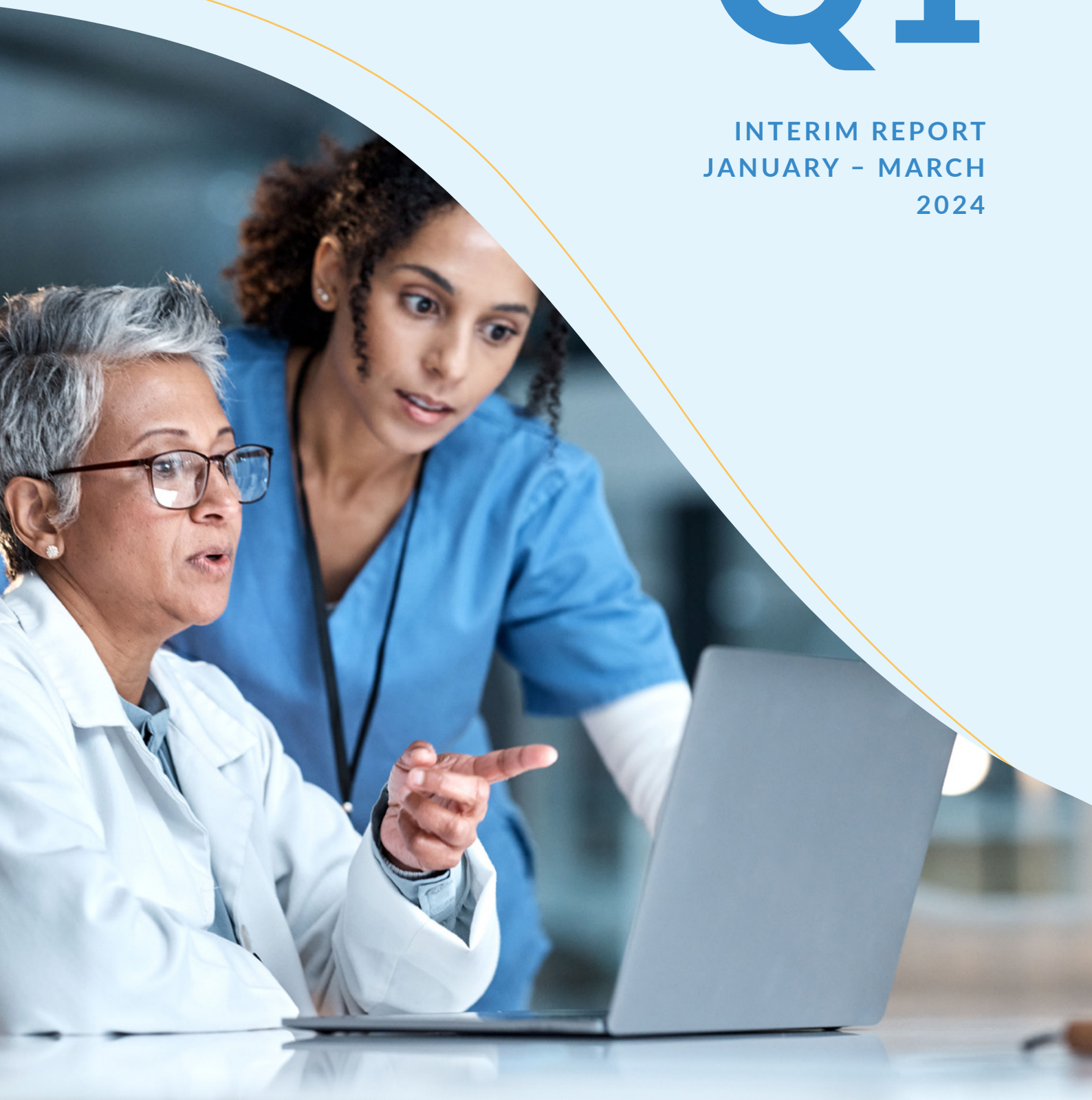
calliditas
THERAPEUTICS

Q1

INTERIM REPORT JANUARY – MARCH 2024



Interim report January – March 2024

JANUARY – MARCH 2024 (COMPARED TO JANUARY – MARCH 2023)

- Net sales amounted to SEK 295.5 million, of which TARPEYO® net sales amounted to SEK 278.3 million, for the three months ended March 31, 2024. For the three months ended March 31, 2023 net sales amounted to SEK 191.4 million, of which TARPEYO net sales amounted to SEK 185.7 million.
- Operating loss amounted to SEK 203.8 million and SEK 180.1 million for the three months ended March 31, 2024 and 2023, respectively.
- Loss per share before and after dilution amounted to SEK 4.59 and SEK 3.49 for the three months ended March 31, 2024 and 2023, respectively.
- Cash amounted to SEK 810.3 million and SEK 1,013.6 million as of March 31, 2024 and 2023, respectively.

"In Q1 we generated another record quarter in terms of demand with 705 enrollments and 354 new prescribers. We are very excited over this positive trend and we continue to see strong demand in Q2."

Renée Aguiar-Lucander / CEO

JAN – MAR 2024

278

MSEK
TARPEYO net sales

JAN – MAR 2024

50%

TARPEYO net sales growth in SEK (vs Q1 2023)

31 MAR 2024

810

MSEK
Cash position

Key takeaways from Q1, 2024

- Calliditas had a record quarter with 705 enrollments, representing a 27% increase over Q4.
- In February, the United States Patent and Trademark Office (USPTO) issued patent no. 11896719, entitled "New Pharmaceutical Compositions". This was Calliditas' second patent for TARPEYO in the United States, and provides product protection until 2043.
- In March, the FDA granted an orphan drug exclusivity period of seven years for TARPEYO®, expiring in December 2030, based on when the company obtained full approval with a new indication for this drug product.
- There was a negative impact on net TARPEYO revenues in the quarter of approximately USD 4.7 million due to a cyberattack on Change Health. The revenues we were not able to record in Q1 because of this technical issue are not lost, but are expected to roll forward over the next several months. This is not expected to have any impact on annual revenues.

Key events after the reporting period

- Preliminary net sales from TARPEYO for the second quarter up until the date of this report amounts to USD 25.5 million.
- Positive read out of the Nefecon Open label Phase 3 extension trial.
- Positive topline results from the setanaxib Phase 2 trial in head and neck cancer.
- Commercial launch of Nefecon in China by partner Everest Medicines.

Key events in upcoming 6 months

- European Commission decision regarding a potential full approval for Kinpeygo for Calliditas' partner STADA.
- Full data read out of setanaxib Phase 2 trial in Primary Biliary Cholangitis.
- Updated KDIGO guidelines.

Outlook 2024: Unchanged

- Calliditas expects continued revenue growth:
  Total net sales from the Nefecon franchise, including milestones, are estimated to be USD 150-180 million for the year ending December 31, 2024.

Calliditas – pioneering new treatments for rare diseases

Calliditas Therapeutics leverages scientific expertise and disease specific insights to help improve the lives of patients. We are a commercial-stage biopharma company that researches, develops and commercializes novel therapies that seek to address significant unmet needs in relation to the treatment of 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 a treatment option that has been demonstrated to be 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 full approval in December 2023, and is today marketed in the US under the brand name TARPEYO®. TARPEYO is now the first and only fully approved treatment for IgAN and is approved based on a measure of kidney function. Nefecon 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. Kinpeygo is currently being reviewed for full marketing authorization by the European Commission and the MHRA.

Nefecon has been granted conditional approval in China, Singapore, and Macau, and is being reviewed by regulators in Hong Kong and South Korea. Nefecon was launched commercially by Everest Medicines in China in May 2024. Calliditas has also entered into a partnership to develop and commercialize Nefecon in Japan.

IgA nephropathy is the most common primary glomerulonephritis worldwide, so the market potential for Nefecon is substantial, as evidenced by our early commercial success and 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 Primary Biliary Cholangitis (PBC) and Alport syndrome, and there is also an investigator led trial ongoing in idiopathic pulmonary fibrosis (IPF). Calliditas read out positive data from a Phase 2 proof-of-concept trial with setanaxib in head and neck cancer in May 2024.

