
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 6-K

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

Date of Report: February 21, 2024

(Commission File No. 001-39308)

CALLIDITAS THERAPEUTICS AB

(Translation of registrant's name into English)

Kungsbron 1, D5

SE-111 22

Stockholm, Sweden

(Address of registrant's principal executive office)

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

Form 20-F Form 40-F

Company Announcement and Year-End Report

On February 21, 2024, the Company announced its unaudited results for the year ended December 31, 2023, which are further described in the Company's Year-End Report January 1 – December 31, 2023, copies of which are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated by reference herein.

The information contained in this Form 6-K, including Exhibits 99.1 and 99.2, is hereby incorporated by reference into the registrant's Registration Statements on Form F-3 (File No. 333-265881) and Form S-8 (File Nos. 333-240126 and 333-272594).

EXHIBIT INDEX

Exhibit	Description
<u>99.1</u>	<u>Company Announcement dated February 21, 2024</u>
<u>99.2</u>	<u>Year-End Report January 1 – December 31, 2023</u>

SIGNATURES

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

CALLIDITAS THERAPEUTICS AB

Date: February 21, 2024

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



Stockholm, Sweden

February 21, 2024

Calliditas Year-end report, January – December 2023

**Calliditas Therapeutics AB (Nasdaq Stockholm: CALTX)
2023: Full approval for TARPEYO in the US; a year of successes**

OCTOBER – DECEMBER 2023
(COMPARED TO OCTOBER – DECEMBER 2022)

- Net sales amounted to SEK 451.6 million, of which TARPEYO® net sales amounted to SEK 347.3 million, for the three months ended December 31, 2023. For the three months ended December 31, 2022, net sales amounted to SEK 429.0 million, of which TARPEYO net sales amounted to SEK 167.3 million.
- Operating income amounted to SEK 41.8 million and SEK 32.5 million for the three months ended December 31, 2023, and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 0.34 and SEK 0.07 for the three months ended December 31, 2023, and 2022, respectively.
- Cash amounted to SEK 973.7 million and SEK 1,249.1 million as of December 31, 2023, and 2022, respectively.

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

- Net sales amounted to SEK 1,206.9 million, of which TARPEYO net sales amounted to SEK 1,075.8 million, for the year ended December 31, 2023. For the year ended December 31, 2022, net sales amounted to SEK 802.9 million, of which TARPEYO net sales amounted to SEK 372.2 million.
- Operating loss amounted to SEK 373.1 million and SEK 421.9 million for the year ended December 31, 2023, and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 8.69 and SEK 7.78 for the year ended December 31, 2023, and 2022, respectively.
- For the year ended December 31, 2023, no dividend is proposed.

“In December we were granted full approval by the FDA for TARPEYO – a crowning achievement after many years of striving to bring an approved disease modifying treatment to patients with primary IgAN.”

CEO Renée Aguiar-Lucander

KEY TAKEAWAYS FROM Q4, 2023

- In November, Calliditas’ partner Everest Medicines announced that China’s National Medical Products Administration (NMPA) had approved Nefecon for the treatment of primary immunoglobulin A nephropathy (IgAN) in adults at risk of disease progression.
- In November, Calliditas announced the initiation of a Phase 2 clinical study to evaluate setanaxib in Alport syndrome.
- In December, Calliditas received approval (Notice of Allowance) regarding a US patent application for TARPEYO®. In the first quarter of 2024, notice was issued regarding the patent, which provides patent in the US through 2043.
- In December, the United States (US) Food and Drug Administration (FDA) granted Calliditas full approval of TARPEYO® for reduction of kidney loss in adult IgAN patients at risk of disease progression.

EXPECTED KEY EVENTS UPCOMING 6 MONTHS

- Read out of the Nefecon Open label Phase 3 extension trial, which will provide data on retreatment with Nefecon.
- The transfer of the Marketing Authorization Holder (MAH) approval to Everest Medicines and commercial launch of Nefecon in China.
- European Commission decision regarding a potential full approval for Kinpego for Calliditas’ partner STADA.
- Full data read out of the setanaxib Phase 2 trial in head and neck cancer.



OUTLOOK FOR 2024

Calliditas expects continued revenue growth:

Total net sales are estimated to be USD 150-180 million for the year ending December 31, 2024

INVESTOR PRESENTATION

February 21, 2024, 14:30 CET

Link to webcast: <https://ir.financialhearings.com/calliditas-therapeutics-q4-report-2023>

To participate via conference call register via this link: <https://conference.financialhearings.com/teleconference/?id=50046870>

For further information, please contact:

Åsa Hillsten, Head of IR & Sustainability, Calliditas

Tel.: +46 76 403 35 43, Email: asa.hillsten@calliditas.com

The information in the press release is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the contact person set out above, on February 21, 2024, at 07:00 a.m. CET.

About Calliditas

Calliditas Therapeutics is a biopharma company headquartered in Stockholm, Sweden, focused on identifying, developing, and commercializing novel treatments in orphan indications with significant unmet medical needs. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT). Visit Calliditas.com for further information.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the development of Calliditas' pipeline. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas' business, operations, clinical trials, intellectual property of the NEFECON franchise globally, competition from other companies, pipeline development, revenue and product sales projections or forecasts, 2024 revenue guidance and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

calliditas
THERAPEUTICS

Q4

YEAR-END REPORT
JANUARY - DECEMBER
2023



Year-end report January – December 2023

OCTOBER – DECEMBER 2023 (COMPARED TO OCTOBER – DECEMBER 2022)

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"In December we were granted full approval by the FDA for TARPEYO – a crowning achievement after many years of striving to bring an approved disease modifying treatment to patients with primary IgAN."

Renée Aguiar-Lucander / CEO

OCT – DEC 2023

347

MSEK
TARPEYO net sales

OCT – DEC 2023

108%

TARPEYO net sales
growth in SEK (vs Q4
2022)

DEC 31, 2023

974

MSEK
Cash position

Key takeaways from Q4, 2023

- In November, Calliditas' partner Everest Medicines announced that China's National Medical Products Administration (NMPA) had approved Nefecon for the treatment of primary immunoglobulin A nephropathy (IgAN) in adults at risk of disease progression.
- In November, Calliditas announced the initiation of a Phase 2 clinical study to evaluate setanaxib in Alport syndrome.
- In December, Calliditas received approval (Notice of Allowance) regarding a US patent application for TARPEYO®. In the first quarter of 2024, notice was issued regarding the patent, which provides patent in the US through 2043.
- In December, the United States (US) Food and Drug Administration (FDA) granted Calliditas full approval of TARPEYO® for reduction of kidney loss in adult IgAN patients at risk of disease progression.

