calliditas
THERAPEUTICS

Q3

INTERIM REPORT JANUARY – SEPTEMBER 2023

Interim Report January – September 2023

JULY – SEPTEMBER 2023 (COMPARED TO JULY – SEPTEMBER 2022)

- Net sales amounted to SEK 294.6 million, of which TARPEYO® net sales amounted to SEK 283.6 million, for the three months ended September 30, 2023. For the three months ended September 30, 2022 net sales amounted to SEK 260.1 million, of which TARPEYO net sales amounted to SEK 123.4 million.
- Operating loss amounted to SEK 159.6 million and SEK 36.2 million for the three months ended September 30, 2023 and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 3.14 and SEK 0.17 for the three months ended September 30, 2023 and 2022, respectively.
- Cash amounted to SEK 786.9 million and SEK 736.2 million as of September 30, 2023 and 2022, respectively.

JANUARY – SEPTEMBER 2023 (COMPARED TO JANUARY – SEPTEMBER 2022)

- Net sales amounted to SEK 755.3 million, of which TARPEYO net sales amounted to SEK 728.5 million, for the nine months ended September 30, 2023. For the nine months ended September 30, 2022 net sales amounted to SEK 373.8 million, of which TARPEYO net sales amounted to SEK 205.0 million.
- Operating loss amounted to SEK 414.8 million and SEK 454.4 million for the nine months ended September 30, 2023 and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 8.34 and SEK 7.72 for the nine months ended September 30, 2023 and 2022, respectively.

"We are looking forward to a potential full approval of TARPEYO for the treatment of IgA Nephropathy on our PDUFA date of December 20, 2023."

Renée Aguiar-Lucander / CEO

JUL – SEP 2023

284

MSEK
TARPEYO net sales

JUL – SEP 2023

130%

TARPEYO net sales growth (vs Q3 2022)

JUL – SEP 2023

787

MSEK
Cash position on 30 September 2023

Key Takeaways from Q3

- In August, the FDA granted priority review for the application for full approval of TARPEYO (budesonide) delayed release capsules for the treatment of IgA nephropathy.
- In August, full data from the Phase 3 NefIgArd study with Nefecon® (TARPEYO®/Kinpeygo®) was published in *The Lancet*.
- In September STADA and Calliditas announced the filing of the application for full marketing authorisation of Kinpeygo in the EU.

Expected Key Events upcoming 6 months

- PDUFA date set as December 20, 2023: potential full approval of TARPEYO in the complete study population for IgAN patients.
- Regulatory decision in China regarding market authorization for Nefecon.
- Regulatory decision in EU regarding full marketing authorisation for Kinpeygo.
- Full data from Phase 2 proof-of-concept study of setanixib in head and neck cancer, expected in H1 2024.

Calliditas – pioneering new treatments for rare diseases

Calliditas Therapeutics leverages scientific expertise and disease-specific insights to improve the lives of patients. We are a commercial-stage biopharma company that researches, develops and commercializes novel therapies that address significant unmet needs in rare diseases. We are committed to expanding treatment options and establishing new standards of care for patients with rare diseases, reflected by our pipeline of innovative medicines that target unmet medical needs.

Our lead product provides provides a treatment option that we believe is disease-modifying for IgA nephropathy (IgAN) – also known as Berger's Disease – a progressive autoimmune disease of the kidney that for many patients leads to end-stage renal disease (ESRD), requiring dialysis or organ transplantation. This drug product, developed under the name Nefecon®, was granted accelerated approval by the FDA in 2021, and is today marketed in the US under the brand name TARPEYO®. It has also been granted conditional marketing authorisation by the European Commission under the brand name Kinpeygo® in the European Economic Area (EEA) and in the UK. TARPEYO and Kinpeygo are currently being reviewed by the FDA and EMA for full approval, with the US PDUFA date set for December 20, 2023.

Nefecon has also been approved in Macau and is being reviewed by regulators in China, Singapore and South Korea, and Calliditas has recently entered into a partnership to develop and commercialize Nefecon in Japan.

IgA nephropathy is the largest of the glomerular nephritis diseases, so the market potential for Nefecon is substantial, as evidenced by out-licensing deals with potential payments exceeding USD 300 million, encompassing upfront payments and predefined milestones, as well as ongoing royalty obligations.

Our late-stage pipeline is based on a first-in-class platform of NOX inhibitors. Our lead compound, setanaxib, inhibits enzymes involved in inflammation and fibrosis pathways and is the first drug of this class to reach the clinical stage. Setanaxib is currently undergoing clinical trials targeting rare diseases characterized by inflammation and fibrosis, including IPF and PBC, and Calliditas is also planning to launch a trial with setanaxib in Alport syndrome. Additionally, based on promising preclinical findings, we are conducting a proof-of-concept trial in head and neck cancer to further support the mode of action of this drug class.

While our headquarters are in Stockholm, Sweden, we maintain a significant presence in the United States, with offices in New York and New Jersey. We also have offices in France and Switzerland, where our discovery team is based. Calliditas Therapeutics ordinary shares were listed on NASDAQ Stockholm in 2018 (CALTX) and subsequently American Depositary shares representing our ordinary shares were listed on the NASDAQ Global Select Market in the United States in 2020 (CALT).

Our Values

AGILITY
We are flexible and able to rapidly pivot and adapt to changing situations and requirements.

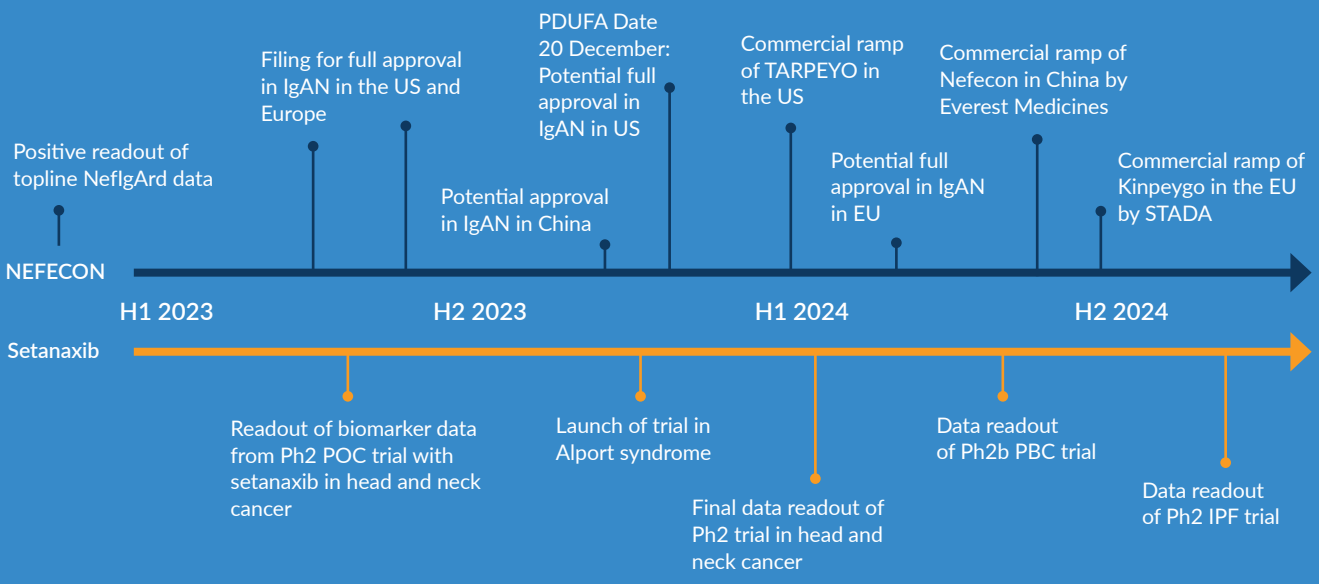
EXPERTISE
We leverage our strong internal experience and competencies while complementing our strengths through knowledge sharing and external collaborations as needed.