While our headquarter is 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.

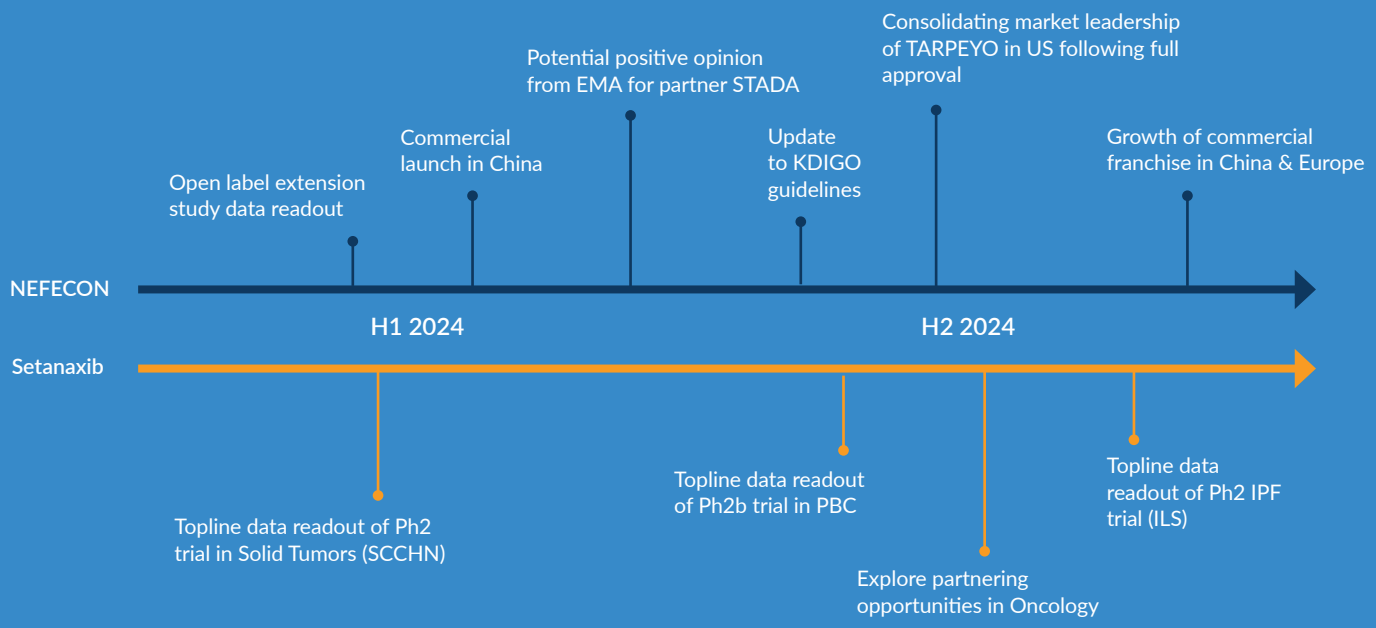
EXPERTISE
We leverage our strong internal experience and competencies while complementing our strengths through knowledge sharing and external collaborations as needed.

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

RECENT AND ANTICIPATED DRIVERS



Key figures

SEK in thousands, except per share amount or as otherwise indicated	Three Months Ended 31 March 2024	Three Months Ended 31 March 2023	Year Ended 31 December 2023
Net sales	295,481	191,352	1,206,888
Of which TARPEYO product sales	278,276	185,691	1,075,829
Operating income (loss)	(203,826)	(180,074)	(373,055)
Income (loss) before Income tax for the period	(247,324)	(208,019)	(457,017)
Earnings (loss) per share before and after dilution (SEK)	(4.59)	(3.49)	(8.69)
Cash flow from (used in) operating activities	(198,205)	(231,940)	(434,655)

(SEK in thousands, except per share amount or as otherwise indicated)	March 31 2024	March 31 2023	December 31 2023
Total registered shares, including shares held by Calliditas, at the end of the period	59,580,087	59,580,087	59,580,087
Equity attributable to equity holders of the Parent Company at the end of the period	120,151	589,403	334,806
Equity ratio at the end of the period in %	7%	33%	18%
Cash at the end of the period	810,317	1,013,600	973,733

Target market expansion following full approval in the US

Following the full approval of TARPEYO by the FDA in December of 2023, we were poised to bring the message of the disease modifying potential of TARPEYO to nephrologists. New marketing materials and training of everyone in the field to reflect the new indication and label were initiated, and in February we rolled out the new program. In Q3 of 2023 we had made the decision to expand the US field force and increase key field functions such as thought leader liaisons, medical directors and field reimbursement managers to address the larger market potential. Our new indication – reduction of kidney loss in patients with primary IgAN at risk of disease progression – now enables us to address the full adult IgAN population at risk, an important change for both patients and physicians. The potential that the drug has to provide a clinically meaningful delay in the need for dialysis or transplantation can now be discussed in interactions with treating nephrologists, as we now can share the exciting and important eGFR data from the Phase 3 trial. It was important to us that we invested in the best possible team with the right focus in order to continue our important pioneering work for IgAN patients. In January we also announced the addition of an experienced senior executive, Maria Törnsén as President North America, who brings over a decade of expertise from the US rare disease market as well as a wealth of experience from account management, optimization of field resources, and franchise building. This was a key complement to our expanded field presence and we are delighted to already see the benefits of her expertise.

This timely expansion leverages the expertise we have built over the last two years and was instrumental in generating another record quarter in terms of enrollments. The 705 enrollments received in Q1 2024 represent a 27% increase over Q4, which in turn was a 51% increase over Q3. This continued strong growth in demand we believe is the result of our strong data and the positive patient and physician experiences with using the drug in a real-world setting, a key leading indicator of expected revenue growth in 2024. We are very excited about this positive trend and are continuing to see strong demand in Q2. We believe that TARPEYO is poised to become the backbone treatment in IgAN as the only disease specific and disease modifying medication on the market, providing eGFR stabilization during treatment which is durable post treatment. The ability to treat when necessary to provide disease management without the high cost and potential safety-related issues of many chronic treatments is important both for patients and physicians dealing with this progressive disease, especially if it potentially can keep patients out of dialysis or transplantation in their lifetime.

Total net revenues for the quarter from TARPEYO amounted to USD 26.8 million (SEK 278 million). Revenues in Q1 were impacted by two important factors. The first was already communicated in our Q4 presentation: namely, that Q1 is typically a somewhat slower quarter due to the insurance reverification process taking place. The second was completely unexpected, namely the cyberattack in February on Change Health, a division of United Health, which is one of three major claims processors in the US. This significant event had a profound effect on the industry generally, and on our hub's ability to verify insurance coverage during the time that the system was down, as our specialty pharmacy exclusively utilizes Change Health. This led to a negative revenue impact of approximately USD 4.7 million for the period. The revenues we were not able to record in Q1 because of this technical issue are not lost, but are expected to roll forward over the next several months, and this is not expected to have an impact on annual revenues, which is also borne out by a strong start to Q2 in terms of TARPEYO net sales, which quarter to date already amount to approximately USD 25.5 million[1] with an additional 5 weeks remaining in the quarter. Our hub manager, Biologics by McKesson, has subsequently implemented routines to better deal with this type of unexpected situation in the future.

Our interactions with payors have continued as planned, and we have had many interactions with P&T committees already. We expect the updated rules to come into effect for many of the larger plans in their next update cycle, which is slated for June/July.

Q1 also saw a significant strengthening of the product protection of TARPEYO as we received seven years of orphan drug status for the new indication, ending in late December of 2030. In addition, we complemented our existing TARPEYO patent portfolio with a new patent, expiring in 2043. We will continue to work to both broaden the patent portfolio as well as achieve greater geographical coverage.