Expected key events upcoming 6 months

- Read out of the Nefecon Open label Phase 3 extension trial, which will provide data on retreatment with Nefecon.
- The transfer of the Marketing Authorization Holder (MAH) approval to Everest Medicines and commercial launch of Nefecon in China.
- European Commission decision regarding a potential full approval for Kinpeyo for Calliditas' partner STADA.
- Full data read out of the setanaxib Phase 2 trial in head and neck cancer.

Outlook 2024

- For 2024, Calliditas expects continued revenue growth: Total net sales 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 FDA-approved treatment for IgAN 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.

Nefecon has also been granted conditional approval in China and approval in Macau and is being reviewed by regulators in Singapore, Hong Kong and South Korea. Calliditas has also recently 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 IPF and PBC, and Calliditas has also launched 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 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

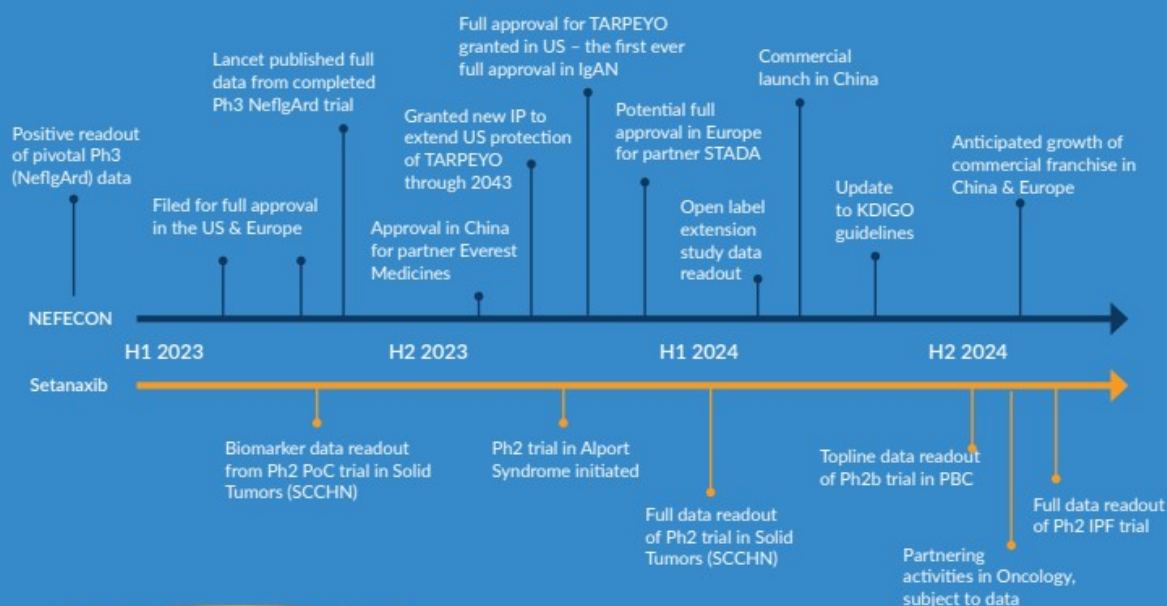
We take responsibility for our actions and hold ourselves to the highest ethical standards, guided by our moral principles to make the right decisions.

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 VALUE DRIVERS



Key figures

(SEK in thousands, except per share amount or as otherwise indicated)	Oct-Dec		Jan-Dec	
	2023	2022	2023	2022
Net sales	451,561	429,042	1,206,888	802,879
<i>Of which TARPEYO product sales</i>	347,308	167,258	1,075,829	372,247
Operating income (loss)	41,765	32,495	(373,055)	(421,943)
Income (loss) before Income tax for the period	(14,256)	10,066	(457,017)	(409,417)
Earnings (loss) per share before and after dilution (SEK)	(0.34)	(0.07)	(8.69)	(7.78)
Cash flow from (used in) operating activities	22,845	230,029	(434,655)	(311,354)

(SEK in thousands, except per share amount or as otherwise indicated)	As of	
	31.12.2023	31.12.2022
Total registered shares, including shares held by Calliditas, at the end of the period	59,580,087	59,580,087
Equity attributable to equity holders of the Parent Company at the end of the period	334,806	766,264
Equity ratio at the end of the period in %	18%	39%
Cash at the end of the period	973,733	1,249,094

Full approval for TARPEYO in the US; a year of successes



On December 20th, 2023, we were granted full approval by the FDA for TARPEYO, our treatment targeting the origin of primary IgA nephropathy. This was a crowning achievement after many years of striving to bring an approved disease modifying treatment to patients with this rare disease. The new label for the US with the indication reduction of kidney loss and the ability to address the full adult IgAN population at risk of disease progression is a significant and positive event for both patients and physicians. As previously reported, the Phase 3 trial successfully met its primary endpoint ($p < 0.0001$) and provided evidence that 9 months of treatment with Nefecon 16 mg/day led to a significant reduction of kidney function loss, which was preserved over the 15 months of observation off drug following treatment. In addition, a durable reduction in proteinuria was observed for the entire period and there was a statistically significant effect on microhematuria as well as on biomarkers such as GdA1. We believe these results support disease modification with the potential to provide a clinically meaningful delay in the need for dialysis or transplantation, and we are delighted that our sales force is now able to share the exciting and important data from our full Phase 3 study with treating physicians in the US.

In November we reported on several important events, including our presentations at the annual Kidney Week Conference organized by ASN (American Society of Nephrology), which this year was held in Philadelphia. At the conference we also presented several posters, including the modelling of the 2-year eGFR slope from the NeflgArd Phase 3 trial predicting long term clinical benefit in a real-world population, adding to the already substantial scientific evidence supporting the potential disease modification of TARPEYO. We also had the opportunity to meet with over 100 nephrologists who provided valuable insight into treatment paradigms and how TARPEYO is being used in practice. It was incredibly rewarding to hear all of the positive stories about patient outcomes and the difference that this medication is having on young adults previously facing an uncertain future and the risk of ending up in dialysis. It was also clear that the publication of the RaDaR registry data and similar longitudinal data from the southern California IgAN cohort of Kaiser Permanente had a profound impact on how the nephrology community was starting to think about this patient population. The data reflected faster progression than expected and significantly higher observed risk for progression amongst patients previously considered "stable" or "controlled". This data, in combination with recently published clinical trial data showing significant eGFR decline amongst patients on optimized RAS blockade, clearly reflects a more serious outlook for patients with this condition than previously thought. Nephrologists are hence increasing their focus on the pathophysiology of IgAN and on treating the underlying cause of the disease to meaningfully impact eGFR, including prescribing TARPEYO, as the only medication approved for IgAN based on kidney function.

November also saw the conditional approval of Nefecon in China, a major milestone considering the large patient population in China. We also announced the Notice of Allowance for a new patent covering TARPEYO, which significantly enhances product protection in the US beyond 2029. We believe both of these events are highly impactful for the long term value creation of the global Nefecon franchise and we look forward to the commercial launch in China later this year.