INTEGRITY
We take responsibility for our actions and hold ourselves to the highest ethical standards, guided by our moral principles to make the right decisions.

PIONEER
We explore novel approaches and empower each other to find new ways of operating in a compliant, innovative and pragmatic manner.

Investment highlights 2023

RECENT AND ANTICIPATED VALUE DRIVERS



Key Figures

	Jul–Sep		Jan–Sep		Jan–Dec
(SEK in thousands, except per share amount or as otherwise indicated)	2023	2022	2023	2022	2022
Net sales	294,592	260,056	755,327	373,837	802,879
Of which TARPEYO product sales	283,591	123,400	728,522	204,989	372,247
Operating profit/(loss)	(159,573)	(36,227)	(414,819)	(454,438)	(421,943)
Profit/(loss) before income tax for the period	(164,082)	(15,958)	(442,760)	(419,483)	(409,417)
Earnings/(loss) per share before and after dilution (SEK)	(3.14)	(0.17)	(8.34)	(7.72)	(7.78)
Cash flow used in operating activities	(62,529)	(124,725)	(457,500)	(541,383)	(311,354)

	As of		As of
(SEK in thousands, except per share amount or as otherwise indicated)	30.09.2023	30.09.2022	31.12.2022
Total registered shares, including shares held by Calliditas, at the end of the period	59,580,087	59,157,587	59,580,087
Equity attributable to equity holders of the Parent Company at the end of the period	352,435	725,936	766,264
Equity ratio at the end of the period in %	22%	48%	39%
Cash at the end of the period	786,883	736,161	1,249,094

Lancet publication of full Phase 3 data set

In August we were excited to see the full data set from our global, randomized, placebo controlled, double-blind Phase 3 clinical trial, NefIgArd, published in *The Lancet*. As previously reported, the trial successfully met its primary endpoint, providing evidence that 9 months of treatment with Nefecon 16 mg/day led to a significant reduction in the decline of eGFR, a measure of kidney function, over 2 years in adult patients with primary IgA nephropathy (IgAN). In addition, a durable reduction in proteinuria was observed for the entire period and the positive effect of Nefecon on eGFR was independent of baseline proteinuria and resulted in an approximate 50% reduction in the decline of eGFR compared with placebo over the 2-year period. We believe these results support the thesis that the drug has the potential to provide a clinically meaningful delay in the need for dialysis or transplantation. We are looking forward to the potential of a full approval of TARPEYO on our PDUFA date of December 20, 2023.

In September we had the opportunity to attend the IIgANN bi-annual conference, which this year was held in Tokyo, Japan. At the summit we presented 5 posters, including confirmatory biomarker analysis showing significant reduction of Gd-IgA1 and circulating immune complexes (IgA-IC), which supports the disease modifying mechanism of the drug. We also had 2 oral presentations, including one looking at racial differences and one showing that treatment with Nefecon increased the number of patients without microhematuria from 34% to 60%, versus 32% to 39% in placebo, which was statistically significant (p=0.0001).

As expected, the third quarter was impacted by summer seasonality, and also saw some turnover in the sales team, resulting in a slight decrease in new enrolments notwithstanding continued growth in new prescribers. Based on early Q4 trends however, we are very encouraged with regards to significant enrolment growth. Total Q3 revenues were SEK 295 million, out of which net revenues from TARPEYO amounted to SEK 284m (USD 26.3m). The operating loss for the quarter was SEK 160m which included SEK 52m of R&D costs of one-time nature mainly stemming from changes to the TRANSFORM trial and discontinuation of a research project. Net decrease in cash in the quarter was SEK 73m and our cash position remains strong with SEK 787m on the balance sheet, which we believe is sufficient to take us to cash flow break even, based on revenue projections for TARPEYO. We have also started to see improved market access statistics with new patients starts taking on average 15-20 days to fill, reflecting our efforts to continuously improve patient access.

Following positive feedback regarding the complete NefIgArd trial results from multiple US advisory board meetings and dozens of face-to-face interactions with nephrologists at recent conferences, we have decided to launch a targeted US focused investment program in order to appropriately support and strengthen our category leadership position. This will involve adding resources across relevant commercial functions in order to fully capitalize on the potential for a full approval in late 2023. We believe that this will maximize our ability to drive significant revenue growth in 2024, with limited cost impact in 2023. Over the next several months we plan to selectively complement our existing teams with the goal to continue to enhance our medical education, patient support and market access activities to facilitate patient access and continue to build a leading franchise based on the NefIgArd trial data set. This increase is targeted and incremental and is not expected to materially increase the commercial cost base in 2024.

I also had the opportunity during the quarter to visit our partner, Everest Medicines, in China and learn more about their pre commercial activities and preparations in expectation of a potential approval later in the year, as well as the highly successful Early Access Patient (EAP) program which was launched in April. Several hundreds of patients signed up for the program, making it one of the most successful EAP programs launched in China. We are hopeful for an approval for Nefecon later this year in China, where the high prevalence of glomerulonephritis leads to many young people ending up in dialysis and where the need for an effective treatment for patients is therefore critical.

Post quarter activities included the American Society of Nephrology Kidney Week meeting in Philadelphia, which provided us with numerous opportunities to meet and engage with nephrologists across the country. The overall sentiment as well as the many encounters with nephrologists were very positive and further cemented our belief that the strong long-term data from our Phase 3 trial in combination with published registry data such as the RaDaR publication have started an important conversation in the nephrology community concerning the need for earlier intervention and treatment of IgAN. More on this in my Q4 report.

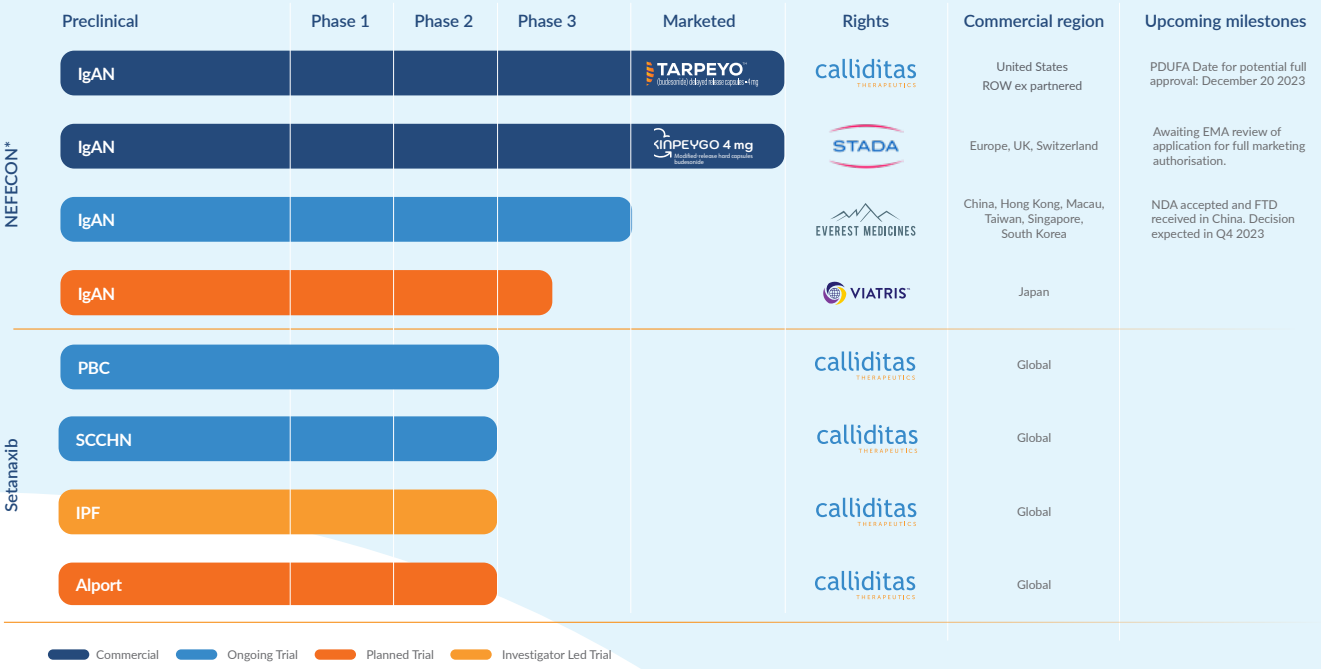
We hold our guidance for 2023 and look forward to the potential of a full approval of TARPEYO in Q4 and an exciting 2024.