Post period we were also very excited to report out topline data from our setanaxib Phase 2 head and neck cancer trial. The highly relevant and clinically meaningful measures of progression free survival and overall survival came out as statistically significant in the patients who received setanaxib and pembrolizumab, compared to the group receiving placebo and pembrolizumab, and in addition we could see clinical evidence of setanaxib's anti fibrotic effect given the statistical significance on T cell activity in the tumors treated with setanaxib. This was beyond our initial expectations for the trial and we are looking forward to engaging in discussions with potential partners, as well as seeing the results from the other Phase 2 trials from our rare disease pipeline.

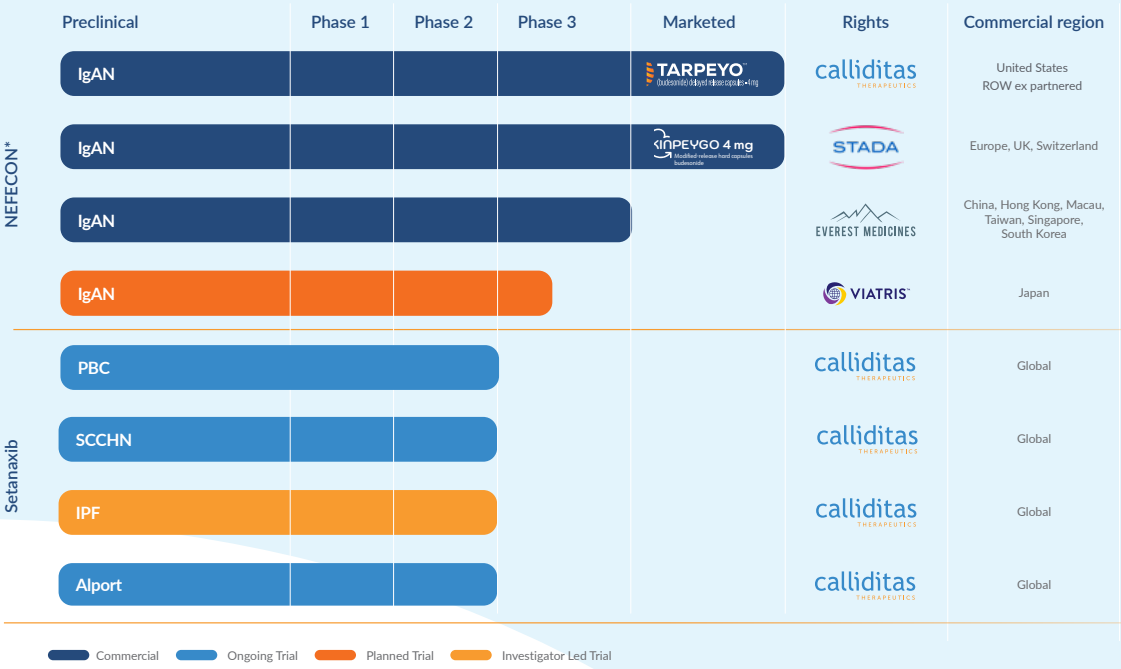
Our cash position remains strong with SEK 810 million on the balance sheet at the end of the quarter, which we believe is sufficient to take us to profitability based on expected revenue growth of TARPEYO. We reiterate our guidance of USD 150 – 180 million of net revenues for the Nefecon franchise in 2024.

Renée Aguiar-Lucander, CEO

[1]Net sales for TARPEYO are preliminary, unaudited and refer to the period April 1 – May 23.

Our pipeline

Calliditas' lead product has been fully approved in the US, and has conditional approval in Europe and China. Our pipeline consists of development programs derived from a first-in-class NOX inhibitor platform. The lead compound, setanaxib, was designed to be a selective NOX 1 and NOX 4 inhibitor and is the first product candidate to reach the clinical stage. Calliditas read out topline data from its trial with setanaxib in squamous cell carcinoma of the head & neck (SCCHN) in May 2024, and is also presently running trials with setanaxib in primary biliary cholangitis (PBC) and Alport syndrome. There is also an ongoing investigator-led trial in idiopathic pulmonary fibrosis (IPF).



* Approved in the US under the tradename TARPEYO® to reduce the loss of kidney function in adults with primary IgAN at risk for disease progression, 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, and granted conditional approval in China under the tradename Nefecon®.

Exciting journey ahead

Expected commercial ramp following full approval of TARPEYO in primary IgA nephropathy for patients at risk of progression

2H 2024: Topline data read-out of Phase 2b trial with setanaxib in PBC, following positive data from head and neck cancer trial

Potential full approval of Kinpeygo in EU and UK

Our commercial product

On December 20, 2023, Calliditas' lead product, TARPEYO, became the first and only drug granted full approval by the US Food and Drug Administration for patients affected by IgA nephropathy (IgAN). It is the only treatment specifically designed to target the origin of 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. It was also granted conditional approval by the European Commission under the brand name Kinpeygo® in July 2022 and by the MHRA for the UK in February 2023. Nefecon received conditional approval in China by the China NMPA in November 2023.

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.

Successful Phase 3 trial readout

NefIgArd is the first Phase 3 trial in IgA nephropathy to show a statistically significant and clinically relevant kidney protective effect as measured by eGFR. Calliditas' full approval for Nefecon from the FDA was based on the strong eGFR data from this trial. The trial confirmed that targeting the origin of the disease with a non chronic approach had a significant long-term impact on kidney function.

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 approval with the FDA and for conditional approval with the European Commission, UK MHRA, and China NMPA. 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. At 9 months the absolute difference in eGFR of the treatment arm was an improvement of 0.7 mL/min/1.73 m^2 versus a loss of 4.6 mL/min/1.73 m^2 for the placebo arm. The treatment benefit was preserved during the period of observation, reflected by a loss of kidney function at two years in the placebo arm of 12.0 mL/min/1.73 m^2 versus 6.1 mL/min/1.73 m^2 for the treatment arm. This was also confirmed by a difference in slope of 3 mL/min/year in favor of TARPEYO.

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 after end of treatment, resulting in a decline of over 50% 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.

Regulatory approvals

On the basis of this positive data, Calliditas submitted an sNDA to the FDA seeking full approval of TARPEYO for the complete study population from the Phase 3 NefIgArd study. On December 20, 2023, the FDA approved TARPEYO (budesonide) delayed release capsules to reduce the loss of kidney function in adults with primary IgAN at risk for disease progression. Marking a significant milestone, TARPEYO is now the first fully FDA-approved treatment for IgAN reflecting the impact on a measure of kidney function.

In September 2023, Calliditas' partner STADA filed with European Commission for full marketing authorisation of Kinpeygo in the EU, and in October 2023 they also filed with the UK MHRA. Nefecon received conditional approval in China in November 2023 and approval in the Macau administrative region in October 2023. Calliditas' partner Everest Medicines will be commercialising this product in these territories.

IgA nephropathy - a significant market opportunity

- While IgAN is a rare disease, it is the most common form of 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 will grow to USD 5 – 8 billion.

Our commercial partnerships

Europe

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 approved treatment for IgAN in the EU. Kinpeygo is 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.

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. An opinion from the CHMP is expected in the first half of 2024.

Greater China

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

Everest first 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.

Nefecon® was awarded conditional approval in IgAN by China's National Medical Products Administration (NMPA) in November 2023. Everest launched Nefecon in mainland China in May 2024.
In addition to being approved and commercially launched in Mainland China, Nefecon® has also received approval in Macau, Hong Kong and Singapore, and was successfully commercially launched and first prescribed in Macau at the end of 2023. New Drug Applications (NDA) for Nefecon® were also successfully accepted for review in Taiwan and South Korea at the end of 2023.

China has the highest prevalence of primary glomerular diseases in the world, with an estimated five million IgAN patients. Results from the Chinese subpopulation analysis of the Phase 3 NefIgArd trial, presented at the American Society of Nephrology (ASN) Kidney Week 2023, provided evidence that the treatment effect of Nefecon in the Chinese cohort was greater than in the global data set with regards to kidney function, proteinuria and microhematuria. In the Chinese cohort, the mean absolute change from baseline in eGFR at 24 months showed an approximately 66% reduction in loss of this measure of kidney function with Nefecon compared with a 50% reduction in loss of eGFR in the global data set.

