fibrosis and ALP reduction (alkaline phosphatase, a widely established independent predictor of prognosis in PBC) in patients with an estimated liver fibrosis stage of F3 or higher. Patients with elevated liver stiffness are at greater risk of disease progression.

The TRANSFORM Study

Calliditas is presently conducting a 52-week, randomized, placebo-controlled, double-blind trial, with an adaptive Phase 2b/3 design.

However, following slower than expected recruitment rates, regulatory feedback, and the transcriptomic data readout in July, further supporting the potential anti-fibrotic mode of action of setanxib, we have decided to pursue a protocol amendment to enable us to read out the data of the Phase 2b portion of the trial and subsequently decide on an appropriate way forward, subject to the data observed. We would expect to be able to read out the data in mid-2024 and expect to reduce the planned trial costs significantly for 2024 and 2025.

The design of the trial is currently under review, with a protocol amendment to be submitted to the FDA.



*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

Further details of this study can be found at www.clinicaltrials.gov, with the reference NCT05014672.

Our Pipeline

	Rights	Commercial region	Significant milestones
IgA Nephropathy (IgAN)	calliditas THERAPEUTICS	United States	Filed for full regulatory approval in the US – June 2023
IgA Nephropathy (IgAN)	STADA	European Economic Area, UK, Switzerland	Support STADA EMA filing in 2023
IgA Nephropathy (IgAN)	EVEREST MEDICINES	China, Hong Kong, Macau, Taiwan, Singapore, South Korea	NDA accepted and FTD received in China. Decision expected in 2H 2023
IgA Nephropathy (IgAN)	VIATRIS	Japan	
Primary Biliary Cholangitis (PBC)**	calliditas THERAPEUTICS	Global	Interim Analysis: Mid 2024 (subject to recruitment)
Head and Neck Cancer (SCCHN)	calliditas THERAPEUTICS	Global	Final Data Readout: 2024
Idiopathic Pulmonary Fibrosis (IPF)	calliditas THERAPEUTICS	Global	
Alport Syndrome	calliditas THERAPEUTICS	Global	Trial launch 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.

** The design of the trial is currently under review with a protocol amendment to be submitted to the FDA to enable a read out of Phase 2b data.

Significant Events

Significant events during the period January 1 – June 30, 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.

- In June 2023, Calliditas had two oral presentations and two abstracts reflecting data and analyses from the NefIgArd Phase 3 Study, evaluating Nefecon (TARPEYO (budesonide) delayed release capsules/Kinpeygo) in patients with IgA nephropathy (IgAN), at the European Renal Association (ERA) Congress 2023, which was held virtually as well as in person in Milan, Italy.

- In June 2023, Calliditas announced the submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) seeking full approval of TARPEYO (budesonide) delayed release capsules (developed under the project name Nefecon) for the entire study population evaluated in the Phase 3 NefIgArd study. The sNDA submission was based on the full data set from the Phase 3 NefIgArd clinical trial, a randomized, double-blind, multicenter study which assessed the efficacy and safety of Nefecon dosed at 16 mg once daily versus placebo on a background of optimized RASi therapy in adult patients with primary IgAN. The trial met its primary endpoint of kidney function, with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in estimated glomerular filtration rate (eGFR) over the two-year period of 9 months of treatment with Nefecon or placebo and 15 months of follow-up off drug.

Significant Events after the end of the period

- In July 2023, Calliditas announced interim data from the proof-of-concept Phase 2 trial in patients with squamous cell carcinoma of the head and neck (SCCHN) with its lead NOX 1 and 4 inhibitor product candidate, setanaxib. The analysis reflects encouraging early clinical progression-free survival (PFS) results and is supportive of the presumed anti-fibrotic mode of action of setanaxib.

- In August 2023, Calliditas announced publication in The Lancet of the full data from the Phase 3 NefIgArd Study with Nefecon (TARPEYO (budesonide) delayed release capsules/Kinpeygo) in adults with Primary IgA nephropathy (IgAN). The Phase 3 trial met the primary endpoint, estimated glomerular filtration rate (eGFR), with Nefecon demonstrating significant kidney protective effect over placebo.

Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Year Ended December 31, 2022
Net sales	269,384	64,047	460,735	113,781	802,879
Operating loss	(75,172)	(209,844)	(255,246)	(418,210)	(421,943)
Loss before income tax for the period	(70,660)	(192,090)	(278,679)	(403,525)	(409,417)
Loss per share before and after dilution (SEK)	(1.71)	(3.62)	(5.21)	(7.57)	(7.78)
Cash flow used in operating activities	(163,031)	(225,234)	(394,971)	(416,658)	(311,354)

(SEK in thousands, except per share amount or as otherwise indicated)	June 30, 2023	June 30, 2022	December 31, 2022
Total registered shares, including shares held by Calliditas, at the end of the period	59,580,087	59,106,188	59,580,087
Equity attributable to equity holders of the Parent Company at the end of the period	504,367	721,094	766,264
Equity ratio at the end of the period in %	30%	49%	39%
Cash at the end of the period	866,181	846,799	1,249,094

January – June 2023

Revenue

Net sales amounted to SEK 269.4 million and SEK 64.0 million for the three months ended June 30, 2023 and 2022, respectively. Net sales for the six months ended June 30, 2023 and 2022 amounted to SEK 460.7 million and SEK 113.8 million, respectively. Net sales for the periods primarily originate from net sales of TARPEYO in the U.S, which amounted to SEK 259.2 million and SEK 63.6 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, net sales from TARPEYO amounted to SEK 444.9 million and SEK 81.6 million, respectively. Royalty income from our partnership in Europe amounted to SEK 8.8 million for the three months ended June 30, 2023 and SEK 13.2 million for the six months ended June 30, 2023. No royalty income were recorded for the three and six months ended June 30, 2022. Further, for the six months ended June 30, 2022, net sales also consisted of the milestone fee from Everest Medicines for the extension of the license agreement for South Korea, which amounted to SEK 28.8 million. For additional information see Note 4.

Cost of Sales

Cost of sales amounted to SEK 14.2 million and SEK 2.4 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022 cost of sales amounted to SEK 23.2 million and SEK 3.0 million, respectively.

Total Operating Expenses

Total operating expenses amounted to SEK 330.3 million and SEK 271.5 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022 total operating expenses amounted to SEK 692.7 million and SEK 529.0 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 89.0 million and SEK 96.3 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022 research and development expenses amounted to SEK 215.6 million and SEK 209.6 million, respectively. The decrease of SEK 7.3 million for the three months ended June 30, 2023 was primarily due to the completion of the NeflgArd study in the first quarter 2023, compared to the corresponding period of the prior year. The increase of SEK 6.0 million for the six months ended June 30, 2023, was primarily due to increased 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 191.5 million and SEK 113.3 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022 marketing and selling expenses amounted SEK 358.7 million and SEK 207.2 million. The increase of SEK 78.2 million for the three months ended June 30, 2023, and SEK 151.5 million for the six months ended June 30, 2023, was primarily related to the costs for sales and marketing of TARPEYO in the U.S., where the marketing activities have been intensified and the salesforce have been increased, compared to the corresponding periods of the prior year.

Administrative Expenses

Administrative expenses amounted to SEK 77.2 million and SEK 58.9 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, administrative expenses amounted to SEK 149.7 million and SEK 107.4 million, respectively. The increase of SEK 18.3 million for the three months ended June 30, 2023, and SEK 42.3 million for the six months ended June 30, 2023, 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 27.3 million and (SEK 3.0 million) for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022 other operating income/(expenses), net amounted to SEK 31.3 million and (SEK 4.8 million), respectively. The increase for the periods was primarily related to a more favourable exchange rate development on operating receivables and liabilities and an updated valuation of the contingent consideration in connection with the business acquisition of Genkyotex SA, due to change of study design which will lead to a delay for the PBC project within the setanaxib platform, compared to the corresponding periods of the prior year.

Net Financial Income and Expenses

Net financial income/(expenses) amounted to SEK 4.5 million and SEK 17.8 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, net financial income/(expenses) amounted to (SEK 23.4 million) and SEK 14.7 million, respectively. The decrease of SEK 13.3 million for the three months ended June 30, 2023, and SEK 38.1 million for the six months ended June 30, 2023 was primarily derived from interest expenses from the Kreos loan and currency effect related to external and internal loans compared to the corresponding periods of the prior year.