Renée Aguiar-Lucander, CEO

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

Our Pipeline

Calliditas' lead product, developed under the name Nefecon, has been approved in the US and Europe and is awaiting approval in China. Our pipeline consists of development programs based on a first-in-class NOX inhibitor platform. The lead compound, setanaxib, is the first NOX inhibitor to reach the clinical 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). There is also an ongoing investigator-led trial in Idiopathic Pulmonary Fibrosis (IPF) and we are planning to initiate a Phase 2 trial in Alport syndrome.



* Approved under accelerated approval in the US under the tradename TARPEYO® to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g, and granted conditional marketing authorization in the EEA and UK under the tradename Kinpeygo® for the treatment of primary IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram.

Exciting Journey Ahead

December 20 2023 PDUFA date; FDA decision on full approval of TAPREYO in primary IgA nephropathy for patients at risk of progression

Regulatory decision in China expected in 2023

Potential full approval of Kinpeygo in EU in 1H 2024

Q4 23: Targeting initiation of Alport syndrome clinical trial

1H 24: Full data from phase 2 study in head and neck cancer

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 authorisation by the European Commission (EC) in July 2022, was the first ever approved medication and is the only treatment specifically designed to target the origin of the autoimmune kidney disease IgA nephropathy (IgAN) and 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 polymeric and are galactose-deficient. In IgAN patients, a combination of a genetic predisposition and 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.

Strong data from the full Phase 3 trial readout

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. Calliditas' supplemental New Drug Application to the FDA was based on the data from this trial, with Calliditas filing for full approval on the basis of the strong eGFR data readout.

The full Phase 3 NefIgArd trial consisted of a total of 364 patients, including 200 patients from the interim analysis, based upon which Calliditas successfully filed for accelerated and conditional approval with the FDA and EMA, respectively. The full trial included 9 months of treatment and 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. The data read-out took place in March 2023, and in August 2023 was published in *The Lancet*.

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 successfully met with a highly statistical p value of <0.0001. 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. 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).

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, declining by over 50%. 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.

Filing for full approval

On the basis of this positive data, Calliditas submitted a sNDA to the FDA seeking full approval of TARPEYO 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 IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. The FDA accepted this filing and granted priority review, setting a PDUFA date of December 20 2023.

In September 2023, Calliditas' partner STADA filed with the EMA for full marketing authorisation of Kinpeygo in the EU, and in October also filed with the UK MHRA.

[1]*Watson S, Padala SA, Hashmi MF, et al. Alport Syndrome. [Updated 2023 Feb 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan- Available from: https://www.ncbi.nlm.nih.gov/books/NBK470419/*

IgA nephropathy - a significant market opportunity

- IgAN is a rare disease, but it is the most common primary glomerulonephritis. Prevalence is estimated to range from 130,000 to 150,000 patients in the US, to be around 200,000 patients in Europe and up to 5 million patients in China.
- In the United States, we estimate there are around 12,000 nephrologists, of which up to two thirds treat patients with IgAN. The majority of patients are seen by approximately 4,000 to 5,000 specialists. About 40% of the patients are treated in academic settings while the remaining are treated in community settings.[1]
- The IgAN patient population at risk of disease progression as defined by KDIGO guidelines is estimated to amount to between 45,000 and 60,000 patients in the US.[2]
- Today the majority of these patients are treated principally with supportive care such as generic ACEs and/or ARBs to control blood pressure, complemented with other broadly indicated cardio and kidney protective drugs.
- As availability and familiarity of approved drugs specifically indicated and approved for IgAN increase and physicians consider more active intervention to preserve kidney function, we estimate the global IgAN market to amount to USD 5 – 8 billion.

Our commercial partnerships

EU

Nefecon® was granted conditional marketing authorisation (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 EU.

Kinpeygo will be marketed in the European Economic Area (EEA), the 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. 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.

Greater China

Calliditas entered into a license agreement to develop and commercialize Nefecon for IgAN in Greater China and Singapore with Everest Medicines (HKEX 1952.HK) in 2019. In March 2022, this agreement was expanded to include South Korea.

Everest'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 Q4 2023.

Everest launched Nefecon in China's Hainan Boao Pilot Zone as a First-in-Disease therapy for IgA nephropathy in April 2023. This program allows innovative overseas drugs and medical devices that have been approved in other territories to be sold and used in real-world clinical settings in Hainan Province before regulatory approval by the NMPA. Several hundreds of patients signed up for this early access program, making it one of the most successful EAP programs launched in China.

In October 2023, Everest received approval for Nefecon in IgAN patients at risk of disease progression from the Pharmaceutical Administration Bureau of the Macau Special Administrative Region, making it the first region in Everest territories that received Nefecon approval.

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 is headquartered in the United States and has a presence in over 165 countries and territories, and also operates approximately 40 manufacturing facilities.

[1] *Veeva OpenData for 2023, including all active HCPs where the primary specialty is Nephrology*
[2] *Spherix RealWorld Dynamix*

Nefecon Has the Potential to Establish a New Standard of Care in IgAN

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) to be disease-modifying.

Mechanism of Action

Targeted immuno-modulator designed to locally target origin of disease

Patient focus

In combination with optimized RASi therapy; option of intermittent, rather than chronic treatment

Efficacy

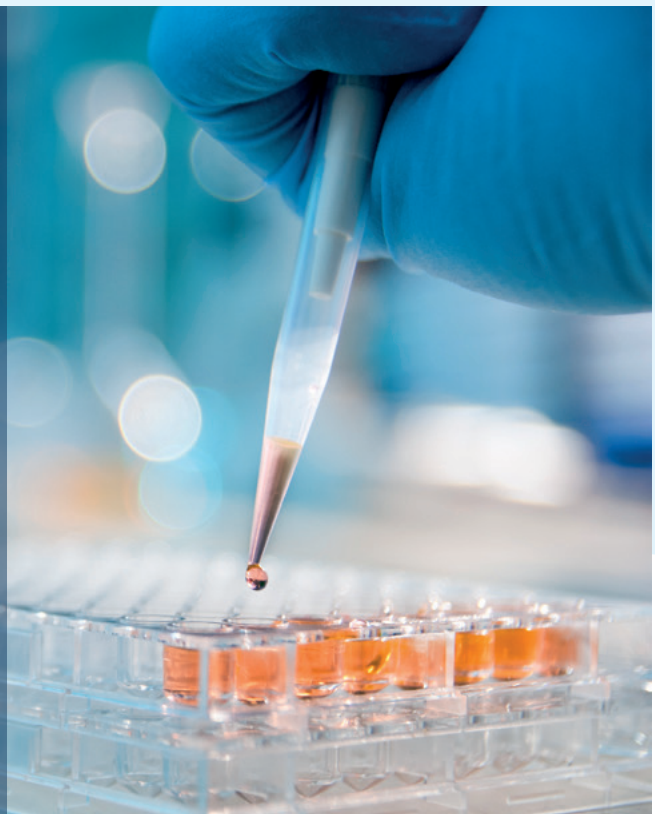
Durable eGFR benefit and sustained proteinuria disease-modifying effects in IgAN

Safety

Well characterized active ingredient and safety profile

IgAN Patients:

- A genetic predisposition is required but not sufficient; most patients are diagnosed in their 20s and 30s
- More than 50% are at risk of developing ESRD within 10-20 years, leading to kidney transplant
- The treatment goal is to preserve eGFR – kidney function
- Proteinuria levels > 1g/24h indicate a risk of disease progression and a worse outlook



Continued TARPEYO Sales Growth

During the third quarter of 2023, Calliditas' commercial team continued to build on the achievements from the previous quarter, further reinforcing TARPEYO's position as a transformative treatment option for IgA nephropathy (IgAN). Notably, this quarter the FDA granted priority review of our supplemental New Drug Application for full approval of TARPEYO, with a PDUFA date set for December 20, 2023. The team is preparing for a new indication launch in anticipation of FDA approval for the use of TARPEYO in the full IgAN patient population studied in the NefIgArd trial.