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.

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

TARPEYO: Moving from supportive care to treating IgAN

TARPEYO and Kinpeygo were the first-ever medications approved for IgAN by the FDA and European Commission, respectively, and the only treatments specifically designed to target the origin of IgAN and to be disease-modifying. TARPEYO is the only fully FDA-approved treatment for IgAN and the only treatment approved based on protection of kidney function.

Mechanism of action

Targeted B cell immunomodulator designed to locally target origin of disease

Patient focus

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

Efficacy

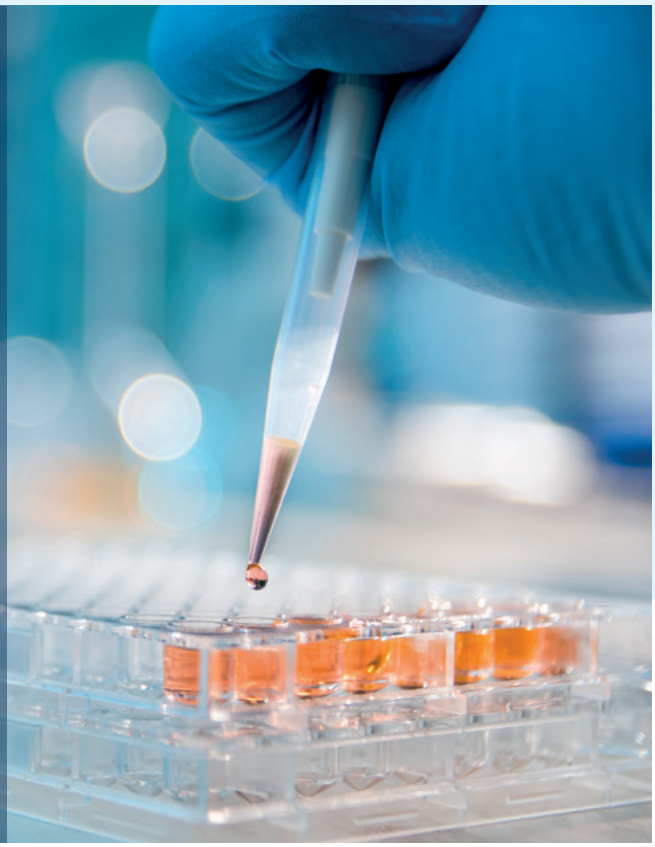
Durable eGFR benefit and sustained proteinuria disease-modifying effects in IgAN

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
- Recently published longitudinal data imply that disease progression is faster and outlook worse than previously thought[1]



[1] *Pitcher D, Braddon F, Hendry B, et al. Long-Term Outcomes in IgA Nephropathy. Clin J Am Soc Nephrol. 2023;18(6):727-738. doi:10.2215/CJN.0000000000000013*
Kwon CS, Daniele P, Forsythe A, Ngai C. A Systematic Literature Review of the Epidemiology, Health-Related Quality of Life Impact, and Economic Burden of Immunoglobulin A Nephropathy. J Health Econ Outcomes Res. 2021 Sep 1;8(2):36-45. doi: 10.36469/001c.26129. PMID: 34692885; PMCID: PMC8410133.

Strong Demand for TARPEYO in Q1

During the first quarter, the Calliditas US team focused on leveraging TARPEYO's full FDA approval and new label to inform and engage nephrology healthcare professionals, payors and patient communities regarding the latest clinical data.

In Q1 2024, TARPEYO set another quarterly record with 705 new patient enrollments, marking a substantial 27% quarter-over-quarter increase, following the 51% quarterly increase seen in Q4. The increase in new prescribers of 354 was also a quarterly record, which is another clear indicator of market acceptance and demand for TARPEYO. The positive momentum is expected to persist throughout 2024, supported by the new label and indication, further reinforcing TARPEYO's positioning as the backbone treatment option in IgAN.

The Q1 revenue was impacted by two factors: the seasonal effect of the open enrollment period in the US, with insurance changes for many patients, and a cyber-attack on the IT network of our exclusive specialty pharmacy's insurance claims processor in the US, Change Healthcare. The estimated negative impact on Q1 revenues of this unexpected disruption is ~$4.7m, which we anticipate will be recorded over the next several months. Importantly, this does not impact our revenue guidance for 2024. We are also highly encouraged by a strong start to Q2 in terms of TARPEYO net sales, which to the date of this report already amount to approximately $25.5m with an additional 5 weeks remaining in the quarter.

KEY METRICS Q1 2024

705

New Patients enrolled in Q1
27% QoQ growth

354

New Prescribers in Q1
LTD Prescribers: 1,993
17% QoQ growth

$26.8M

Net sales of TARPEYO in Q1 2024

QUARTERLY HIGHLIGHTS Q1

New Label Promotional Launch

First and only product FDA-approved to reduce the loss of kidney function.

Patient Educational Webinar with IgAN

Foundation & TARPEYO Patient Ambassadors.

4 Presentations at WCN with analysis from NefIgArd

Phase 3 trial and QoL data.

EXCITING JOURNEY AHEAD

Continue US promotional efforts to drive TARPEYO´s positioning as a disease modifying foundational therapy in IgAN.

Drive scientific exchange and data dissemination at major scientific congress and programs (e.g. ERA, NKF,ASN).

Leverage KDIGO guidelines expected in 2024.

Educate and inform US payors on the full approval to ensure TARPEYO payor policies are reflecting new label.

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 positive topline data data in May 2024, as well as in primary biliary cholangitis (PBC) and Alport syndrome.

NOX Enzyme Inhibitors

NOX enzymes, also known as nicotinamide adenine dinucleotide phosphate (NADPH) oxidases, are the only known enzymes that are solely dedicated to producing reactive oxygen species (ROS). At appropriate concentrations, ROS help regulate cell proliferation, differentiation, and migration, as well as modulate the innate immune response, inflammation, and fibrosis.

The disruption of redox homeostasis has been implicated in multiple disease pathways, with oxidative stress caused by excess ROS being a likely underlying mechanism for many disorders, including cardiovascular diseases, neurodegenerative disorders, and cancer. As such, NOX enzyme inhibitors emerged as promising novel experimental drugs in a new therapeutic class.

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 IV collagen. The type IV 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 ESRD.

It is estimated that approximately 67,000 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.

Based on supportive pre-clinical work, Calliditas launched a randomized, placebo-controlled Phase 2 study in Alport syndrome including around 20 patients. The study will evaluate overall safety as well as impact on proteinuria. The study was initiated in November 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 for the treatment of Alport syndrome with setanaxib by the FDA in September 2023, and by the EMA in November 2023.

Primary biliary cholangitis

PBC is a progressive and chronic autoimmune disease of the liver that causes 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 United States, 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. 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 111 patients with PBC demonstrated that setanaxib had a more pronounced effect on fibrosis and ALP reduction (alkaline phosphatase, an 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 are expecting to read out data from approximately 75 patients in Q3 2024.

Pipeline: NOX Inhibitor platform

Setanaxib in squamous cell carcinoma of the head and neck

In May 2024, Calliditas read out topline data from its proof-of-concept Phase 2 trial evaluating setanaxib in combination with pembrolizumab in patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). The trial is a randomized, placebo-controlled, double-blind Phase 2 study investigating the effect of setanaxib 800mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks, (a standard treatment regimen for SCCHN) with the full dataset reflecting all patients having had the opportunity to complete at least 15 weeks of treatment. The basis for the analysis consisted of 55 enrolled patients with recurrent or metastatic SCCHN and moderate or high CAF-density tumors. A tumor biopsy was taken prior to randomization and then again after at least 9 weeks of treatment.

Phase 2 data readout

The treatment groups were well-balanced with no clinically relevant differences between the groups observed at baseline.