The fourth quarter saw a significant increase in revenues as well as over 50% growth in prescriptions over Q3, reflecting both improved familiarity with the drug and the impact of the full data being published in *The Lancet* in August. Total Q4 revenues were SEK 452 million, out of which net revenues from TARPEYO amounted to SEK 347 million (USD 32.6m). Total revenues for the year amounted to SEK 1,207 million out of which TARPEYO net revenues represented SEK 1,076 million, a growth of 189% over 2022. In Q4 we also posted a positive cashflow from operating activities of SEK 23 million, a milestone we had communicated early in the year and that we were excited to achieve. Our cash position remains strong with SEK 974 million on the balance sheet at the end of the year, supported by our positive cash flow in Q4 and continued revenue growth expectations.

In December we announced the refinancing with Athyrium Capital LP of our outstanding credit line in order to extend the interest-only period beyond 2023. Due to our robust commercial franchise we were able to achieve the same interest rate on an increased credit line. This reflects the strength of our corporate profile, allowing us to leverage it in order to have a balanced capital structure and avoiding shareholder dilution, whilst improving our cash position in challenging market conditions.

We are extremely proud of what we have achieved as a team in 2023: We delivered highly statistically significant data from our full Phase 3 trial, cementing our global leading position in IgAN, achieved another breakthrough "first" by being granted full approval for TARPEYO in the US with a new and broader label, significantly strengthened our TARPEYO IP estate and achieved conditional approval for Nefecon in China. In addition, we achieved net TARPEYO revenues in excess of one billion Swedish krona, progressed our late-stage pipeline and supported several key regulatory processes related to Kinpeygo and Nefecon in Europe and Asia. I want to thank everybody at Calliditas for their commitment, ingenuity, agility and hard work. It takes an amazing team effort to deliver this kind of a score card in 12 months. It has indeed been a busy and highly successful 2023 and we look forward to an exciting 2024!

Renée Aguiar-Lucander, CEO



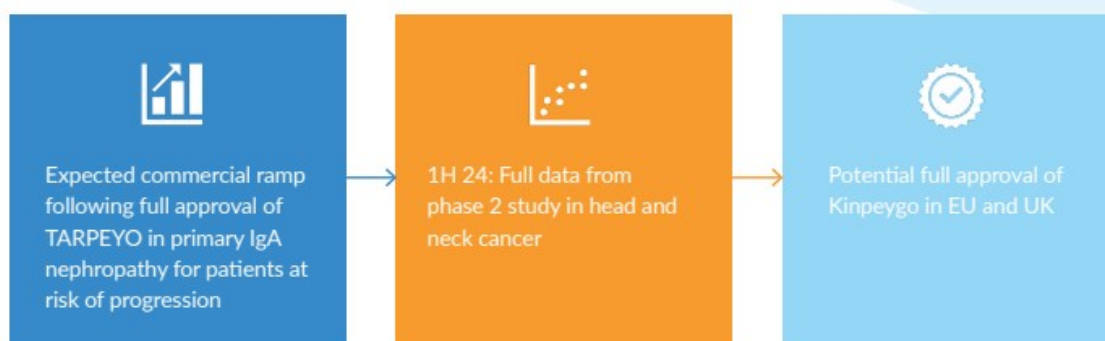
Our pipeline

Calliditas' lead product, developed under the name Nefecon, has been approved in the US, Europe, and China. Our pipeline consists of development programs based on a first-in-class NOX inhibitor platform. The lead compound, setanaxib, is a selective NOX 1 and NOX 4 inhibitor and is the first NOX inhibitor to reach the clinical stage. Calliditas is presently running trials with setanaxib in primary biliary cholangitis (PBC), squamous cell carcinoma of the head and neck (SCCHN), 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



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

NeflgArd 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 NeflgArd 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 m² versus a loss of 4.6 mL/min/1.73 m² 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 m² versus 6.1 mL/min/1.73 m² 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 NeflgArd 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

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.

Following the positive data readout from the full NefIgArd trial, Calliditas is collaborating with STADA on the application for full approval of Kinpeygo by the European Commission and the MHRA in the full study population.

Greater China

Calliditas entered into a licensing 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.

The Chinese regulatory authority National Medical Products Administration (NMPA) granted Nefecon conditional approval for the treatment of primary IgAN in adults at risk of disease progression in November 2023. Nefecon has also been approved by the Pharmaceutical Administration Bureau of the Macau Special Administrative Region.

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 early access programs launched in China.



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.

¹Veeva OpenData for 2023, including all active HCPs where the primary specialty is Nephrology
²Sphertix RealWorld Dynamix

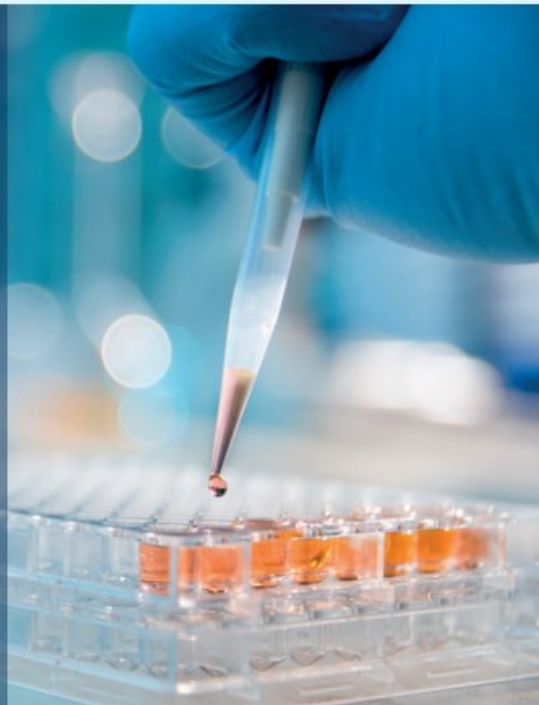
TARPEYO: Moving from supportive care to treating IgAN

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.

 <p>Mechanism of action</p> <p>Targeted B cell immunomodulator designed to locally target origin of disease</p>	 <p>Patient focus</p> <p>In combination with optimized RASi therapy; option of intermittent, rather than chronic treatment</p>	 <p>Efficacy</p> <p>Durable eGFR benefit and sustained proteinuria disease-modifying effects in IgAN</p>	 <p>Safety</p> <p>Well characterized active ingredient and safety profile</p>
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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 thought¹



¹ Fischer D, Bradden E, Hendry B, et al. Long-Term Outcomes in IgA Nephropathy. *Clin J Am Soc Nephrol*. 2022;15(6):727-736. doi:10.2220/CJN.000000000000018
Hess CE, Daniels R, Farquhar A, Hjal 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*. 2022 Sep 2;8(2):34-45. doi:10.1016/j.jheale.2022.05.001. PMID: 34692855; PMCID: PMC9121198.