Tax

Total income tax/(expense) amounted to (SEK 21.3 million) and (SEK 0.3 million) for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, total income tax/(expense) amounted to (SEK 0.8 million) and SEK 4.0 million, respectively. The increase for the periods were primarily explained by taxable profit for the U.S. subsidiaries. The Group's tax losses carried-forward have not been recognized as deferred tax assets, other than to the extent such tax losses can be used to offset temporary differences.

Result for the Period

For the three months ended June 30, 2023 and 2022, loss for the period amounted to SEK 91.9 million and SEK 192.4 million, and the corresponding loss per share before and after dilution amounted to SEK 1.71 and SEK 3.62, respectively. For the six months ended June 30, 2023 and 2022, loss for the period amounted to SEK 279.5 million and SEK 399.5 million, and the corresponding loss per share before and after dilution amounted to SEK 5.21 and SEK 7.57, respectively.

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 163.0 million and SEK 225.2 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, cash flow used in operating activities amounted to SEK 395.0 million and SEK 416.7 million, respectively. The increase for the periods were primarily explained by an improved operating result primarily driven by the sales growth for TARPEYO in the U.S., compared to the corresponding periods of the prior year.

Cash flow used in investing activities amounted to SEK 1.1 million and SEK 0.1 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, cash flow used in investing activities amounted to SEK 4.0 million and SEK 2.8 million, respectively. The increase for the periods were primarily explained by acquisition of equipment.

Cash flow from/(used in) financing activities amounted to (SEK 3.0 million) and SEK 235.9 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, cash flow from/(used in) financing activities amounted to (SEK 6.0 million) and SEK 295.9 million, respectively. The decrease for the periods was mainly derived from the draw down of the second tranche of the Kreos loan facility of SEK 236.5 million during the second quarter of 2022 and, in addition, for the six-month period, the decrease was also derived from the payments related to the exercise of the Warrant Program 2018/2022, which occurred in the corresponding periods of the prior year.

Net increase/(decrease) in cash amounted to (SEK 167.1 million) and SEK 10.5 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, net decrease in cash amounted to SEK 404.9 million and SEK 123.5 million, respectively. Cash amounted to SEK 866.2 million and SEK 846.8 million as of June 30, 2023 and 2022, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 504.4 million and SEK 721.1 million as of June 30, 2023 and 2022, respectively. The number of registered shares amounted to 59,580,087 and 59,106,188 as of June 30, 2023 and 2022, respectively. The increase in number of shares between the periods was derived from a new share issue in December 2022 of 422,500 shares related to the Warrant Program 2019/2022 and a new share issue in August 2022 of 51,399 shares related to the Board LTIP 2019 Program.

Treasury Shares

As of June 30, 2023, Calliditas had 5,908,018 ordinary shares held as treasury shares by the Parent Company. At the Annual General Meeting 2023, authorization was given that Calliditas can transfer (sale) these ordinary shares with the purpose to finance an acquisition of operations, to procure capital to finance the development of projects, repayment of loans or to commercialize Calliditas' products. See Note 7 for further information.

Personnel

The average number of employees were 174 and 81 employees for the three months ended June 30, 2023 and 2022, respectively and 169 and 76 employees for the six months ended June 30, 2023 and 2022, respectively.

Incentive Programs

During the three months ended June 30, 2023, 413,000 options have been allocated for the ESOP 2022 Program and 40,957 share awards have been allocated for the Board LTIP 2023 Program. For more information on incentive programs, see Note 9.

Updated 2023 Outlook

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

- Net sales from TARPEYO are estimated to be USD 100-120 million for the year ending December 31, 2023 (corresponding to approx. SEK 1,047-1,257 million, using a SEK/USD average exchange rate of 10.47), where the previous expectation of net sales from TARPEYO was estimated to be 120-150 MUSD for the year ending December 31, 2023.