KEY METRICS Q3

367
New Patients enrolled in Q3 2023
YTD patients enrolled: 1,198

197
New Prescribers in Q3 2023
LTD Prescribers: 1,338

86%
Of patients enrolled in TARPEYO Touchpoints got TARPEYO* YTD

$26.3M
Net sales of TARPEYO in Q3

*Does not include patients that are still waiting final insurance decision

QUARTERLY HIGHLIGHTS

FDA grants priority review for full approval of TARPEYO in the NefIgArd Pahse 3 trial population – PDUFA December 20, 2023.

Full Results from the NefIgArd Phase 3 trial published in *The Lancet*.

Engaging with the IgAN community at the SPARK 2023 symposium hosted by the IgA Nephropathy Foundation
>200 patients attended.

7 presentations at the IIGaNN conference, reporting results of NefIgArd Phase 3 trial and biomarker data.

Exciting Journey Ahead

7 abstracts accepted for presentations at ASN. Opportunity for P2P education and scientific data exchange at ASN, November 1-4 2023, in Philadelphia.

December 20 2023
PDUFA Date

Potential for full approval.

New indication promotional launch - new label for full NefIgArd Phase 3 trial population, based on evidence of slowing kidney function decline*.

*Subject to review and approval by FDA

Pipeline: NOX Inhibitor Platform

Calliditas' pipeline consists of development programs based on a first-in-class NOX inhibitor platform. Calliditas is presently running clinical 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 Q4 2023.

NOX Enzyme Inhibitors

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 producing 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 stage, inhibits NOX1 and NOX4, enzymes that are implicated in fibrosis and inflammation pathways and that represent a high-potential therapeutic target.

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 30,000 to 60,000 people in the United States 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 EU and the US.[1]

Based on significant and supportive in vivo pre-clinical work, Calliditas plans to launch a randomized, placebo-controlled clinical trial in Alport syndrome involving around 20 patients, evaluating overall safety as well as impact on proteinuria. We expect the study to be initiated in Q4 2023 and on the basis of the data readout we will decide on a full regulatory program in Alport. Calliditas was granted orphan drug designation by the FDA for the treatment of Alport syndrome with setanaxib in September 2023, and in October 2023 the EMA Committee for Orphan Medicinal Products (COMP) issued a positive opinion on the company's application for orphan drug designation in the EU for setanaxib in Alport syndrome.

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.

Calliditas is conducting a randomized, placebo-controlled, double-blind Phase 2b trial in PBC patients with elevated liver stiffness. We have submitted a protocol amendment to the FDA to adapt the design of this trial, and are expecting to read out data in mid-2024.

[1] *Watson S, Padala SA, Hashmi MF, et al. Alport Syndrome. [Updated 2023 Aug 14]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470419/*

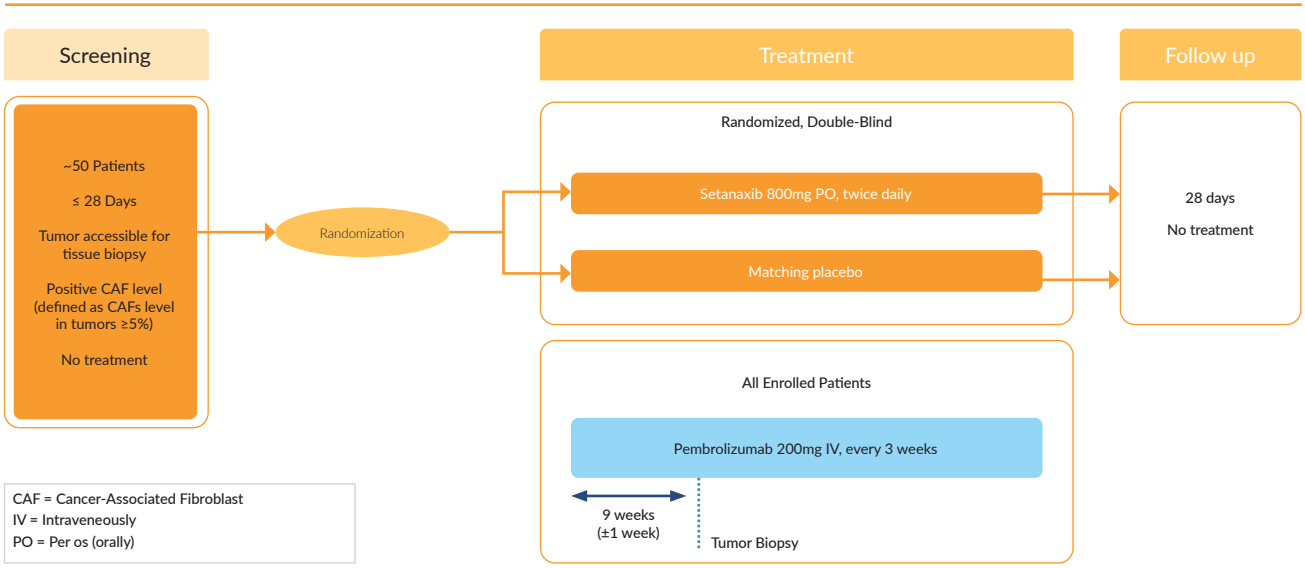
Pipeline: NOX Inhibitor Platform

Setanaxib in Squamous Cell Carcinoma of the Head and 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 1H 2024.

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



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

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.

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 Foxp3 and 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 readout, with the longest period on drug being reported as 21 weeks, related to a patient in the setanaxib arm.

Calliditas Chief Medical Officer Richard Philipson

The interim readout of the head and neck cancer study means that we have now seen the first Calliditas-generated data on setanaxib. What stood out to you most in these data?

We were really encouraged by the transcriptomic data from tumor tissue that showed evidence that setanaxib is modulating fibrosis pathways, which fits very well with the mechanism of action of the drug. We also saw interesting numerical differences in progression-free survival favoring patients treated with setanaxib (on top of pembrolizumab), noting that we did not do any formal statistical testing in this interim data review.
These data set the scene very nicely for the final analysis of data that will come in the first half of 2024, where we would like to see that, when given with pembrolizumab, setanaxib slows tumor growth and improves progression-free survival, compared to pembrolizumab alone.

The full NefIgArd data were recently published in *The Lancet*. How important do you think this is for nephrologists navigating the IgAN landscape?

The publication of the final analysis of the NefIgArd study is a landmark for Nefecon and more generally for the field in IgA nephropathy. We know that nephrologists are really keen to see high-quality scientific and clinical data supporting the use of Nefecon; the article in *The Lancet*, which was accepted through a fast-track review process, provides a clear and comprehensive description of kidney function outcomes over the 2-year study. When looking at the outcomes of the study, what has particularly impressed me is the clearly beneficial effects of Nefecon on kidney function (estimated glomerular filtration rate [eGFR]) achieved during 9 months of treatment, which is maintained through the subsequent 15 months of observation off-treatment. This is accompanied by a sustained and durable improvement in proteinuria that is also maintained during the off-treatment period.