Patients treated with pembrolizumab and setanaxib showed statistically significant improvements in the key secondary endpoints of progression-free survival, (PFS median 5 months versus 2.9 months; Hazard ratio= 0.58) and overall survival (OS at 6 months 92% vs 68%; OS at 9 months 88% vs 58%; Hazard ratio=0.45) compared to patients treated with pembrolizumab and placebo.

There was also an improvement in disease-control rate in setanaxib-treated patients, with 70% in the setanaxib arm showing a best response of at least stable disease compared to 52% in the placebo arm.

"It is very encouraging to see statistical significance on important clinical outcomes in this relatively small study, which provides an excellent basis for advancing setanaxib in this hard-to-treat population."

Kevin Harrington, Professor in Biological Cancer Therapies at The Institute of Cancer Research (ICR) London, Consultant Clinical Oncologist at The Royal Marsden NHS Foundation, London, and Investigator on the trial.

No significant difference in the primary endpoint of best percentage change from baseline in tumor size was observed.

Transcriptomic analysis of tumor biopsy samples showed a statistically significant increase in CD8+ T-cells in tumor tissue from patients treated with setanaxib, indicating an increase in tumor immunological activity consistent with the mechanism of action of setanaxib. The tolerability of setanaxib when given with pembrolizumab was generally good, with no new safety signals identified.

Expanded patent protection

In April 2024, Calliditas received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application no. 16/760,910 entitled "Use of NOX Inhibitors for Treatment of Cancer". This Notice of Allowance is expected to result in the issuance of a U.S. patent once administrative processes are completed. The allowed claims cover a method of treating a solid tumor presenting resistance to PD-1 inhibitor immunotherapy by administering setanaxib in combination with a PD-1 inhibitor. The patent, when issued, will have an anticipated expiration date in 2038.

Calliditas President North America Maria Törnsén

You have joined Calliditas with over 20 years of experience in the pharmaceutical industry. Can you talk about your career and your experiences in the industry thus far?

I started my career as a sales representative in the north of Sweden. Looking back, I would say this was a bit of by luck, as I met representatives from Eli Lilly Sweden at a career day at Lund University as I was finishing up my Master's degree. Little did I know that this initial meeting would bring me the career I have enjoyed over the last 22 years and the majority spent outside my home country of Sweden. From early days of sales and marketing with Eli Lilly and Merck Serono in Sweden, I emigrated in 2008 when I got the opportunity to move into a global role with Merck Serono in Switzerland. Since 2011, I have almost exclusively spent my career in rare diseases at organizations such as Shire, Sanofi Genzyme and Sarepta in global, European and US roles. I have had the opportunity to work in diseases where there is no therapy available, in areas with several approved therapies and with programs at all stages of development and commercialization.

What experiences from your previous positions do you think have been most valuable as you have taken over as President, North America at Calliditas?

While all rare diseases are unique, I have through working on over fifteen different rare diseases learned that there are many similarities, which I have been able to bring from one organization to the next one.

First, patients with rare diseases typically face a long journey to diagnosis which sometimes includes a misdiagnosis and seeing multiple specialists. This is why understanding the patient journey is critical, to ensure we put in place the right type of education, to the right stakeholders, at the right time to shorten time to diagnosis and raise the urgency to treat.

Second, once a patient has received a diagnosis, there are in most cases no treatments available, or access is challenging. More than 95% of rare diseases have no treatments available today, so the healthcare provider may be limited to offering supportive care. At Calliditas, we can provide a treatment for one of the rare diseases, TARPEYO for IgA nephropathy (IgAN) and we also have an experienced access team who can help ensure eligible patients gain access to TARPEYO.

Finally, I would also highlight the aspect of community support and how important that is for someone living with a rare disease. As rare diseases are not well known to most people, a person diagnosed with a rare disease may be challenged with finding accurate information and get the support they need. That's why the patient organizations play such a critical role for rare disease patients, and I am proud that Calliditas is working with multiple patient organizations supporting people living with IgAN and other kidney diseases.

What excited you about the prospect of leading Calliditas' commercial efforts in the US?

In December 2023, we gained full approval for TARPEYO for the treatment of IgAN. This was a pivotal moment for Calliditas, but most importantly for the IgAN community. This is the first time a product has proven to reduce the loss of kidney function in IgAN, which is something the community has been waiting for, for a long time. I am excited about the opportunity to engage with healthcare providers, patient organizations and payors to educate on the new indication for TARPEYO and ensure appropriate patients can have access to our therapy.

I am equally excited about our clinical programs and our NOX enzyme inhibitors platform. Over the next twelve months, we will have multiple data readouts in disease areas with high unmet need. This may allow us an opportunity to potentially help other patients in the future.

What do you think the full approval and expanded label will mean for TARPEYO in the context of standard of care?

For many years, the IgAN community has not had an approved therapy which has shown to reduce the loss of kidney function. Since the full approval of TARPEYO, they now have that. We can not underestimate the importance of this full approval, as it gives healthcare providers an opportunity to not only manage proteinuria, but also tell their patients it can help preserve their kidney function. It will also facilitate discussions with payors and improve patient access. This is a benefit for IgAN patients, as many are diagnosed before the age of 40 and will live with this disease for many decades.

What key events and milestones in the upcoming year do you think might drive TARPEYO sales and profile?

The full approval in December 2023 was the most important milestone for Calliditas. This full approval provides access to a broader IgAN population. During the first half of 2024, our focus is on educating payors and healthcare providers on the new label, to ensure broader access to TARPEYO.

The data from our open label extension (OLE) study is also important in helping us better understand the potential benefit of providing a second 9-month treatment of TARPEYO.

Another important milestone we are anticipating this year is the update of the KDIGO guidelines. These guidelines were last updated in 2021, prior to the full approval of TARPEYO. We know that many nephrologists use these guidelines as they make decisions on how to treat their patients with IgAN. We are anticipating that the updated guidelines will include TARPEYO, and that they may also expand the definition of the "at risk" population who should be treated.

What can you share with regards to progress related to payor interactions on the new label in the first quarter of the year?

Our focus in Q1 has been on educating payors on the new label for TARPEYO. We have invested in our field-based team, both in terms of national account managers, whose focus is commercial and government payors, and our field reimbursement managers, who are focused on educating nephrology offices on the prior authorization process and facilitating patient access.

Our national account team, alongside our field based medical team, have been engaging with payors since the full approval was granted. This has included multiple scientific presentations on the new label, providing payors with a summary of the differences compared to the previous label, and answering their questions. With this information in hand, we are expecting the major payors to update their policies over the next six months, which should facilitate access to TARPEYO.

Continued focus on CSRD implementation

During the first quarter, Calliditas took further steps in the implementation of the upcoming legal requirement, CSRD, by establishing a roadmap for the project and preparing several key performance indicators to ensure progress in its sustainability work.

During the first quarter, Calliditas continued the efforts to develop its sustainability work with a focus on the issues that, in accordance with the double materiality assessment, will guide the strategic sustainability work and reporting going forward. Based on current sustainability reporting, an analysis was made to get a clear picture of the information and data that is available, and what needs to be added to comply with CSRD and its associated standards.

To ensure that the right priorities are set in the long-term sustainability work, a roadmap was developed during the first quarter. It defines what Calliditas needs to work on in order to drive its sustainability work forward, together with how the work is to be done, the timeline, as well as who, alternatively which function, is responsible.

Key figures for continuous follow-up

With the ambition to increase the pace of sustainability work and data collection, several selected key performance indicators were developed during the first quarter to continuously monitor the progress of some of Calliditas' material sustainability matters. The selection was made based on the metrics and targets included in a number of the ESRS on which Calliditas will report starting in fiscal year 2025. An overview:

Environment
- Share of all purchased electricity from renewable sources

Social
- Number of incidents linked to work-related injuries, ill health cases and fatalities
- Number of days lost due to work-related ill health
- Number of employees who left Calliditas/Employee turnover

Governance
- Percentage of employees trained in Calliditas' Code of Conduct
- Percentage of business partners who have signed Calliditas' Code of Conduct

Continued work to drive transition

For Calliditas, the long-term work to develop policies, processes, targets, and activities continues. In addition, Calliditas will gradually add key performance indicators to increase progress in the sustainability work and the implementation of CSRD.