TARPEYO is now the first and only therapy fully approved by the FDA in IgAN

In Q4, Calliditas reached a pivotal milestone with the historic FDA approval of TARPEYO on December 20th, 2023, establishing it as the first and only approved treatment for reducing the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN). The FDA approval is for adults with primary IgAN at risk of disease progression, irrespective of proteinuria levels, and sets a new standard in the treatment of IgAN.

In November, Calliditas showcased a strong presence at ASN Kidney Week 2024 with investigators presenting additional analyses of the Phase 3 NeflgArd trial highlighting statistically significant and clinically meaningful treatment benefit of TARPEYO.

These scientific presentations, coupled with our engagements with key nephrology stakeholders, reflect our strategic efforts

in continuing to educate key stakeholders about TARPEYO and driving scientific exchange.

During Q4 2024, TARPEYO saw over 50% quarter over quarter growth in patient enrollments and new prescribers, with 555 new prescriptions and 301 new prescribers, signaling strong market acceptance and demand for this therapy.

KEY METRICS Q4 2023

 **555**

New prescriptions in Q4
YTD prescriptions: 1,753
51% QoQ growth

 **301**

New Prescribers in Q4
LTD Prescribers: 1,639
53% QoQ growth

 **\$32.6M**

Net sales of TARPEYO in Q4

QUARTERLY HIGHLIGHTS Q4

Full FDA approval of TARPEYO for the treatment of IgAN

The first and only product to reduce the loss of kidney function in adults with IgAN

Advancing the science at ASN

7 abstracts presented at ASN. Peer-reviewed publication on Neflgan biomarker data. Strong engagements with key opinion leaders, nephrologists, and advocacy organizations to drive education

Strengthened product protection

A new patent for TARPEYO was allowed. The patent was subsequently included in the Orange Book and is strengthening product protection until 2043.

Driving patient engagements

Patient webinar on TARPEYO with IgAN foundation. Launched patient ambassador stories via social media

EXCITING JOURNEY AHEAD

The full FDA approval enables Calliditas to commercialize TARPEYO based on the new label and Phase 3 trial data to address the full at-risk patient population, to broaden TARPEYO's uptake and adoption with nephrologists, and to establish its placement as an essential and foundational part of the new Standard of Care (SoC) for IgAN patients as a disease-modifying therapy, designed to target an underlying cause of the disease.

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 2023, 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 mid-2024.

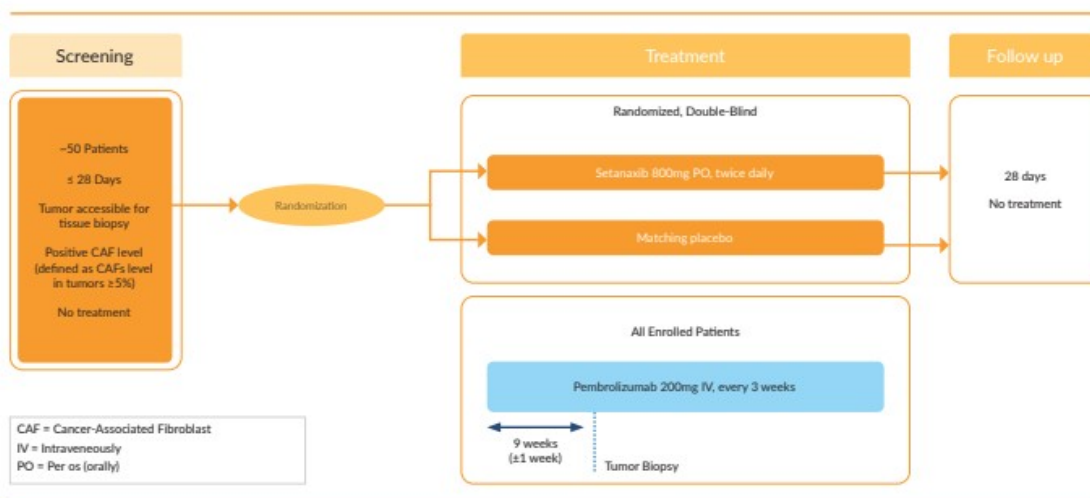
Pipeline: NOX Inhibitor platform

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 data from 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. The biomarker analysis included transcriptomic analysis and evaluated pathology markers such as SMA, Foxp3 regulatory T cells and PDL-1 Combined Positive Score. 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. Six 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.

The transcriptomic analysis showed that the two top pathways impacted by the treatment were fibrosis-related signalling pathways (the Idiopathic Pulmonary Fibrosis Signalling 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.

Calliditas Vice President Regulatory Affairs Frank Bringstrup



Last year, Calliditas filed for full approval of TARPEYO with the FDA. What was that process like? How were you able to get such a fast turnaround between the data readout in March and the filing a few months later in June?

Our submission team was motivated and forward leaning, and as a result of a great team effort the filing to FDA for full approval of TARPEYO® was successfully completed ahead of time. We managed to compress the timelines by frontloading the submission document writing as the clinical study results became available, finalising interdependent documents and adding individual documents to the electronic submission dossier as they became available.

Considerations from a commercial perspective based on the data were included and implemented in the storyline for the high-level documents, so that the turn-around for the submission was fast, and at the same time we could ensure that the dossier would be optimised for negotiations for a competitive label. A request for Priority Review was included with the filing for full approval and was granted by FDA, and this, in combination with the early submission, enabled an approval date in December 2023.

Our regulatory team has also been supporting STADA with its filing with EMA and the UK MHRA – how has that process been going?

Since June 2023, our regulatory team has been supporting STADA with its filing to the EMA and the MHRA for full approval and to fulfil the 'Specific Obligation' from the conditional approval. We aligned on a specific filing strategy with STADA before its submission, and some of the documents for the submission were prepared and provided to STADA by the Calliditas team. The EMA/CHMP review and UK MHRA review are ongoing.

How did the regulatory team support its partner Everest Medicines in its successful filing with the China NMPA?

The documents for the China NDA filing were prepared in close collaboration between the Calliditas and Everest regulatory teams, and in October 2022 the NDA was submitted by Everest to the CDE/NMPA with Calliditas as the applicant. In November 2022 the NDA was accepted for review by CDE/NMPA, and in December 2022 the NMPA granted Priority Review of Nefecon for the treatment of primary immunoglobulin A nephropathy (IgAN) in adults at risk of rapid disease progression.

From the outset of the China NDA review process, an internal Calliditas-Everest pre-defined 'Q&A' process was put in place, so as to ensure that we could collaborate on an optimal response strategy for any questions from the regulatory authority to effectively manage the response preparations. This regulatory 'Q&A phase' was managed successfully, and in November 2023 the NMPA approved Nefecon® for the treatment of primary IgAN in adults at risk of disease progression.