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 105.6 million and SEK 0.4 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022 net sales amounted to SEK 274.0 million and SEK 32.2 million, respectively. The increase for the periods was primarily derived from sales of TARPEYO compared to the corresponding periods of the prior year. Operating loss amounted to SEK 118.1 million and SEK 152.1 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022 operating loss amounted to SEK 164.7 million and SEK 254.7 million, respectively. The improvement for the periods was primarily derived from the increase in revenues compared to the corresponding periods of the prior year. Non-current financial assets have increased by SEK 162.3 million to SEK 1,049.7 million as of June 30, 2023, compared to December 31, 2022, which was primarily derived from intercompany transactions.

Declaration by the Board of Directors

The Board of Directors and CEO declare that the interim report for the six months ended June 30, 2023 gives a fair view of the business development, financial position and result of operation of the Parent Company and the Group and describes significant risks and uncertainties that the Parent Company and its subsidiaries are facing.

Stockholm, August 17, 2023

Board of Directors

Elmar Schnee
Chairman of the board

Henrik Stenqvist
Board member

Diane Parks
Board member

Hilde Furberg
Board member

Frederick Driscoll
Board member

Elisabeth Björk
Board member

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 June 30, 2023 and for the six 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 interim 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 17 August 2023

Ernst & Young AB

Jakob Grunditz
Authorized Public Accountant

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Year Ended December 31, 2022
Net sales	4	269,384	64,047	460,735	113,781	802,879
Cost of sales		(14,214)	(2,385)	(23,242)	(2,999)	(15,201)
Gross profit		**255,169**	**61,662**	**437,493**	**110,781**	**787,678**
Research and development expenses		(88,986)	(96,290)	(215,639)	(209,633)	(414,749)
Marketing and selling expenses		(191,472)	(113,272)	(358,696)	(207,169)	(515,190)
Administrative expenses		(77,151)	(58,907)	(149,698)	(107,438)	(259,469)
Other operating income/(expenses), net		27,267	(3,038)	31,294	(4,752)	(20,212)
Operating loss		**(75,172)**	**(209,844)**	**(255,246)**	**(418,210)**	**(421,943)**
Net financial income/(expenses)		4,512	17,754	(23,433)	14,686	12,526
Loss before income tax		**(70,660)**	**(192,090)**	**(278,679)**	**(403,525)**	**(409,417)**
Income tax		(21,274)	(339)	(780)	4,048	(2,851)
Loss for the period		**(91,934)**	**(192,429)**	**(279,459)**	**(399,477)**	**(412,268)**
Attributable to:						
Equity holders of the Parent Company		(91,934)	(192,429)	(279,459)	(399,477)	(412,268)
		(91,934)	**(192,429)**	**(279,459)**	**(399,477)**	**(412,268)**
Loss per share before and after dilution (SEK)		(1.71)	(3.62)	(5.21)	(7.57)	(7.78)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Year Ended December 31, 2022
Loss for the period	(91,934)	(192,429)	(279,459)	(399,477)	(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	(4,040)	31,269	(2,881)	30,069	36,287
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods	**(4,040)**	**31,269**	**(2,881)**	**30,069**	**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	(556)	1,177	(1,218)	2,471	2,763
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods	**(556)**	**1,177**	**(1,218)**	**2,471**	**2,763**
Other comprehensive income/(loss) for the period	**(4,596)**	**32,445**	**(4,099)**	**32,539**	**39,050**
Total comprehensive income/(loss) for the period	**(96,530)**	**(159,984)**	**(283,558)**	**(366,938)**	**(373,218)**
Attributable to:					
Equity holders of the Parent Company	(96,530)	(159,984)	(283,558)	(366,938)	(373,218)
	(96,530)	**(159,984)**	**(283,558)**	**(366,938)**	**(373,218)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	June 30, 2023	June 30, 2022	December 31, 2022
ASSETS				
Non-current assets				
Intangible assets		515,028	460,304	483,841
Equipment		9,222	7,034	7,468
Right-of-use assets		32,271	29,586	24,452
Non-current financial assets		16,617	5,807	11,210
Deferred tax assets		22,423	5,420	13,799
Total non-current assets		**595,560**	**508,151**	**540,770**
Current assets				
Inventories		17,697	730	3,647
Current receivables		146,365	52,873	88,721
Prepaid expenses and accrued income		83,343	49,739	70,741
Cash		866,181	846,799	1,249,094
Total current assets		**1,113,587**	**950,142**	**1,412,204**
TOTAL ASSETS		**1,709,147**	**1,458,293**	**1,952,973**
EQUITY AND LIABILITIES				
Equity				
Equity attributable to equity holders of the Parent Company		504,367	721,094	766,264
Total equity	*7,8,9*	**504,367**	**721,094**	**766,264**
Non-current liabilities				
Provisions	*9*	15,146	8,859	12,675
Contingent consideration	*6*	69,290	59,559	75,880
Deferred tax liabilities		41,950	32,259	39,752
Non-current interest-bearing liabilities		759,052	437,392	713,030
Lease liabilities		20,512	20,635	15,792
Other non-current liabilities		8,521	-	4,350
Total non-current liabilities		**914,471**	**558,705**	**861,479**
Current liabilities				
Accounts payable		72,037	81,666	160,404
Other current liabilities		30,742	15,893	28,381
Accrued expenses and deferred revenue		187,531	80,935	136,446
Total current liabilities		**290,309**	**178,494**	**325,231**
TOTAL EQUITY AND LIABILITIES		**1,709,147**	**1,458,293**	**1,952,973**