Calliditas' material sustainability areas

The sustainability matters that are most important for Calliditas to work with, monitor and report on are gathered in seven main areas divided as follows:

Environmental matters
- Climate change mitigation and adaptation
- Circular economy and waste

Social matters
- Employee health and safety
- Access to products
- Health and safety of end-users

Governance matters
- Anti-corruption and anti-bribery
- Animal protection

January – March 2024

Revenue

Net sales amounted to SEK 295.5 million and SEK 191.4 million for the three months ended March 31, 2024 and 2023, respectively. Net sales primarily originated from net sales of TARPEYO® in the US, which amounted to SEK 278.3 million and SEK 185.7 million for the three months ended March 31, 2024 and 2023, respectively. Royalty income from our partnerships amounted to SEK 13.0 million and SEK 4.4 million for the three months ended March 31, 2024 and 2023, respectively. For additional information see Note 4.

Cost of Sales

Cost of sales amounted to SEK 14.0 million and SEK 9.0 million for the three months ended March 31, 2024 and 2023, respectively.

Total Operating Expenses

Total operating expenses amounted to SEK 485.3 million and SEK 362.4 million for the three months ended March 31, 2024 and 2023, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 150.6 million and SEK 126.7 million for the three months ended March 31, 2024 and 2023, respectively. The increase of SEK 23.9 million for the period was primarily due to increased clinical activities for the Nox-platform, including the ongoing setanaxib trials.

Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 240.1 million and SEK 167.2 million for the three months ended March 31, 2024 and 2023, respectively. The increase of SEK 72.9 million was primarily related to intensified marketing activities of TARPEYO and increased US salesforce due to the TARPEYO full approval in the US.

Administrative Expenses

Administrative expenses amounted to SEK 102.0 million and SEK 72.5 million for the three months ended March 31, 2024 and 2023, respectively. The increase of SEK 29.5 million for the period was primarily related to increased costs from a larger organization and increased regulatory requirements.

Other Operating Incomes/Expenses, net

Other operating income (expenses), net amounted to SEK 7.5 million and SEK 4.0 million for the three months ended March 31, 2024 and 2023, respectively. The improvement was primarily attributable to movements in exchange rates related to operating receivables and liabilities.

Net Financial Income and Expenses

Net financial income (expenses) amounted to (SEK 43.5 million) and (SEK 27.9 million) for the three months ended March 31, 2024 and 2023, respectively. The change in the net amount of (SEK 15.5 million) was primarily derived from interest expenses and currency effects primarily related to translation effects.

Tax

Total income tax (expense) amounted to SEK 1.2 million and SEK 20.5 million for the three months ended March 31, 2024 and 2023, respectively. The change in income tax was primarily explained by carried-forward losses recognized regarding U.S. subsidiaries in the first quarter of 2023. 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 March 31, 2024 and 2023, loss for the period amounted to SEK 246.2 million and SEK 187.5 million, and the corresponding loss per share before and after dilution amounted to SEK 4.59 and SEK 3.49, respectively.

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 198.2 million and SEK 231.9 million for the three months ended March 31, 2024 and 2023, respectively. The decrease is mainly attributable to the change in current receivables.

Cash flow used in investing activities amounted to SEK 3.9 million and SEK 2.9 million for the three months ended March 31, 2024 and 2023, respectively. The change was primarily explained by acquisition of equipment.

Cash flow used in financing activities amounted to SEK 5.5 million and SEK 3.0 million for the three months ended March 31, 2024 and 2023, respectively.

Net decrease in cash amounted to SEK 207.5 million and SEK 237.8 million for the three months periods ended March 31, 2024 and 2023, respectively. Cash amounted to SEK 810.3 million and SEK 1,013.6 million as of March 31, 2024 and 2023, respectively.

Personnel

The average number of employees were 219 and 170 for the three months ended March 31, 2024 and 2023, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 120.2 million and SEK 589.4 million as of March 31, 2024 and 2023, respectively. The number of registered shares amounted to 59,580,087 and 59,580,087 as of March 31, 2024 and 2023, respectively.

Treasury Shares

As of March 31, 2024, 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 March 31, 2024. See Note 7 and 8 for further information.

Incentive Programs

During the three months ended March 31, 2024, 555,000 options have been allocated for the ESOP 2023 Program. For more information on incentive programs, see Note 9.

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 138.2 million and SEK 168.4 million for the three months ended March 31, 2024 and 2023, respectively. The decrease is primarily attributable to change in the price mix of product sales compared to previous year.
Operating loss amounted to SEK 174.0 million and SEK 46.6 million for the three months ended March 31, 2024 and 2023, respectively. The decrease of SEK 127.4 million was primarily related to higher costs related to intensified marketing activities, increased regulatory requirements, and the larger organization.

Executive Management

The Executive Management of Calliditas Therapeutics AB consists of: CEO Renée Aguiar-Lucander, CFO Fredrik Johansson, CMO Richard Philipson, Group General Counsel Brian Gorman, President North America Maria Törnsén, Vice President Regulatory Affairs Frank Bringstrup, Head of Technical Operations Lars Stubberud and Head of Human Resources Sandra Frithiof.

Nomination Committee AGM 2024

The nomination committee for the AGM 2024 consists of: Patrick Sobocki, appointed by Stiftelsen Industrifonden, Karl Tobieson, appointed by Linc AB and Spike Loy, appointed by BVF.

Annual General Meeting 2024

The 2024 Annual General Meeting will be held 17 June at 14.00 p.m. CET, Klarabergsviadukten 90, Stockholm, Sweden. All documentation will be published on the company's website.

Unchanged Outlook 2024

For 2024, Calliditas expects continued revenue growth: Total net sales from the Nefecon franchise, including milestones, are estimated to be USD 150-180 million for the year ending 31 December, 2024.

The Share

As of 31 March 2024, 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 28 March, 2024, the closing price for the Calliditas Therapeutics share CALTX was SEK 113.4. The total number of shareholders as of 31 March, 2024 was approximately 18,000.

Shareholder Structure

Ten largest shareholders as of March, 2024	%
BVF Partners LP	10,51
Linc AB	10,01
Stiftelsen Industrifonden	5,28
Polar Capital	3,94
Unionen	3,60
Avanza Pension	3,24
Handelsbanken Fonder	2,95
Fjärde AP-fonden	2,94
Sofinnova Partners	2,36
Öhman Fonder	2,23
Subtotal, 10 largest shareholders	**47,06**
Treasury shares	**9,92**
Other shareholders	**43,02**
Total	**100.00**

Calliditas R&D Day

On 30 May Calliditas will hold an R&D Day at Inderes Event Studio, Västra Trädgårdsgatan 19, Stockholm at 15.00 p.m CET. The event is available online and also possible to attend live. To attend, live or online, please register at: https://financialhearings.com/event/49948/register/live_event

Auditor's Review

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

Stockholm 23 May, 2024
Renée Aguiar-Lucander
CEO

Significant Events

Significant Events During the Period 1 January – 31 March, 2024

- On 7 January, Calliditas announced that Maria Törnsén was appointed to the position of President North America. Ms. Törnsén is responsible for all US based operations and reports to the CEO.
- On 13 February, Calliditas announced that the United States Patent and Trademark Office (USPTO) issued patent no. 11896719, entitled "New Pharmaceutical Compositions", on 24 January, 2024 with validity 13 February, 2024. This is Calliditas' second patent for TARPEYO in the United States, and provides product protection until 13 February 2043.
- On 6 March, Calliditas announced that the FDA granted an orphan drug exclusivity period of seven years for TARPEYO®, expiring in December 2030, based on when the company obtained full approval with an expanded indication for this drug product.