You have been VP of Regulatory Affairs at Calliditas since 2019, and have overseen an incredibly exciting time, including the initial approvals of TARPEYO and Kinpeygo and now full approval for TARPEYO. What has been your chief focus as leader in this role?

My primary focus has been to get fast to the market with first cycle approvals and competitive labelling. Reducing the time to market for medicines treating a serious disease like IgAN is critical for patients, as well as for the product and for Calliditas' success. Execution of our strategy is a key part of our success. It has been incredibly exciting to successfully bring to market the first approved product for IgAN patients.

Continued focus on sustainability: Defining material matters

For Calliditas to strategically carry out the relevant sustainability efforts and the sustainability reporting that meets transparency and accuracy requirements, the Company must be well acquainted with its most important sustainability matters from an environmental, social and corporate perspective.

The assessment was performed in accordance with the increased EU requirements on sustainability reporting – the Corporate Sustainability Reporting Directive (CSRD) and the associated mandatory reporting standards, the European Sustainability Reporting Standards (ESRS). Calliditas will be subject to the new requirements in its reporting for the 2025 financial year.

Double materiality assessment

In the first step of the assessment, a gross list was prepared with Calliditas' potential material sustainability matters. Each sustainability matter on the gross list was then evaluated based on its impact on people and the environment and its impact on Calliditas' financial position. The assessment was performed by external experts in consultation with senior executives at Calliditas with knowledge of the specific relevant matters.

The result from the assessment of each sustainability matter was illustrated in a matrix and validated by a group of people with similar positions and knowledge in the various areas. The thresholds used to determine the material areas were defined and validated in this group and approved by the CEO.

Example: Corruption and bribery

The industry in which Calliditas operates has historically been subject to an increased risk of corruption and bribery. This was sufficient reason to include this sustainability matter on the gross list. It was established in the assessment that, while there are no actual cases of corruption, corruption remains a potential risk. When a potential case of corruption was evaluated based on its impact on Calliditas as a company and its impact on people and the environment, it was found that even though the likelihood of such an incident was considered to be low, the risks were high enough for the matter to be assigned a relatively high comparative figure.

Calliditas' material sustainability matters

The methodically performed double materiality assessment showed that Calliditas' sustainability impact can be found in seven main areas. These areas were then categorized depending on whether the impact is environmental, social or governmental. Going forward, these material sustainability matters will govern Calliditas' strategic sustainability efforts and sustainability reporting.

"The methodically performed double materiality assessment showed that Calliditas' sustainability impact can be found in seven main areas. These areas were then categorised depending on whether the impact is environmental, social or governmental. Going forward, these material sustainability matters will govern Calliditas' strategic sustainability efforts and sustainability reporting."

Åsa Hillsten
Head of IR & Sustainability

Environmental matters

- Climate change is an important issue, given its global scope and impact as an issue that affects everyone to some extent.
- Circular economy and waste are relevant issues to Calliditas, as Calliditas produces relevant amounts of waste in the course of carrying out its preclinical and commercial activities. The requirements dictating the proper packaging of its drug product also limit the possibilities for circularity.

Social matters

- The health and safety for our own workforce is an area in which the company has a material impact, as well as being one that Calliditas has a high degree of control over.
- For Calliditas to have a positive impact on the health of patients, its products must be accessible to end users.
- The safety and quality of the product is hugely important, both for patients' health and for Calliditas' credibility.

Governance matters

- The industry in which Calliditas operates has historically been exposed to an increased risk of corruption and bribery. Calliditas takes this seriously, as it may potentially have major impact.
- The management of animal welfare is particularly important given that Calliditas engages in animal testing.

January – December 2023

Revenue

Net sales amounted to SEK 451.6 million and SEK 429.0 million for the three months ended December 31, 2023 and 2022, respectively. Net sales for the year ended December 31, 2023 and 2022 amounted to SEK 1,206.9 million and SEK 802.9 million, respectively. Net sales primarily originate from net sales of TARPEYO® in the US, which amounted to SEK 347.3 million and SEK 167.3 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, net sales from TARPEYO amounted to SEK 1,075.8 million and SEK 372.2 million, respectively. Royalty income from our partnerships amounted to SEK 14.0 million for the three months ended December 31, 2023 and SEK 36.8 million for the year ended December 31, 2023. For both the three months and the year ended December 31, 2022 the royalty income from our partnerships amounted to SEK 2.3 million. Outlicensing of product amounted to SEK 82.7 million and SEK 257.9 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, outlicensing of product amounted to SEK 82.7 million and SEK 421.7 million, respectively. For 2023, outlicensing of product consisted of regulatory milestone fees from Everest Medicines.

For additional information see Note 4.

Cost of Sales

Cost of sales amounted to SEK 22.3 million and SEK 7.9 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022 cost of sales amounted to SEK 60.5 million and SEK 15.2 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 387.5 million and SEK 388.7 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022 total operating expenses amounted to SEK 1,519.5 million and SEK 1,209.6 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 106.7 million and SEK 102.2 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022 research and development expenses amounted to SEK 502.2 million and SEK 414.7 million, respectively. The increase of SEK 4.5 million for the three months ended December 31, 2023 and the increase of SEK 87.5 million for the year ended December 31, 2023, were primarily due to increased clinical activities for the Nox-platform, including the

ongoing setanaxib trials. Included in the increase for the full year, was the recognition of a one-time effect from the impairment of SEK 32.1 million regarding in-licensing of Budenofalk.

Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 198.5 million and SEK 191.9 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022 marketing and selling expenses amounted SEK 727.7 million and SEK 515.2 million, respectively. The increases of SEK 6.6 million for the three months ended December 31, 2023, and SEK 212.5 million for the year ended December 31, 2023, were primarily related to the increased 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 94.6 million and SEK 81.0 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, administrative expenses amounted to SEK 333.0 million and SEK 259.5 million, respectively. The increases of SEK 13.6 million for the three months ended December 31, 2023, and SEK 73.5 million for the year ended December 31, 2023, were 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 12.3 million and (SEK 13.5 million) for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022 other operating income (expenses), net amounted to SEK 43.5 million and (SEK 20.2 million), respectively. The improvement in both periods 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 56.0 million) and (SEK 22.4 million) for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, net financial income (expenses) amounted to (SEK 84.0 million) and SEK 12.5 million, respectively. The decrease of SEK 33.6 million for the three months ended December 31, 2023, and SEK 96.5 million for the year ended December 31, 2023 were primarily derived from interest expenses and fees related to borrowing and currency effects primary related to translation effects.