The open-label extension study for Nefecon is currently ongoing with a readout expected in mid-2024. What will you be looking for in this data set?

This is a very interesting and important study that will help us understand the impact of re-treatment with Nefecon. In the open-label extension study (OLE), all enrolled patients receive a 9-month treatment course of Nefecon. Some of these patients will already have received a 9-month course of treatment with Nefecon in the main NefIgArd study (followed by 15 months of observation off-treatment), whereas the remaining patients will be receiving Nefecon for the first time (since they received placebo in the main study). We will be able to look at how the second course of treatment impacts proteinuria and eGFR, and therefore better understand the potential benefits of re-treatment with Nefecon. We hope to publish these outcomes shortly after the final analysis of the study is completed.

You joined Calliditas in mid-2020. What has been the most exciting development on the medical side since you have been at the company?

In the three years since I joined the company, Calliditas has grown substantially, and is a very different company compared to the one I joined in July 2020. On the medical side, we have built internal expertise in Clinical Operations, Biostatistics, Scientific Communications and Pharmacovigilance, and I am particularly excited by how we have been able to take compelling preclinical data in diseases such as head & neck cancer and Alport syndrome, and translate these to clinical studies that will allow us to evaluate the safety and clinical effects of setanaxib in these diseases. We are absolutely committed to developing medicines that make a difference for patients with rare diseases, and I am very proud of the excellent network of relationships with experts that we have built in nephrology, liver disease and head & neck cancer.

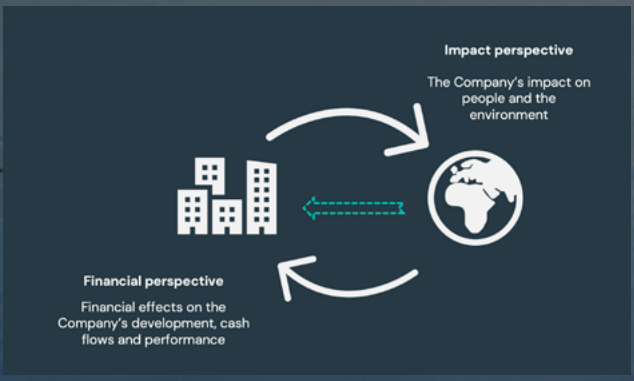
Calliditas develops its sustainability efforts with its sights set on CSRD reporting

Calliditas is committed to focusing on sustainability and is looking forward to intensifying its efforts and becoming increasingly transparent regarding sustainability issues. In the EU, the Corporate Sustainability Reporting Directive (CSRD) will introduce new reporting requirements and provide both direction and a methodology for our sustainability efforts.

Materiality assessment as the first step

As a first step in Calliditas' intensified sustainability ambitions, we have begun our work by carrying out a double materiality assessment. This assessment will help to define the sustainability issues that are most relevant to Calliditas. In line with the CSRD, these issues are defined based on two perspectives. The impact perspective is based on how people and the environment are impacted by Calliditas' operations, and the financial perspective is based on how Calliditas is impacted financially by external factors.

The defined material topics will then form the basis of Calliditas' sustainability strategy, targets and operations. They will also form the basis of Calliditas' future CSRD-compliant sustainability reporting.



We have our sights set on the 2025 Annual and Sustainability Report

Calliditas will be subject to the CSRD as of the 2025 financial year, for which the report will be published in 2026. To ensure that Calliditas' actual sustainability work is performed in a timely and thorough manner, the work on implementing the CSRD in Calliditas' sustainability efforts has already begun. As a first step, the Board of Directors and the Management Team received training on the topic. This training provided an overview of the new rules and regulations, described how Calliditas will be affected, and highlighted the increased responsibility of the board and management team.

Sustainability issues have always been highly important to Calliditas. Through our business model, we contribute to improving the lives of patients with rare diseases with high unmet medical needs. Considering the industry in which Calliditas operates, ethical and responsible business practices are of the utmost importance. It is also imperative to us at Calliditas to offer our employees a safe, healthy and stimulating workplace. This includes non-discrimination and a workplace culture that offers equal opportunities for all. Calliditas also has major upstream and downstream responsibility in its value chain, and therefore has ambitions to reduce the Company's environmental impact and resource usage.

"We have made solid strides in our work regarding sustainability. It is important for Calliditas to carry out our work in a socially and environmentally ethical and responsible manner, and to be compliant with the new CSRD directive."

Åsa Hillsten
Head of IR & Sustainability

The CSRD entails stricter requirements on quality as well as quantity in sustainability reporting

The CSRD is part of the EU's package of measures to promote fair and transparent sustainability reporting. This is part of a bigger picture of the EU's ambition to ensure that financing and capital reach companies have sustainable investments and business models, so that the EU meets the requirements of the Paris Agreement and the 17 Sustainable Development Goals.

The requirements in the CSRD are more comprehensive than previous sustainability reporting requirements and cover numerous disclosures linked to Environmental, Social and Governance (ESG) issues. Additional disclosures relate to the reporting of sustainability governance in general and the development of annual sustainability reports. Calliditas is looking forward to undertaking the work necessary to meet the CSRD requirements and take strides in becoming a more sustainable business.

January – September 2023

Revenue

Net sales amounted to SEK 294.6 million and SEK 260.1 million for the three months ended September 30, 2023 and 2022, respectively. Net sales for the nine months ended September 30, 2023 and 2022 amounted to SEK 755.3 million and SEK 373.8 million, respectively. Net sales for the periods primarily originate from net sales of TARPEYO® in the US, which amounted to SEK 283.6 million and SEK 123.4 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, net sales from TARPEYO amounted to SEK 728.5 million and SEK 205.0 million, respectively. Royalty income from our partnership in Europe amounted to SEK 9.6 million for the third quarter of 2023 and SEK 22.8 million for the first nine months of 2023, regarding the comparison periods 2022, no royalty income was recognized. For the three and nine months ended September 30, 2023, no milestones were recognized. For the three months ended September 30, 2022, net sales amounted to SEK 135.0 million and consisted of milestone fees from the commercialization of Kinpeygo® in Europe. Further, regarding the nine months ended September 30, 2022 the milestone fees amounted to SEK 163.8 million and included milestone fee regarding Everst Medicines. For additional information see Note 4.

Cost of Sales

Cost of sales amounted to SEK 14.9 million and SEK 4.3 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022 cost of sales amounted to SEK 38.2 million and SEK 7.3 million, respectively. The increase in the 2023 periods, was related to the higher volume of product sales.

Total Operating Expenses

Total operating expenses amounted to SEK 439.2 million and SEK 292.0 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022 total operating expenses amounted to SEK 1,132.0 million and SEK 821.0 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 179.9 million and SEK 102.9 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022 research and development expenses amounted to SEK 395.5 million and SEK 312.5 million, respectively. The increase of SEK 77.0 million for the three months ended September 30, 2023 and the increase of SEK 83.0 million for the nine months ended September 30, 2023, was primarily due to increased clinical activities for the nox-platform, including the ongoing setanaxib trials, and the one-time effect from the impairment of SEK 32.1 million regarding Budenofalk, an in-licensing that was established in 2019, compared to the corresponding periods of the prior year.

Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 170.5 million and SEK 116.1 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022 marketing and selling expenses amounted SEK 529.2 million and SEK 323.3 million, respectively. The increases of SEK 54.4 million for the three months ended September 30, 2023, and SEK 205.9 million for the nine months ended September 30, 2023, were primarily related to the costs for sales and marketing of TARPEYO in the US, where marketing activities have been intensified and the salesforce has been increased, compared to the corresponding periods of the prior year.

Administrative Expenses

Administrative expenses amounted to SEK 88.6 million and SEK 71.0 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, administrative expenses amounted to SEK 238.4 million and SEK 178.4 million, respectively. The increases of SEK 17.6 million for the three months ended September 30, 2023, and SEK 59.9 million for the nine months ended September 30, 2023, were primarily related to increases due to a larger organization and increased regulatory requirements.