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Six Months Ended June 30, 2023	Six Months Ended June 30, 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	(279,459)	(399,477)	(412,268)
Other comprehensive income/(loss)	(4,099)	32,539	39,050
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	**(283,558)**	**(366,938)**	**(373,218)**
Transactions with owners:			
Issuance of treasury shares	-	236	236
Repurchase of treasury shares	-	(236)	(236)
Exercise of warrants	-	63,644	95,121
Share-based payments	21,661	16,107	36,080
Total transactions with owners	**21,661**	**79,751**	**131,201**
Closing balance equity attributable to equity holders of the Parent Company	**504,367**	**721,094**	**766,264**
Closing balance equity	**504,367**	**721,094**	**766,264**

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Year Ended December 31, 2022
Operating activities					
Operating loss	(75,172)	(209,844)	(255,246)	(418,210)	(421,943)
Adjustment for non-cash-items	(7,266)	14,104	19,876	19,171	61,260
Interest received	724	2	732	2	3,553
Interest paid	(17,915)	(5,437)	(33,376)	(10,846)	(35,252)
Income taxes paid	(13,839)	(2,930)	(15,175)	(2,930)	(7,392)
Cash flow used in operating activities before changes in working capital	**(113,468)**	**(204,105)**	**(283,189)**	**(412,813)**	**(399,774)**
Cash flow from/(used in) changes in working capital	(49,564)	(21,129)	(111,782)	(3,845)	88,420
Cash flow used in operating activities	**(163,031)**	**(225,234)**	**(394,971)**	**(416,658)**	**(311,354)**
Cash flow used in investing activities	**(1,060)**	**(139)**	**(3,973)**	**(2,790)**	**(5,144)**
Issuance of treasury shares	-	236	-	236	236
Repurchase of treasury shares	-	(236)	-	(236)	(236)
Exercise of warrants	-	1,932	-	63,644	95,121
New borrowings	-	236,462	-	236,462	491,745
Costs attributable to new loans	-	-	-	-	(1,260)
Repayment of lease liabilities	(3,015)	(2,527)	(5,984)	(4,185)	(9,615)
Cash flow from/(used in) financing activities	**(3,015)**	**235,867**	**(5,984)**	**295,922**	**575,990**
Net increase/(decrease) in cash	**(167,106)**	**10,494**	**(404,928)**	**(123,526)**	**259,493**
Cash at the beginning of the period	**1,013,600**	**825,408**	**1,249,094**	**955,507**	**955,507**
Net foreign exchange gains/(loss) on cash	19,687	10,897	22,015	14,818	34,094
Cash at the end of the period	**866,181**	**846,799**	**866,181**	**846,799**	**1,249,094**