Tax

Total tax income (expense) amounted to (SEK 4.1 million) and (SEK 13.7 million) for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, total tax income (expense) amounted to (SEK 9.2 million) and (SEK 2.9 million), respectively. For the year ended December 31, 2023, the increased tax expense was primarily explained by taxable income 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 December 31, 2023 and 2022, loss for the period amounted to SEK 18.4 million and SEK 3.7 million, and the corresponding loss per share before and after dilution amounted to SEK 0.34 and SEK 0.07, respectively. For the year ended December 31, 2023 and 2022, loss for the period amounted to SEK 466.2 million and SEK 412.3 million, and the corresponding loss per share before and after dilution amounted to SEK 8.69 and SEK 7.78, respectively.

Cash Flow and Cash Position

Cash flow from operating activities amounted to SEK 22.9 million and SEK 230.0 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, cash flow used in operating activities amounted to SEK 434.7 million and SEK 311.4 million, respectively. The decrease in the periods is mainly attributable to the change in current receivables.

Cash flow used in investing activities amounted to SEK 2.4 million and SEK 1.5 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, cash flow used in investing activities amounted to SEK 13.7 million and SEK 5.1 million, respectively. The increase for both periods was primarily explained by acquisition of equipment.

Cash flow from financing activities amounted to SEK 208.5 million and SEK 282.6 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, cash flow from financing activities amounted to SEK 199.7 million and SEK 576.0 million, respectively. The decrease in the periods is mainly attributable to reduced net borrowing compared to the same periods previous year.

Net increase (decrease) in cash amounted to SEK 229.0 million and SEK 511.2 million for the three months periods ended December 31, 2023 and 2022, respectively, and (SEK 248.8 million) and SEK 259.5 million for the year ended December 31, 2023 and 2022, respectively. Cash amounted to SEK 973.7 million and SEK 1,249.1 million as of December 31, 2023 and 2022, respectively.

Personnel

The average number of employees were 192 and 100 for the three months ended December 31, 2023 and 2022, respectively and 181 and 86 employees for the year ended December 31 2023 and 2022, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 334.8 million and SEK 766.3 million as of December 31, 2023 and 2022, respectively. The number of registered shares amounted to 59,580,087 and 59,580,087 as of December 31, 2023 and 2022, respectively.

Treasury Shares

As of December 31, 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 December 31, 2023, 450,000 options have been allocated for the ESOP 2023 Program. For more information on incentive programs, see Note 9.

Outlook 2024

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

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 337.2 million and SEK 297.1 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022 net sales amounted to SEK 805.6 million and SEK 549.0 million, respectively. The increase in both periods ended December 31, 2023, is primarily attributable to higher volume of product sales compared to the previous year.

Operating income amounted to SEK 101.1 million and SEK 86.7 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022 operating loss amounted to SEK 167.8 million and SEK 215.4 million, respectively.

Significant Events

Significant Events During the Period October 1 – December 31, 2023

- On October 3, Calliditas announced filing with UK MHRA for Kinpeygo in IgA nephropathy.
- On October 5, The 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 Industriefonden, Karl Tobieson, appointed by Linc AB, Spike Loy, appointed by BVF and Elmar Schnee (chairman of the board of directors).
- On October 27, Calliditas announced that its commercial partner Everest Medicines received approval for Nefecon for the Treatment of Primary IgA Nephropathy from the Pharmaceutical Administration Bureau of the Macau Special Administrative Region, China.
- On November 24, Calliditas' partner Everest Medicines announces China NMPA's conditional approval of Nefecon for the treatment of primary IgA nephropathy.
- On 1 December, Calliditas announced that the company had added Head of Technical Operations Lars Stubberud to its management team. Additionally, the company added Brian Gorman as its new Group General Counsel replacing Jonathan Schur with changes taking effect on January 1, 2024.
- On 11 December, Calliditas announced that it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application no. 18/100,396 entitled "New Pharmaceutical Compositions."
- On December 20, the United States (US) Food and Drug Administration (FDA) granted Calliditas full approval of TARPEYO® (budesonide) delayed release capsules to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.
- On December 27, Calliditas announced that the company had signed and fully drawn a term loan of 92 million Euros with funds managed by Athyrium Capital Management, LP ("Athyrium"). Proceeds from the loan has fully replaced the company's previous 68 million Euro loan with Kreos Capital.

Significant Events After the end of the Period, 2024

- On January 7, Calliditas announced that Maria Tömsén was appointed to the position of President North America with immediate entry into service. Ms Tömsén will be responsible for all US based operations and will report to the CEO.
- On February 13 Calliditas announced that the United States Patent and Trademark Office (USPTO) issued patent no. 11896719, entitled "New Pharmaceutical Compositions, on January 24, 2024 with validity as of February 13, 2024. The patent was subsequently included in the Orange Book. This is Calliditas' second patent for TARPEYO in the United States and provides product protection until 2043.

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.

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 income and positive cash flow. For the year ended 31 December 2023, no dividend is proposed.

Refinance of term loan

On December 27, 2023 Calliditas announced that the company had signed and fully drawn a term loan of EUR 92 million with funds managed by Athyrium Capital Management, LP. Proceeds from the loan have been utilized for full repayment of the company's loan with Kreos Capital of EUR 68 million.

Nomination Committee AGM 2024 appointed

On October 2023 Calliditas announced that the company's major owners have appointed a nomination committee for the AGM 2024. 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). 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 December 31, 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 December 29, 2023, the closing price for the Calliditas Therapeutics share CALTX was SEK 127.1. The total number of shareholders as of December 31, 2023 was approximately 19,000.

Annual General Meeting 2024

The 2024 Annual General Meeting will be held May 13 at 14.00 p.m. CET, Klarabergsviadukten 90, Stockholm, Sweden. All documentation is published on the company's website.

Shareholder Structure

Ten largest shareholders as of December, 2023	%
BVF Partners LP	10,51
Linc AB	10,01
Stiftelsen Industrifonden	5,28
Polar Capital	3,90
Avanza Pension	3,52
Unionen	3,31
Handelsbanken Fonder	2,98
Fjärde AP-fonden	2,94
Sofinnova Partners	2,36
Öhman Fonder	2,23
Subtotal, 10 largest shareholders	47,04
Treasury shares	9,92
Other shareholders	43,04
Total	100,00

Review

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

Stockholm 21 February, 2024

Renée Aguiar-Lucander

Supplemental Information

■ Presentation to investors, analysts and press

- Calliditas invites investors, analysts and press to a presentation of the Year-end Report 2023 at 14:30 p.m CET on 21 February, 2024. The report was published today 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 Tömsén. The presentations will be given in English.
- Time: Tuesday 14:30 p.m. CET on 21 February, 2024
- Link to webcast
<https://ir.financialhearings.com/calliditas-therapeutics-q4-report-2023>
- To participate via conference call register via this link
<https://conference.financialhearings.com/teleconference/?id=50046870>
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

ANNUAL REPORT 2023

Will be published digitally
April 2024

INTERIM REPORT Q1

January – March 2024
7 May

ANNUAL GENERAL MEETING 2024

Klarabergsviadukten 90, Stockholm
13 May

INTERIM REPORT Q2

January – June 2024
13 August

■ 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 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 2024 total net sales 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.