Other Operating Incomes/Expenses, net

Other operating income/(expenses), net amounted to (SEK 0.2 million) and (SEK 1.9 million) for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022 other operating income/(expenses), net amounted to SEK 31.1 million and (SEK 6.7 million), respectively. The increase in both periods was primarily attributable to movements in exchange rate related to operating receivables and liabilities.

Net Financial Income and Expenses

Net financial income/(expenses) amounted to (SEK 4.5 million) and SEK 20.3 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, net financial income/(expenses) amounted to (SEK 27.9 million) and SEK 35.0 million, respectively. The decrease of SEK 24.8 million for the three months ended September 30, 2023, and SEK 62.9 million for the nine months ended September 30, 2023 were primarily derived from interest expenses related to borrowing and currency effects.

Tax

Total tax income/(expense) amounted to (SEK 4.3 million) and SEK 6.9 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, total tax income/(expense) amounted to (SEK 5.1 million) and SEK 10.9 million, respectively. The increased tax expense for both periods was primarily explained by taxable profit for the US 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 September 30, 2023 and 2022, loss for the period amounted to SEK 168.4 million and SEK 9.1 million, and the corresponding loss per share before and after dilution amounted to SEK 3.14 and SEK 0.17, respectively. For the nine months ended September 30, 2023 and 2022, loss for the period amounted to SEK 447.8 million and SEK 408.6 million, and the corresponding loss per share before and after dilution amounted to SEK 8.34 and SEK 7.72, respectively.

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 62.5 million and SEK 124.7 million for the three months ended September 30, 2023 and 2022, respectively, and the improvement compared to previous year, is explained by the stronger working capital. For the nine months ended September 30, 2023 and 2022, cash flow used in operating activities amounted to SEK 457.5 million and SEK 541.4 million, respectively, and the improvement is primarily explained by the increased operating result driven by sales growth for TARPEYO® in the US, and additional the stronger working capital had a positive impact.

Cash flow used in investing activities amounted to SEK 7.4 million and SEK 0.9 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, cash flow used in investing activities amounted to SEK 11.4 million and SEK 3.7 million, respectively. The increase for the both periods was primarily explained by acquisition of equipment.

Cash flow used in financing activities amounted to SEK 2.9 million and SEK 2.6 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, cash flow from financing activities amounted to (SEK 8.9 million) and SEK 293.4 million, respectively. The decrease for the periods was mainly attributable to previous years utilization of an external loan facility of SEK 236.5 million.

Net decrease in cash amounted to SEK 72.8 million and SEK 128.2 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, net decrease in cash amounted to SEK 477.8 million and SEK 251.7 million, respectively. Cash amounted to SEK 786.9 million and SEK 736.2 million as of September 30, 2023 and 2022, respectively.

Personnel

The average number of employees were 179 and 92 for the three months ended September 30, 2023 and 2022, respectively and 174 and 81 employees for the nine months ended September 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 352.4 million and SEK 725.9 million as of September 30, 2023 and 2022, respectively. The number of registered shares amounted to 59,580,087 and 59,157,587 as of September 30, 2023 and 2022, respectively.

Treasury Shares

As of September 30, 2023, Calliditas had 5,908,018 ordinary shares held as treasury shares by the Parent Company. At the Annual General Meeting in 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.

Incentive Programs

During the three months ended September 30, 2023, 965,000 options have been allocated for the ESOP 2023 Program. For more information on incentive programs, see Note 9.

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 (corresponding to approx. SEK 1,047-1,257 million, using a SEK/USD average exchange rate of 10.47).

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 194.4 million and SEK 219.6 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022 net sales amounted to SEK 468.4 million and SEK 251.8 million, respectively. The decrease for the three months ended September 30, 2023, compared to corresponding period prior year refers to milestone fees from the commercialization of Kinpeygo in Europe, which amounted to SEK 135.0 million. Further, for the nine months ended September 30, 2022, the milestone fees amounted to SEK 163.8 million.

The increase in net sale for the nine months ended September 30, 2023, was primarily derived from sales of TARPEYO compared to the corresponding period of the prior year. Operating loss amounted to SEK 104.1 million and SEK 47.4 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022 operating loss amounted to SEK 268.9 million and SEK 302.1 million, respectively.

Significant Events

Significant Events During the Period July 1 – September 30, 2023

- On July 13 Calliditas announced supportive interim data from Phase 2 head and neck cancer trial with lead NOX inhibitor candidate, setanaxib.
- On August 15 Calliditas announced full results from the NefIgArd Phase 3 trial published in The Lancet.
- On August 18 FDA granted priority review for full approval of TARPEYO® for the treatment of IgA Nephropathy.
- On September 27 Calliditas granted orphan drug designation by the FDA for the treatment of Alport syndrome with setanaxib.
- On September 28 STADA and Calliditas announced the filing for full marketing authorization of Kinpeygo® in the EU.
- On September 29 Calliditas presented Data from the NefIgArd Phase 3 trial at the 17th International Symposium on IgA Nephropathy (IIgANN) Tokyo 2023.

Significant Events After the Period

- On October 3 Calliditas announced filing with UK MHRA for Kinpeygo in IgA nephropathy.
- On October 5 European Medicines Agency Committee for Orphan Medicinal Products provided positive opinion on Calliditas' application for setanaxib in Alport syndrome.
- On October 23 Calliditas announced the Nomination Committee for the AGM 2024 was appointed. The Nomination Committee consists of Patrick Sobocki, appointed by Stiftelsen Industrifonden, Karl Tobieson, appointed by Linc AB, Spike Loy, appointed by BVF and Elmar Schnee (chairman of the board of directors).
- 27 October Calliditas announced that its commercial partner Everest Medicines received approval from the Pharmaceutical Administration Bureau of the Macau Special Administrative Region, China.

Executive Management

The Executive Management of Calliditas Therapeutics AB consists of: CEO Renée Aguiar-Lucander, CFO Fredrik Johansson, CMO Richard Philipson, Group General Counsel Jonathan Schur, President North America Andrew Udell, Vice President Regulatory Affairs Frank Bringstrup and Head of Human Resource Sandra Frithiof.

Dividend

Any future dividend and the size thereof, will be determined based on long-term growth, earnings trends and capital requirements of Calliditas. The Board of Directors does not intend to propose any dividend before the company generates long-term sustainable profits and positive cash flow. There was no dividend paid for the 2022 financial year.

Annual General Meeting 2024

The 2024 Annual General Meeting will be held in May, 2024 in Stockholm, Sweden. All documentation from previous AGMs are published on the companys´ website at https://www.callid-itas.se/en/governance/general-meeting/general-meetings/

Nomination Committee AGM 2024 appointed

On October 2023 Calliditas announced that the companys´ major owners have appointed a nomination committee for the AGM 2024. The nomination committee, which is appointed in accordance with the principles adopted by the extraordinary general meeting in 2017, consists of: Patrick Sobocki, appointed by Stiftelsen Industrifonden, Karl Tobieson, appointed by Linc AB, Spike Loy, appointed by BVF, and Elmar Schnee (chairman of the board of directors). Shareholders who wish to submit proposals to the nomination committee for the annual general meeting 2024, can do so by e-mail to finance@calliditas.com. Proposals should be submitted to the nomination committee before March 15, 2024.

The Share

As of September 30, 2023, the number of shares amounted to 59,580,087 ordinary shares, of which, 5,908,018 are held as treasury shares by the Parent Company. As of September 29, 2023, the closing price for the Calliditas Therapeutics share CALTX was SEK 97.5. The total number of shareholders as of September 30, 2023 was approximately 15,000.