Condensed Parent Company Statements of Income

(SEK in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Year Ended December 31, 2022
Net sales	105,617	420	273,987	32,191	548,977
Cost of sales	(14,199)	(2,385)	(23,211)	(2,999)	(15,141)
Gross profit/(loss)	**91,419**	**(1,965)**	**250,776**	**29,192**	**533,836**
Research and development expenses	(77,820)	(88,708)	(196,609)	(192,389)	(384,453)
Marketing and selling expenses	(107,068)	(38,401)	(195,739)	(62,808)	(310,372)
Administrative expenses	(61,848)	(49,997)	(121,033)	(94,342)	(212,971)
Other operating income/(expenses), net	37,229	26,922	97,882	65,664	158,597
Operating loss	**(118,088)**	**(152,149)**	**(164,723)**	**(254,683)**	**(215,364)**
Net financial income/(expenses)	(3,984)	9,236	(22,318)	5,841	6,816
Loss before income tax	**(122,072)**	**(142,913)**	**(187,041)**	**(248,842)**	**(208,548)**
Income tax	-	-	-	-	-
Loss for the period	**(122,072)**	**(142,913)**	**(187,041)**	**(248,842)**	**(208,548)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Year Ended December 31, 2022
Loss for the period	(122,072)	(142,913)	(187,041)	(248,842)	(208,548)
Other comprehensive income/(loss)	-	-	-	-	-
Total comprehensive income/(loss)	**(122,072)**	**(142,913)**	**(187,041)**	**(248,842)**	**(208,548)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	June 30, 2023	June 30, 2022	December 31, 2022
ASSETS				
Non-current assets				
Intangible assets		32,132	32,132	32,132
Equipment		455	679	567
Non-current financial assets		1,049,716	743,169	887,456
Total non-current assets		**1,082,303**	**775,979**	**920,154**
Current assets				
Inventories		17,697	730	3,647
Current receivables		71,974	25,069	129,090
Prepaid expenses and accrued income		64,648	34,245	61,092
Cash		754,802	790,377	1,059,655
Total current assets		**909,121**	**850,421**	**1,253,485**
TOTAL ASSETS		**1,991,423**	**1,626,401**	**2,173,639**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Total restricted equity		5,475	5,456	5,475
Total non-restricted equity		960,101	1,033,756	1,125,480
Total shareholders' equity	*7,9*	**965,577**	**1,039,212**	**1,130,956**
Non-current liabilities				
Provisions	*9*	10,685	5,149	9,512
Non-current interest-bearing liabilities		759,052	437,392	713,030
Other non-current liabilities		8,626	105	4,455
Total non-current liabilities		**778,363**	**442,646**	**726,997**
Current liabilities				
Accounts payable		31,210	41,346	100,469
Other current liabilities		119,076	50,334	141,750
Accrued expenses and deferred revenue		97,197	52,863	73,468
Total current liabilities		**247,484**	**144,543**	**315,686**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,991,423**	**1,626,401**	**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 six months ended June 30, 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 August 17, 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 31.

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

Operational Risks

Research and drug development up to approved registration is subject to considerable risk and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to the technological 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 June 30,		Six Months Ended June 30,		Year Ended December 31,
(SEK in thousands)	2023	2022	2023	2022	2022
Type of goods or services					
Product sales	260,631	63,627	447,571	81,590	375,515
Outlicensing of product	-	-	-	28,804	421,689
Royalty income	8,752	-	13,164	-	2,287
Performance of certain regulatory services	-	420	-	3,387	3,387
Total	**269,383**	**64,047**	**460,735**	**113,781**	**802,879**
Geographical markets					
USA	259,239	63,627	444,931	81,590	372,247
Europe	10,144	420	15,804	3,387	143,955
Asia	-	-	-	28,804	286,677
Total	**269,383**	**64,047**	**460,735**	**113,781**	**802,879**

Net sales for the periods primarily originate from net sales of TARPEYO in the U.S, which amounted to SEK 259.2 million and SEK 63.6 million for the three months ended June 30, 2023 and 2022, respectively. For the six months ended June 30, 2023 and 2022, net sales from TARPEYO amounted to SEK 444.9 million and SEK 81.6 million, respectively. Royalty income from our partnership in Europe amounted to SEK 8.8 million for the three months ended June 30, 2023 and SEK 13.2 million for the six months ended June 30, 2023. No royalty income were recorded for the three and six months ended June 30, 2022. Further, for the six months ended June 30, 2022, net sales also consisted of the milestone fee from Everest Medicines for the extension of the license agreement for South Korea, which amounted to SEK 28.8 million.