Registered office

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

The information in the Year-end 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 February 21, 2024, at 7:00 a.m. CET.

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended December 31,		Year Ended December 31,	
		2023	2022	2023	2022
Net sales	4	451,561	429,042	1,206,888	802,879
Cost of sales		(22,299)	(7,879)	(60,463)	(15,201)
Gross income		429,262	421,163	1,146,425	787,678
Research and development expenses		(106,677)	(102,239)	(502,223)	(414,749)
Marketing and selling expenses		(198,542)	(191,887)	(727,740)	(515,190)
Administrative expenses		(94,624)	(81,028)	(332,991)	(259,469)
Other operating income/(expenses), net		12,346	(13,514)	43,473	(20,212)
Operating income (loss)		41,765	32,495	(373,055)	(421,943)
Net financial income/(expenses)		(56,021)	(22,428)	(83,962)	12,526
Income (loss) before income tax		(14,256)	10,066	(457,017)	(409,417)
Income tax		(4,112)	(13,747)	(9,168)	(2,851)
Net income (loss) for the period		(18,368)	(3,681)	(466,185)	(412,268)
Attributable to:					
Equity holders of the Parent Company		(18,368)	(3,681)	(466,185)	(412,268)
		(18,368)	(3,681)	(466,185)	(412,268)
Income (loss) per share before and after dilution (SEK)	8	(0.34)	(0.07)	(8.69)	(7.78)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Net income (loss) for the period	(18,368)	(3,681)	(466,185)	(412,268)
Other comprehensive income				
<i>Other comprehensive income (loss) that may be reclassified to income or loss in subsequent periods:</i>				
Exchange differences on translation of foreign operations	(12,373)	1,661	(14,538)	36,287
Other comprehensive income (loss) that may be reclassified to income or loss in subsequent periods	(12,373)	1,661	(14,538)	36,287
<i>Other comprehensive income (loss) that will not be reclassified to income or loss in subsequent periods:</i>				
Remeasurement gain (loss) on defined benefit plans	(2,268)	387	(3,071)	2,763
Other comprehensive income (loss) that will not be reclassified to income or loss in subsequent periods	(2,268)	387	(3,071)	2,763
Other comprehensive income (loss) for the period	(14,640)	2,047	(17,609)	39,050
Total comprehensive income (loss) for the period	(33,009)	(1,634)	(483,794)	(373,218)
Attributable to:				
Equity holders of the Parent Company	(33,009)	(1,634)	(483,794)	(373,218)
	(33,009)	(1,634)	(483,794)	(373,218)

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	December 31,	
		2023	2022
ASSETS			
Non-current assets			
Intangible assets		479,338	483,841
Equipment		16,053	7,468
Right-of-use assets		38,186	24,452
Non-current financial assets		24,201	11,210
Deferred tax assets		26,315	13,799
Total non-current assets		584,093	540,770
Current assets			
Inventories		20,428	3,647
Current receivables		196,666	88,721
Prepaid expenses and accrued income		84,324	70,741
Cash		973,733	1,249,094
Total current assets		1,275,152	1,412,204
TOTAL ASSETS		1,859,245	1,952,973
EQUITY AND LIABILITIES			
Equity			
Equity attributable to equity holders of the Parent Company		334,806	766,264
Total equity	7,8,9	334,806	766,264
Non-current liabilities			
Provisions	9	36,116	12,675
Contingent consideration	6	56,561	75,880
Deferred tax liabilities		41,641	39,752
Non-current interest-bearing liabilities		939,508	713,030
Lease liabilities		27,088	15,792
Other non-current liabilities		16,381	4,350
Total non-current liabilities		1,117,295	861,479
Current liabilities			
Accounts payable		100,564	160,404
Other current liabilities		25,953	28,381
Accrued expenses and deferred revenue		280,627	136,446
Total current liabilities		407,144	325,231
TOTAL EQUITY AND LIABILITIES		1,859,245	1,952,973

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Year Ended December 31,	
	2023	2022
Opening balance equity attributable to equity holders of the Parent Company	766,264	1,008,281
Income (loss) for the period	(466,185)	(412,268)
Other comprehensive income (loss)	(17,609)	39,050
Total comprehensive income (loss) for the period attributable to equity holders of the Parent Company	(483,794)	(373,218)
Transactions with owners:		
Issuance of treasury shares	-	236
Repurchase of treasury shares	-	(236)
Exercise of warrants	-	95,121
Share-based payments	52,337	36,080
Total transactions with owners	52,337	131,201
Closing balance equity attributable to equity holders of the Parent Company	334,806	766,264
Closing balance equity	334,806	766,264

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating activities				
Operating income (loss)	41,765	32,495	(373,055)	(421,943)
Adjustment for non-cash-items	24,054	30,916	102,478	61,260
Interest received	30,601	3,551	32,905	3,553
Interest paid	(42,163)	(11,576)	(94,497)	(35,252)
Income taxes paid	(3,291)	(2,675)	(22,747)	(7,392)
Cash flow from (used in) operating activities before changes in working capital	50,966	52,712	(354,915)	(399,774)
Cash flow from (used in) changes in working capital	(28,121)	177,318	(79,740)	88,420
Cash flow from (used in) operating activities	22,845	230,029	(434,655)	(311,354)
Cash flow used in investing activities	(2,354)	(1,466)	(13,745)	(5,144)
Issuance of treasury shares	-	-	-	236
Repurchase of treasury shares	-	-	-	(236)
Exercise of warrants	-	31,476	-	95,121
New borrowings	962,889	255,282	962,889	491,745
Costs attributable to new loans	(26,625)	(1,260)	(26,625)	(1,260)
Repayment of borrowing	(724,479)	-	(724,479)	-
Repayment of lease liabilities	(3,263)	(2,861)	(12,134)	(9,615)
Cash flow from financing activities	208,522	282,638	199,650	575,990
Net increase (decrease) in cash	229,012	511,201	(248,750)	259,493
Cash at the beginning of the period	786,883	736,161	1,249,094	955,507
Net foreign exchange gains (loss) in cash	(42,162)	1,732	(26,611)	34,094
Cash at the end of the period	973,733	1,249,094	973,733	1,249,094