Significant Events After the end of the Period

- On 8 April, Calliditas announced that the Company received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application no. 16/760,910 entitled "Use of NOX Inhibitors for Treatment of Cancer". This Notice of Allowance is expected to result in the issuance of a U.S. patent once administrative processes are completed.
- On 24 April, Calliditas announced that the global open-label extension (OLE) study to the Phase 3 NefIgArd study showed a treatment response consistent with the NefIgArd study across endpoints of urine protein to creatinine ration (UPCR) and estimated glomerular filtration rate (eGFR) at 9 months across all IgAN patients, including those who had previously received Nefecon in the NefIgArd study.
- On 6 May, Calliditas announced topline data from the proof-of-concept Phase 2 trial evaluating setanaxib, its lead NOX enzyme inhibitor, in combination with pembrolizumab, in patients with squamous cell carcinoma of the head and neck (SCCHN). The analysis showed statistically significant improvements in progression-free survival (PFS), as well as in overall survival (OS), with statistically significant changes in tumor biology consistent with the mechanism of action of setanaxib.
- On 14 May, Calliditas announced that its partner Everest Medicines launched Nefecon® in China, which is estimated to have up to 5 million patients suffering from the progressive autoimmune disease.
- Preliminary net sales from TARPEYO for the second quarter up until the date of this report amounts to USD 25.5 million.

Supplemental Information

Presentation to investors, analysts and press

- Calliditas invites investors, analysts and press to a presentation of the Q1 Report 2024 at 14:30 p.m. CET on 23 May, 2024. The report was published on 23 May at 7:00 a.m. CET.
- Calliditas' CEO Renée Aguiar-Lucander will present the report together with CFO Fredrik Johansson, CMO Richard Philipson and President North America Maria Törnsén. The presentations will be given in English.
- Time: Thursday 14:30 p.m. CET on 23 May, 2024
- Link to webcast
  https://ir.financialhearings.com/calliditas-therapeutics-q1-report-2024
- To participate via conference call register via this link:
  https://conference.financialhearings.com/teleconference/?id=50047214
  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

Calliditas R&D Day 2024
Västra Trädgårdsgatan 19, Stockholm
30 May

ANNUAL GENERAL MEETING 2024
Klarabergsviadukten 90, Stockholm
17 June

INTERIM REPORT Q2
January – June 2024
13 August

INTERIM REPORT Q3
January – September 2024
11 November

For further information please contact

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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, Kinpeygo and Nefecon, 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 2024 total net sales guidance and cash runway and preliminary net sales for the second quarter of 2024 to date, 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.

Registered office

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

The information in the 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 May 23, 2024, at 7:00 a.m. CET.

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023	Year Ended December 31, 2023
Net sales	4	295,481	191,352	1,206,888
Cost of sales		(14,012)	(9,028)	(60,463)
Gross income		**281,469**	**182,323**	**1,146,425**
Research and development expenses		(150,613)	(126,653)	(502,223)
Marketing and selling expenses		(240,147)	(167,224)	(727,740)
Administrative expenses		(102,018)	(72,548)	(332,991)
Other operating income/(expenses), net		7,483	4,027	43,473
Operating income (loss)		**(203,826)**	**(180,074)**	**(373,055)**
Net financial income/(expenses)		(43,498)	(27,944)	(83,962)
Income (loss) before income tax		**(247,324)**	**(208,019)**	**(457,017)**
Income tax		1,164	20,494	(9,168)
Net income (loss) for the period		**(246,160)**	**(187,525)**	**(466,185)**
Attributable to:				
Equity holders of the Parent Company		(246,160)	(187,525)	(466,185)
		(246,160)	**(187,525)**	**(466,185)**
Loss per share before and after dilution (SEK)	8	(4.59)	(3.49)	(8.69)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023	Year Ended December 31, 2023
Net income (loss) for the period	(246,160)	(187,525)	(466,185)
Other comprehensive income			
Other comprehensive income (loss) that may be reclassified to income or loss in subsequent periods:			
Exchange differences on translation of foreign operations	16,351	1,159	(14,538)
Other comprehensive income (loss) that may be reclassified to income or loss in subsequent periods	**16,351**	**1,159**	**(14,538)**
Other comprehensive income (loss) that will not be reclassified to income or loss in subsequent periods:			
Remeasurement gain (loss) on defined benefit plans	12	(662)	(3,071)
Other comprehensive income (loss) that will not be reclassified to income or loss in subsequent periods	**12**	**(662)**	**(3,071)**
Other comprehensive income (loss) for the period	**16,363**	**497**	**(17,609)**
Total comprehensive income (loss) for the period	**(229,797)**	**(187,028)**	**(483,794)**
Attributable to:			
Equity holders of the Parent Company	(229,797)	(187,028)	(483,794)
	(229,797)	**(187,028)**	**(483,794)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	March 31, 2024	March 31, 2023	December 31, 2023
ASSETS				
Non-current assets				
Intangible assets		424,227	439,180	430,754
Goodwill		47,848	45,911	48,584
Equipment		18,397	8,417	16,053
Right-of-use assets		46,988	34,142	38,186
Non-current financial assets		25,097	13,390	24,201
Deferred tax assets		26,835	27,970	26,315
Total non-current assets		**589,392**	**569,010**	**584,093**
Current assets				
Inventories		29,303	12,160	20,428
Current receivables		182,824	109,551	196,666
Prepaid expenses and accrued income		76,459	84,396	84,324
Cash		810,317	1,013,600	973,733
Total current assets		**1,098,903**	**1,219,706**	**1,275,152**
TOTAL ASSETS		**1,688,295**	**1,788,716**	**1,859,245**
EQUITY AND LIABILITIES				
Equity				
Equity attributable to equity holders of the Parent Company		120,151	589,403	334,806
Total equity	*7,8,9*	**120,151**	**589,403**	**334,806**
Non-current liabilities				
Provisions	*9*	30,463	24,471	36,116
Contingent consideration	*6*	60,458	78,816	56,561
Deferred tax liabilities		35,152	33,728	41,641
Non-current interest-bearing liabilities		986,390	723,995	939,508
Lease liabilities		30,228	22,903	27,088
Other non-current liabilities		17,282	5,320	16,381
Total non-current liabilities		**1,159,973**	**889,233**	**1,117,295**
Current liabilities				
Accounts payable		101,384	108,000	100,564
Other current liabilities		33,383	33,158	25,953
Accrued expenses and deferred revenue		273,404	168,922	280,627
Total current liabilities		**408,171**	**310,080**	**407,144**
TOTAL EQUITY AND LIABILITIES		**1,688,295**	**1,788,716**	**1,859,245**

Condensed Consolidated Statements of Changes in Equity

	Three Months Ended March 31,		Year Ended December 31,
(SEK in thousands)	2024	2023	2023
Opening balance equity attributable to equity holders of the Parent Company	**334,806**	**766,264**	**766,264**
Loss for the period	(246,160)	(187,525)	(466,185)
Other comprehensive income/(loss)	16,363	497	(17,609)
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	**(229,797)**	**(187,028)**	**(483,794)**
Transactions with owners:			
Share-based payments	15,142	10,167	52,337
Total transactions with owners	**15,142**	**10,167**	**52,337**
Closing balance equity attributable to equity holders of the Parent Company	**120,151**	**589,403**	**334,806**
Closing balance equity	**120,151**	**589,403**	**334,806**

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023	Year Ended December 31, 2023
Operating activities			
Operating loss	(203,826)	(180,074)	(373,055)
Adjustment for non-cash items	16,259	27,141	102,478
Interest received	2,516	7	32,905
Interest paid	(26,534)	(15,460)	(94,497)
Income taxes paid	(244)	(1,336)	(22,747)
Cash flow from (used in) operating activities before changes in working capital	**(211,829)**	**(169,722)**	**(354,915)**
Cash flow from (used in) changes in working capital	13,624	(62,218)	(79,740)
Cash flow from (used in) operating activities	**(198,205)**	**(231,940)**	**(434,655)**
Cash flow from (used in) investing activities	**(3,858)**	**(2,913)**	**(13,745)**
New borrowings	-	-	962,889
Costs attributable to new loans	-	-	(26,625)
Repayment of borrowing	-	-	(724,479)
Repayment of lease liabilities	(5,467)	(2,969)	(12,134)
Cash flow from (used in) financing activities	**(5,467)**	**(2,969)**	**199,650**
Net increase (decrease) in cash	**(207,530)**	**(237,822)**	**(248,750)**
Cash at the beginning of the period	**973,733**	**1,249,094**	**1,249,094**
Net foreign exchange gains (loss) in cash	44,114	2,327	(26,611)
Cash at the end of the period	**810,317**	**1,013,600**	**973,733**