The total liability for expected returns and rebates amounts to SEK 46.1 million and SEK 6.9 million as of June 30, 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 June 30, 2023 and 2022, the affecting profit/(loss) for the period amounted to SEK 12.5 million and (SEK 1.4 million), respectively and for the six months ended June 30, 2023 and 2022, the affecting profit/(loss) for the period amounted to SEK 10.6 million and (SEK 2.7 million), respectively, which are recognized in other operating income/(expenses), net. This was attributable to the change of study design which will lead to a delay for the PBC project within the setanaxib platform. For more information see the Annual Report for 2022.

Note 7 - Treasury Shares

As of June 30, 2023, Calliditas had 5,908,018 ordinary shares held as treasury shares by the Parent Company. At the Annual General Meeting 2023, authorization was given that Calliditas can transfer (sale) these ordinary shares with the purpose to finance an acquisition of operations, to procure capital to finance the development of projects, repayment of loans or to commercialize Calliditas' products. No transfer (sale) of treasury shares have occurred as of June 30, 2023.
The total number of issued shares as of June 30, 2023, is presented in Note 8.

Note 8 - Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	June 30, 2023	June 30, 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	-	6,764,604	7,231,003
Shares subscribed but not registered during the period	-	-	7,500
Total registered and subscribed but not registered shares at the end of the period	**59,580,087**	**59,106,188**	**59,580,087**
Shares			
Ordinary shares	59,580,087	53,198,170	59,580,087
C-shares	-	5,908,018	-
Total	**59,580,087**	**59,106,188**	**59,580,087**
- of which shares are held by Calliditas	*5,908,018*	*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**	**53,198,170**	**53,672,069**
Share capital at the end of the period	2,383	2,364	2,383
Equity attributable to equity holders of the Parent Company	504,367	721,094	766,264
Total equity at the end of the period	**504,367**	**721,094**	**766,264**

(SEK in thousands, except per share amounts and number of shares)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Year Ended December 31, 2022
Loss per share before and after dilution, SEK	(1.71)	(3.62)	(5.21)	(7.57)	(7.78)
Weighted-average number of ordinary shares outstanding for the period, before and after dilution	53,672,069	53,190,170	53,672,069	52,788,020	53,022,550

Reserves for translation from foreign operations amounted to SEK 6.4 million and SEK 3.1 million which are included in retained earnings in equity as of June 30, 2023 and 2022, respectively.

Note 9 - Incentive Programs

	June 30, 2023			June 30, 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 2020	-	-	-	-	-	31,371	31,371
Board LTIP 2021	-	22,882	22,882	-	-	26,968	26,968
Board LTIP 2022	-	37,136	37,136	-	-	40,706	40,706
Board LTIP 2023	-	40,957	40,957	-	-	-	-
ESOP 2020	1,364,730	-	1,364,730	-	1,444,000	-	1,444,000
ESOP 2021	1,468,500	-	1,468,500	-	1,495,000	-	1,495,000
ESOP 2022	1,961,000	-	1,961,000	-	-	-	-
Total Outstanding	**4,794,230**	**100,975**	**4,895,205**	**422,500**	**2,939,000**	**99,045**	**3,460,545**

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.

Board LTIP 2023:

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 2023 Annual General Meeting to July 1, 2026.

ESOP Programs

Calliditas implements option programs for employees and key consultants in Calliditas. The options are granted 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

	June 30,		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	504,367	721,094	766,264
Total assets at the end of the period	1,709,147	1,458,293	1,952,973
Equity ratio at the end of the period in %	**30%**	**49%**	**39%**

Financial Calendar

Interim Report for the period January 1 – September 30, 2023	November 7, 2023
Year-End Report for the period January 1 – December 31, 2023	February 22, 2024
Interim Report for the period January 1 – March 31, 2024	May 16, 2024

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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" 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 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.

The information in the Interim Report is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Market Act. The information was sent for publication, through the agency of the contact persons set out above, on August 17, 2023, at 7:00 a.m. CET.

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