Condensed Parent Company Statements of Income

(SEK in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Net sales	337,158	297,144	805,551	548,977
Cost of sales	(22,283)	(7,820)	(60,399)	(15,141)
Gross income	314,875	289,324	745,151	533,836
Research and development expenses	(92,693)	(97,724)	(456,970)	(384,453)
Marketing and selling expenses	(107,211)	(113,499)	(402,436)	(310,372)
Administrative expenses	(79,948)	(61,252)	(273,359)	(212,971)
Other operating income/(expenses), net	66,037	69,847	219,818	158,597
Operating income (loss)	101,060	86,696	(167,796)	(215,364)
Net financial income/(expenses)	(74,259)	(6,525)	(105,722)	6,816
Income (loss) before income tax	26,801	80,172	(273,518)	(208,548)
Income tax	-	-	-	-
Income (loss) for the period	26,801	80,172	(273,518)	(208,548)

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Income (loss) for the period	26,801	80,172	(273,518)	(208,548)
Other comprehensive income (loss)	-	-	-	-
Total comprehensive income (loss)	26,801	80,172	(273,518)	(208,548)

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	December 31,	
		2023	2022
ASSETS			
Non-current assets			
Intangible assets		-	32,132
Equipment		342	567
Non-current financial assets		1,125,186	887,456
Total non-current assets		1,125,528	920,154
Current assets			
Inventories		20,428	3,647
Current receivables		223,700	129,090
Prepaid expenses and accrued income		67,603	61,092
Cash		817,871	1,059,655
Total current assets		1,129,602	1,253,485
TOTAL ASSETS		2,255,130	2,173,639
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Total restricted equity		5,475	5,475
Total non-restricted equity		904,299	1,125,480
Total shareholders' equity	7,9	909,774	1,130,956
Non-current liabilities			
Provisions	9	25,924	9,512
Non-current interest-bearing liabilities		939,508	713,030
Other non-current liabilities		16,486	4,455
Total non-current liabilities		981,918	726,997
Current liabilities			
Accounts payable		62,562	100,469
Other current liabilities		113,685	141,750
Accrued expenses and deferred revenue		187,191	73,468
Total current liabilities		363,438	315,686
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		2,255,130	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 year ended December 31, 2023 and 2022.

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

These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on February 21, 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 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 policies 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 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 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

(SEK in thousands)	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Type of goods or services				
Product sales	354,855	168,882	1,087,418	375,516
Outlicensing of product	82,712	257,873	82,712	421,689
Royalty income	13,994	2,287	36,758	2,287
Performance of certain regulatory services	-	-	-	3,387
Total	451,561	429,042	1,206,888	802,879
Geographical markets				
USA	347,308	167,258	1,075,829	372,247
Europe	12,809	3,911	39,614	143,955
Asia	91,444	257,873	91,445	286,677
Total	451,561	429,042	1,206,888	802,879

Net sales for the periods primarily originate from net sales of TARPEYO in the US, which amounted to SEK 347.3 million and SEK 167.3 million for the three months ended December 31, 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, net sales from TARPEYO amounted to SEK 1,075.8 million and SEK 372.2 million, respectively. Royalty income from our partnerships amounted to SEK 14.0 million and SEK 2.3 million for the fourth quarter of 2023 and 2022, respectively. For the year ended December 31, 2023 and 2022, royalty income amounted to SEK 36.8 million and SEK 2.3 million respectively.

Outlicensing of product amounted to SEK 82.7 million and SEK 257.9 million for the three months ended December 31, 2023 and 2022 respectively. For the year ended December 31, 2023 and 2022, outlicensing of product amounted to SEK 82.7 million and SEK 421.7 million respectively. For 2023, outlicensing of product consisted entirely of regulatory milestone fees from Everest Medicines.

The total liability for expected returns and rebates amounts to SEK 39.9 million and SEK 24.3 million as of December 31, 2023 and 2022, respectively, which are recognized in total 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.

In the fourth quarter of 2023, Calliditas refinanced the existing term loan with a SEK 1,018.1 million senior secured facility with Athyrium Capital. Proceeds from the loan have primarily been utilized for the full repayment of the company's loan of SEK 724.5 million with Kreos Capital. The fair value of the loan at the end of the period amounts to SEK 939.5 million. The credit agreement contains financial covenants specifying minimum cash liquidity and minimum product revenue. The credit agreement contains customary affirmative and negative covenants for a senior secured loan.

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. For the three months ended December 31, 2023 and 2022, the income/(loss) for the period amounted to SEK 10.1 million and (SEK 11.8 million) respectively and for the year ended December 31, 2023 and 2022, the affecting income/(loss) for the period amounted to SEK 18.8 million and (SEK 15.9 million), respectively, which are recognized in other operating income/(expenses), net. This was mainly attributable to the change of study design for the PBC project and revised timelines within the setanaxib platform. For more information see the Annual Report for 2022.

Note 7 - Treasury Shares

As of December 31, 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 December 31, 2023.

The total number of issued shares as of December 31, 2023, is presented in Note 8.

Note 8 - Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	December 31,			
	2023	2022		
Total registered shares at the beginning of the period	59,580,087	52,341,584		
New issue of shares during the period	-	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	59,580,087		
Shares				
Ordinary shares	59,580,087	59,580,087		
Total	59,580,087	59,580,087		
- of which shares are held by Calliditas	5,908,018	5,908,018		
Total registered and subscribed but not registered shares at the end of the period, net of shares held by Calliditas	53,672,069	53,672,069		
Share capital at the end of the period	2,383	2,383		
Equity attributable to equity holders of the Parent Company	334,806	766,264		
Total equity at the end of the period	334,806	766,264		
	Three Months Ended December 31,		Year Ended December 31,	
(SEK in thousands, except per share amounts and number of shares)	2023	2022	2023	2022
Income (loss) per share before and after dilution, SEK	(0.34)	(0.07)	(8.69)	(7.78)
Weighted-average number of ordinary shares outstanding for the period, before and after dilution	53,672,069	53,259,179	53,672,069	53,022,550

Reserves for translation from foreign operations amounted to (SEK 5.2 million) and SEK 9.3 million which are included in retained earnings in equity as of December 31, 2023 and 2022, respectively.

Note 9 - Incentive Programs

	December 31, 2023			December 31, 2022		
	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	1,371,666	-	1,371,666
ESOP 2021	1,434,500	-	1,434,500	1,479,500	-	1,479,500
ESOP 2022	1,884,500	-	1,884,500	1,101,000	-	1,101,000
ESOP 2023	1,415,000	-	1,415,000	-	-	-
Total Outstanding	6,098,730	100,975	6,199,705	3,952,166	94,878	4,047,044

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

(SEK in thousands or otherwise indicated)	December 31,	
	2023	2022
Equity ratio at the end of the period in %		
Total shareholders' equity at the end of the period	334,806	766,264
Total assets at the end of the period	1,859,245	1,952,973
Equity ratio at the end of the period in %	18%	39%