Shareholder Structure

Ten largest shareholders as of September, 2023	%
BVF Partners LP	10.51
Linc AB	10.01
Stiftelsen Industrifonden	5.28
Avanza Pension	3.81
Handelsbanken Fonder	3.47
Fjärde AP-fonden	3.19
Unionen	3.02
Polar Capital	2.94
Sofinnova Partners	2.36
The Invus Group	1.79
Subtotal, 10 largest shareholders	**46.38**
Treasury shares	**9.92**
Other shareholders	**43.70**
Total	**100.00**

Review

This interim report has not been subject to review by the company's auditors.

Stockholm 7 November, 2023
Renée Aguiar-Lucander

Supplemental Information

Presentation to Investors, Analysts and Press

- Calliditas invites investors, analysts and press to a presentation of the Quarterly Report 2023 at 14:30 pm. on November 7. The report will be published at 7:00 am the same day.
- Calliditas' CEO Renée Aguiar-Lucander will present the report together with CFO Fredrik Johansson, CMO Richard Philipson and President North America Andrew Udell. The presentations will be given in English.
- Time: Tuesday 14:30 pm CET. on November 7.
- Link to webcast **https://financialhearings.com/event/46414**
- To participate via conference call register via this link: **https://conference.financialhearings.com/teleconference/?id=2001082** After registration, you will receive a phone number and a conference ID to log in to the conference call. Via the telephone conference, there is an opportunity to ask oral questions.

Upcoming Events

FEBRUARY 22, 2024

Year-end report, Q4
January – December 2023

ANNUAL REPORT 2023

Will be published digitally
in April, 2024

MAY 16, 2024

Interim Report, Q1
January – March 2024

For further information please contact

Renée Aguiar-Lucander / CEO
+46 (0)8 411 30 05
renee.lucander@calliditas.com

Åsa Hillsten / Head of IR & Sustainability
+46 (0) 764 03 35 43
asa.hillsten@calliditas.com

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 net sales of TARPEYO guidance and cash runway, 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.

Registred Office

Calliditas Therapeutics AB
Kungsbron 1
SE 111 22 Stockholm, Sweden

calliditas.com / ir@calliditas.com

This interim report has not been reviewed or audited by the Company's auditors.

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

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Year Ended December 31, 2022
Net sales	4	294,592	260,056	755,327	373,837	802,879
Cost of sales		(14,921)	(4,322)	(38,164)	(7,322)	(15,201)
Gross profit		**279,671**	**255,734**	**717,163**	**366,515**	**787,678**
Research and development expenses		(179,906)	(102,877)	(395,546)	(312,510)	(414,749)
Marketing and selling expenses		(170,502)	(116,135)	(529,197)	(323,303)	(515,190)
Administrative expenses		(88,668)	(71,003)	(238,367)	(178,441)	(259,469)
Other operating income/(expenses), net		(167)	(1,946)	31,127	(6,699)	(20,212)
Operating loss		**(159,573)**	**(36,227)**	**(414,819)**	**(454,438)**	**(421,943)**
Net financial income/(expenses)		(4,509)	20,269	(27,941)	34,955	12,526
Loss before income tax		**(164,082)**	**(15,958)**	**(442,760)**	**(419,483)**	**(409,417)**
Income tax		(4,276)	6,848	(5,056)	10,896	(2,851)
Loss for the period		**(168,357)**	**(9,111)**	**(447,817)**	**(408,587)**	**(412,268)**
Attributable to:						
Equity holders of the Parent Company		(168,357)	(9,111)	(447,817)	(408,587)	(412,268)
		(168,357)	**(9,111)**	**(447,817)**	**(408,587)**	**(412,268)**
Loss per share before and after dilution (SEK)	8	(3.14)	(0.17)	(8.34)	(7.72)	(7.78)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Year Ended December 31, 2022
Loss for the period	(168,357)	(9,111)	(447,817)	(408,587)	(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	715	4,558	(2,166)	34,626	36,287
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods	**715**	**4,558**	**(2,166)**	**34,626**	**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	415	(94)	(803)	2,377	2,763
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods	**415**	**(94)**	**(803)**	**2,377**	**2,763**
Other comprehensive income/(loss) for the period	**1,130**	**4,464**	**(2,969)**	**37,003**	**39,050**
Total comprehensive income/(loss) for the period	**(167,227)**	**(4,647)**	**(450,786)**	**(371,584)**	**(373,218)**
Attributable to:					
Equity holders of the Parent Company	(167,227)	(4,647)	(450,786)	(371,584)	(373,218)
	(167,227)	**(4,647)**	**(450,786)**	**(371,584)**	**(373,218)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	September 30, 2023	September 30, 2022	December 31, 2022
ASSETS				
Non-current assets				
Intangible assets		476,511	487,348	483,841
Equipment		15,457	7,700	7,468
Right-of-use assets		40,056	28,161	24,452
Non-current financial assets		20,865	6,909	11,210
Deferred tax assets		22,990	14,889	13,799
Total non-current assets		**575,879**	**545,007**	**540,770**
Current assets				
Inventories		16,005	582	3,647
Current receivables		130,529	187,179	88,721
Prepaid expenses and accrued income		102,596	49,175	70,741
Cash		786,883	736,161	1,249,094
Total current assets		**1,036,012**	**973,099**	**1,412,204**
TOTAL ASSETS		**1,611,891**	**1,518,106**	**1,952,973**
EQUITY AND LIABILITIES				
Equity				
Equity attributable to equity holders of the Parent Company		352,435	725,936	766,264
Total equity	*7,8,9*	**352,435**	**725,936**	**766,264**
Non-current liabilities				
Provisions	*9*	20,739	8,030	12,675
Contingent consideration	*6*	69,491	62,365	75,880
Deferred tax liabilities		41,395	34,338	39,752
Non-current interest-bearing liabilities		740,744	448,129	713,030
Lease liabilities		29,417	19,188	15,792
Other non-current liabilities		12,959	-	4,350
Total non-current liabilities		**914,745**	**572,049**	**861,479**
Current liabilities				
Accounts payable		67,165	95,763	160,404
Other current liabilities		25,926	14,796	28,381
Accrued expenses and deferred revenue		251,620	109,561	136,446
Total current liabilities		**344,711**	**220,120**	**325,231**
TOTAL EQUITY AND LIABILITIES		**1,611,891**	**1,518,106**	**1,952,973**

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Nine Months Ended September 30, 2023	Nine Months Ended September 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	(447,817)	(408,587)	(412,268)
Other comprehensive income/(loss)	(2,969)	37,003	39,050
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	**(450,786)**	**(371,584)**	**(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	36,957	25,595	36,080
Total transactions with owners	**36,957**	**89,239**	**131,201**
Closing balance equity attributable to equity holders of the Parent Company	**352,435**	**725,936**	**766,264**
Closing balance equity	**352,435**	**725,936**	**766,264**

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Year Ended December 31, 2022
Operating activities					
Operating loss	(159,573)	(36,227)	(414,819)	(454,438)	(421,943)
Adjustment for non-cash-items	58,549	11,173	78,424	30,344	61,260
Interest received	1,573	0	2,304	2	3,553
Interest paid	(18,959)	(12,830)	(52,334)	(23,676)	(35,252)
Income taxes paid	(4,281)	(1,788)	(19,456)	(4,718)	(7,392)
Cash flow used in operating activities before changes in working capital	**(122,692)**	**(39,672)**	**(405,881)**	**(452,485)**	**(399,774)**
Cash flow from/(used in) changes in working capital	60,163	(85,053)	(51,619)	(88,898)	88,420
Cash flow used in operating activities	**(62,529)**	**(124,725)**	**(457,500)**	**(541,383)**	**(311,354)**
Cash flow used in investing activities	**(7,417)**	**(888)**	**(11,391)**	**(3,678)**	**(5,144)**
Issuance of treasury shares	-	-	-	236	236
Repurchase of treasury shares	-	-	-	(236)	(236)
Exercise of warrants	-	-	-	63,644	95,121
New borrowings	-	-	-	236,462	491,745
Costs attributable to new loans	-	-	-	-	(1,260)
Repayment of lease liabilities	(2,888)	(2,569)	(8,872)	(6,754)	(9,615)
Cash flow from/(used in) financing activities	**(2,888)**	**(2,569)**	**(8,872)**	**293,353**	**575,990**
Net increase/(decrease) in cash	**(72,834)**	**(128,182)**	**(477,762)**	**(251,708)**	**259,493**
Cash at the beginning of the period	**866,181**	**846,799**	**1,249,094**	**955,507**	**955,507**
Net foreign exchange gains/(loss) on cash	(6,464)	17,544	15,551	32,362	34,094
Cash at the end of the period	**786,883**	**736,161**	**786,883**	**736,161**	**1,249,094**