Condensed Parent Company Statements of Income

(SEK in thousands)	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023	Year Ended December 31, 2023
Net sales	138,199	168,370	805,551
Cost of sales	(13,976)	(9,013)	(60,399)
Gross income (loss)	**124,223**	**159,358**	**745,151**
Research and development expenses	(137,644)	(118,789)	(456,970)
Marketing and selling expenses	(109,670)	(88,671)	(402,436)
Administrative expenses	(84,160)	(59,185)	(273,359)
Other operating income/(expenses), net	33,286	60,653	219,818
Operating loss	**(173,965)**	**(46,635)**	**(167,796)**
Net financial income/(expenses)	10,403	(18,333)	(105,722)
Loss before income tax	**(163,562)**	**(64,968)**	**(273,518)**
Income tax	-	-	-
Loss for the period	**(163,562)**	**(64,968)**	**(273,518)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023	Year Ended December 31, 2023
Loss for the period	(163,562)	(64,968)	(273,518)
Other comprehensive income (loss)	-	-	-
Total comprehensive income (loss)	**(163,562)**	**(64,968)**	**(273,518)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	March 31, 2024	March 31, 2023	December 31, 2023
ASSETS				
Non-current assets				
Intangible assets		-	32,132	-
Equipment		2,218	511	342
Non-current financial assets		1,168,909	977,553	1,125,186
Total non-current assets		**1,171,127**	**1,010,195**	**1,125,528**
Current assets				
Inventories		29,303	12,160	20,428
Current receivables		378,450	211,193	223,700
Prepaid expenses and accrued income		47,835	65,046	67,603
Cash		554,834	776,220	817,871
Total current assets		**1,010,422**	**1,064,619**	**1,129,602**
TOTAL ASSETS		**2,181,549**	**2,074,814**	**2,255,130**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Total restricted equity		5,475	5,475	5,475
Total non-restricted equity		755,880	1,070,679	904,299
Total shareholders' equity	*7,9*	**761,355**	**1,076,155**	**909,774**
Non-current liabilities				
Provisions	*9*	21,286	18,769	25,924
Non-current interest-bearing liabilities		986,390	723,995	939,508
Other non-current liabilities		17,387	5,425	16,486
Total non-current liabilities		**1,025,063**	**748,189**	**981,918**
Current liabilities				
Accounts payable		52,248	53,835	62,562
Other current liabilities		165,949	93,023	113,685
Accrued expenses and deferred revenue		176,934	103,611	187,191
Total current liabilities		**395,131**	**250,470**	**363,438**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**2,181,549**	**2,074,814**	**2,255,130**

Notes to Condensed Consolidated Financial Statements

Note 1 - Description of Business

Calliditas Therapeutics AB (publ) ("Calliditas" or the "Parent Company"), with corporate registration number 556659-9766, and its subsidiaries (collectively, the "Group") conducts commercial and development activities in pharmaceuticals. These interim condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the three months ended March 31, 2024 and 2023.

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

These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on May 23, 2024. 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 2023. None of the new or amended standards and interpretations that became effective January 1, 2024, have had a significant impact on the Group's financial reporting. Significant accounting policies can be found in the Annual Report 2023, from pages 45 and onwards including disclosures at respective note.

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 30.

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

Operational Risks

Research and drug development up to approved registration and marketing 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 received full 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, and in China under the brand name Nefecon, and are dependent on renewal of the conditional marketing authorizations. 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.

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 EUR 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 2023.
For more information and full disclosure regarding the operational and financial risks, reference is made to the Annual Report for 2023 and the Annual Report on Form 20-F, filed with the SEC in April 2024.

Note 4 - Revenue from Contracts with Customers

	Three Months Ended March 31,		Year Ended December 31,
(SEK in thousands)	2024	2023	2023
Type of goods or services			
Product sales	282,530	186,940	1,087,418
Outlicensing of product	-	-	82,712
Royalty income	12,951	4,412	36,758
Total	**295,481**	**191,352**	**1,206,888**
Geographical markets			
USA	278,276	185,691	1,075,829
Europe	16,859	5,661	39,614
Asia	346	-	91,445
Total	**295,481**	**191,352**	**1,206,888**

Net sales for the periods primarily originate from net sales of TARPEYO in the US, which amounted to SEK 278.3 million and SEK 185.7 million for the three months ended March 31, 2024 and 2023, respectively. Royalty income from our partnerships amounted to SEK 13.0 million and SEK 4.4 million for the first quarter of 2024 and 2023, respectively. For the first three months ended March 31, 2024 and 2023, no milestones were recognized. For 2023, outlicensing of product consisted entirely of milestone fees from Everest Medicines.

The total liability for expected returns and rebates amounts to SEK 2.7 million and SEK 39.8 million as of March 31, 2024 and 2023, respectively, which are recognized in other current liabilities.

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 is recognized at fair value, measured at Level 3 of the IFRS value hierarchy. The fair value of the contingent consideration has been estimated 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 12.2 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.

Calliditas holds a credit agreement that contains customary affirmative and negative covenants for a senior secured loan, such as minimum cash liquidity and minimum product revenue. The fair value at the end of the period amounts to SEK 1,011.4 million.

Note 7 - Treasury Shares

As of March 31, 2024, 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 March 31, 2024. The total number of issued shares as of March 31, 2024, is disclosed in Note 8.

Note 8 - Shareholders' Equity

	March 31,		December 31,
(SEK in thousands, except per share amounts and number of shares)	2024	2023	2023
Total registered shares at the beginning of the period	59,580,087	59,580,087	59,580,087
Total registered and subscribed but not registered shares at the end of the period	**59,580,087**	**59,580,087**	**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	2,383	2,383
Equity attributable to equity holders of the Parent Company	120,151	589,403	334,806
Total equity at the end of the period	**120,151**	**589,403**	**334,806**

	Three Months Ended March 31,		Year Ended December 31,
(SEK in thousands, except per share amounts and number of shares)	2024	2023	2023
Loss per share before and after dilution, SEK	(4.59)	(3.49)	(8.69)
Weighted-average number of ordinary shares outstanding for the period, before and after dilution	53,672,069	53,672,069	53,672,069

Reserves for translation from foreign operations amounted to SEK 11.1 million and SEK 10.5 million which are included in retained earnings in equity as of March 31, 2024 and 2023, respectively.

Note 9 - Incentive Programs

	March 31, 2024			March 31, 2023		
	Options Outstanding	Share Awards Outstanding	Total Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding
Incentive Programs						
Board LTIP 2020	-	-	-	-	29,928	29,928
Board LTIP 2021	-	22,882	22,882	-	24,244	24,244
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	1,364,730	-	1,364,730
ESOP 2021	1,390,500	-	1,390,500	1,479,500	-	1,479,500
ESOP 2022	1,826,000	-	1,826,000	1,548,000	-	1,548,000
ESOP 2023	1,880,000	-	1,880,000	-	-	-
Total Outstanding	**6,461,230**	**100,975**	**6,562,205**	**4,392,230**	**94,878**	**4,487,108**

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 are 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 are 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 are 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 share-holders.

Reconciliations of Alternative Performance Measures

	March 31,		December 31,
(SEK in thousands or otherwise indicated)	2024	2023	2023
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	120,151	589,403	334,806
Total assets at the end of the period	1,688,295	1,788,716	1,859,245
Equity ratio at the end of the period in %	**7%**	**33%**	**18%**