Condensed Parent Company Statements of Income

(SEK in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Year Ended December 31, 2022
Net sales	194,405	219,642	468,392	251,833	548,977
Cost of sales	(14,905)	(4,322)	(38,116)	(7,322)	(15,141)
Gross profit/(loss)	**179,500**	**215,320**	**430,276**	**244,511**	**533,836**
Research and development expenses	(167,668)	(94,340)	(364,277)	(286,729)	(384,453)
Marketing and selling expenses	(99,486)	(134,066)	(295,226)	(196,873)	(310,372)
Administrative expenses	(72,378)	(57,378)	(193,411)	(151,720)	(212,971)
Other operating income/(expenses), net	55,899	23,086	153,781	88,750	158,597
Operating loss	**(104,133)**	**(47,377)**	**(268,856)**	**(302,061)**	**(215,364)**
Net financial income/(expenses)	(9,145)	7,500	(31,463)	13,341	6,816
Loss before income tax	**(113,278)**	**(39,877)**	**(300,319)**	**(288,720)**	**(208,548)**
Income tax	-	-	-	-	-
Loss for the period	**(113,278)**	**(39,877)**	**(300,319)**	**(288,720)**	**(208,548)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Year Ended December 31, 2022
Loss for the period	(113,278)	(39,877)	(300,319)	(288,720)	(208,548)
Other comprehensive income/(loss)	-	-	-	-	-
Total comprehensive income/(loss)	**(113,278)**	**(39,877)**	**(300,319)**	**(288,720)**	**(208,548)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	September 30, 2023	September 30, 2022	December 31, 2022
ASSETS				
Non-current assets				
Intangible assets		-	32,132	32,132
Equipment		399	623	567
Non-current financial assets		1,142,950	800,703	887,456
Total non-current assets		**1,143,349**	**833,457**	**920,154**
Current assets				
Inventories		16,005	582	3,647
Current receivables		113,964	212,114	129,090
Prepaid expenses and accrued income		75,993	27,410	61,092
Cash and bank		641,927	632,236	1,059,655
Total current assets		**847,889**	**872,343**	**1,253,485**
TOTAL ASSETS		**1,991,238**	**1,705,800**	**2,173,639**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Total restricted equity		5,475	5,458	5,475
Total non-restricted equity		862,118	1,003,365	1,125,480
Total shareholders' equity	*7,9*	**867,594**	**1,008,823**	**1,130,956**
Non-current liabilities				
Provisions	*9*	15,665	4,209	9,512
Non-current interest-bearing liabilities		740,744	448,129	713,030
Other non-current liabilities		13,064	105	4,455
Total non-current liabilities		**769,473**	**452,443**	**726,997**
Current liabilities				
Accounts payable		35,225	44,217	100,469
Other current liabilities		157,330	139,699	141,750
Accrued expenses and deferred revenue		161,616	60,617	73,468
Total current liabilities		**354,171**	**244,534**	**315,686**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,991,238**	**1,705,800**	**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 nine months ended September 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 November 7, 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 US. 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. The impact on the financial statements is described in the Financial overview in the section Research and Development Expenses.

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 US 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 September 30,		Nine Months Ended September 30,		Year Ended December 31,
(SEK in thousands)	2023	2022	2023	2022	2022
Type of goods or services					
Product sales	284,992	125,045	732,563	206,634	375,515
Outlicensing of product	-	135,011	-	163,816	421,689
Royalty income	9,600	-	22,764	-	2,287
Performance of certain regulatory services	-	-	-	3,387	3,387
Total	**294,592**	**260,056**	**755,327**	**373,837**	**802,879**
Geographical markets					
USA	283,591	123,400	728,522	204,989	372,247
Europe	11,001	136,656	26,805	140,044	143,955
Asia	-	-	-	28,804	286,677
Total	**294,592**	**260,056**	**755,327**	**373,837**	**802,879**

Net sales for the periods primarily originate from net sales of TARPEYO in the US, which amounted to SEK 283.6 million and SEK 123.4 million for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, net sales from TARPEYO amounted to SEK 728.5 million and SEK 205.0 million, respectively.
Royalty income from our partnership in Europe amounted to SEK 9.6 (-) million for the third quarter of 2023 and SEK 22.8 (-) million for the first nine months of 2023. For the three and nine months ended September 30, 2023, no milestones were recognized. For the three months ended September 30, 2022, net sales amounted to SEK 135.0 million and consisted of milestone fees from the commercialization of Kinpeygo in Europe. Further, for the nine months ended September 30, 2022 the milestone fee amounted to SEK 163.8 million and included milestone fee regarding Everst Medicines.

The total liability for expected returns and rebates amounts to SEK 44.1 million and SEK 17.2 million as of September 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, other current liabilities, and accrued expenses, 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 September 30, 2023 and 2022, the profit/(loss) for the period amounted to (SEK 1.8 million) and (SEK 1.4 million), respectively and for the nine months ended September 30, 2023 and 2022, the affecting profit/(loss) for the period amounted to SEK 8.8 million and (SEK 4.1 million), respectively, which are recognized in other operating income/(expenses), net. This was attributable to the change of study design for the PBC project within the setanaxib platform. For more information see the Annual Report for 2022.

Note 7 - Treasury Shares

As of September 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 September 30, 2023. The total number of issued shares as of September 30, 2023, is presented in Note 8.

Note 8 - Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	September 30, 2023	September 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	-	6,816,003	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**	**59,157,587**	**59,580,087**
Shares			
Ordinary shares	59,580,087	59,157,587	59,580,087
Total	**59,580,087**	**59,157,587**	**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**	**53,249,569**	**53,672,069**
Share capital at the end of the period	2,383	2,666	2,383
Equity attributable to equity holders of the Parent Company	352,435	725,936	766,264
Total equity at the end of the period	**352,435**	**725,936**	**766,264**

(SEK in thousands, except per share amounts and number of shares)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Year Ended December 31, 2022
Loss per share before and after dilution, SEK	(3.14)	(0.17)	(8.34)	(7.72)	(7.78)
Weighted-average number of ordinary shares outstanding for the period, before and after dilution	53,672,069	53,247,334	53,672,069	52,942,807	53,022,550

Reserves for translation from foreign operations amounted to SEK 7.1 million and SEK 7.6 million which are included in retained earnings in equity as of September 30, 2023 and 2022, respectively.

Note 9 - Incentive Programs

	September 30, 2023			September 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	-	1,371,666	-	1,371,666
ESOP 2021	1,456,500	-	1,456,500	-	1,490,000	-	1,490,000
ESOP 2022	1,906,000		1,906,000	-	1,101,000		1,101,000
ESOP 2023	965,000	-	965,000	-	-	-	-
Total Outstanding	**5,692,230**	**100,975**	**5,793,205**	**422,500**	**3,962,666**	**99,045**	**4,484,211**

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

	September 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	352,435	725,936	766,264
Total assets at the end of the period	1,611,891	1,518,106	1,952,973
Equity ratio at the end of the period in %	**22%**	**48%**	**39%**