calliditas
THERAPEUTICS

Q2

INTERIM REPORT JANUARY – JUNE 2024

Interim Report January – June 2024

APRIL – JUNE 2024 (COMPARED TO APRIL – JUNE 2023)

- Net sales amounted to SEK 559.8 million, of which TARPEYO® net sales amounted to SEK 493.4 million, for the three months ended June 30, 2024. For the three months ended June 30, 2023 net sales amounted to SEK 269.4 million, of which TARPEYO net sales amounted to SEK 259.2 million.
- Operating loss amounted to SEK 31.5 million and SEK 75.2 million for the three months ended June 30, 2024 and 2023, respectively. However, expenses related to the Asahi Kasei offer and expenses related to provisions for social security contribution for incentive programs were included in the quarter, totaling SEK 101.7 million. Excluding these expenses, the adjusted operating profit[1] amounted to SEK 70.2 million for the three months ended June 30, 2024.
- Loss per share before and after dilution amounted to SEK 0.88 and SEK 1.71 for the three months ended June 30, 2024 and 2023, respectively.
- Cash amounted to SEK 797.3 million and SEK 866.2 million as of June 30, 2024 and 2023, respectively.

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

- Net sales amounted to SEK 855.3 million, of which TARPEYO net sales amounted to SEK 771.6 million, for the six months ended June 30, 2024. For the six months ended June 30, 2023 net sales amounted to SEK 460.7 million, of which TARPEYO net sales amounted to SEK 444.9 million.
- Operating loss amounted to SEK 235.3 million and SEK 255.2 million for the six months ended June 30, 2024 and 2023, respectively. However, expenses related to the Asahi Kasei offer and expenses related to provisions for social security contribution for incentive programs were included in the second quarter, totaling SEK 101.7 million. Excluding these expenses the adjusted operating loss[1] amounted to SEK 133.6 million for the six months ended June 30, 2024.
- Loss per share before and after dilution amounted to SEK 5.47 and SEK 5.21 for the six months ended June 30, 2024 and 2023, respectively.

APR – JUN 2024
493 MSEK
TARPEYO net sales

APR – JUN 2024
90% TARPEYO net sales growth in SEK (vs Q2 2023)

JUN 30, 2024
797 MSEK
Cash position

Key takeaways from Q2, 2024

- In April, Calliditas read out positive data from the Nefecon Open Label Phase 3 Extension trial.
- In May, Calliditas read out positive topline results from the setanaxib Phase 2 trial in head and neck cancer.
- In May, Calliditas' partner Everest Medicines announced the commercial launch of Nefecon in China.
- In May, Calliditas' partner STADA received a positive CHMP opinion recommending full approval for Kinpeygo® in EU for the treatment of IgA nephropathy
- In June, Calliditas announced the issuance by the United States Patent and Trademark Office (USPTO) of a new patent for setanaxib for treatment of cancer. The patent will have an expiration date in 2039.

Key events after the reporting period

- In July, Calliditas partner STADA received European Commission decision for full approval of Kinpeygo for the treatment of IgA Nephropathy.
- In July, Calliditas announced positive TRANSFORM Phase 2b topline data in primary biliary cholangitis.

Asahi Kasei Offer

- Asahi Kasei Corporation announced on May 28, 2024 a public cash offer to acquire all shares in Calliditas for SEK 208 in cash per share (SEK 416 in cash per ADS. The Offer represents a premium of 83 per cent compared to the closing price of the Shares on Nasdaq Stockholm on May 27, 2024.
- The acceptance period of the offer commenced on July 18, 2024 and expires on August 30, 2024, subject to any extensions.

Outlook 2024: Updated

- Calliditas expects continued revenue growth:
  Total net sales from the Nefecon franchise, including milestones, are estimated to be USD 165-185 million for the year ending December 31, 2024.

[1] Management uses and presents IFRS results as well as the non-IFRS measure of adjusted operating profit to evaluate and communicate its performance. While non-IFRS measures should not be construed as alternatives to IFRS measures, management believes non-IFRS measures are useful to further understand Calliditas's current performance, performance trends, and financial condition. Adjusted operating profit is defined as IFRS operating profit (loss), less provisions for social security contributions for incentive programs and advisor fees for the Asahi Kasei public offer. A reconciliation of adjusted operating profit to operating profit (loss), which is the most directly comparable IFRS measure, is set forth on page 31 of this report.

Calliditas – pioneering new treatments for rare diseases

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

Our lead product provides a treatment option that has been demonstrated to be disease-modifying for IgA nephropathy (IgAN) – also known as Berger's Disease – a progressive autoimmune disease of the kidney that for many patients leads to end-stage renal disease (ESRD), requiring dialysis or organ transplantation. This drug product, developed under the name Nefecon®, was granted accelerated approval by the FDA in 2021 and full approval in December 2023, and is today marketed in the US under the brand name TARPEYO®. TARPEYO is now the first and only fully approved treatment for IgAN and is approved based on a measure of kidney function. Nefecon has also been granted full marketing authorisation by the European Commission under the brand name Kinpeygo® in the European Economic Area (EEA) and conditional marketing authorisation in the UK.

Nefecon has been granted conditional approval in China, Singapore, Hong Kong and Macau, and is being reviewed by regulators in South Korea. Nefecon was launched commercially by Everest Medicines in China in May 2024. Calliditas has also entered into a partnership with Viatris 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 Alport syndrome, and there is also an investigator led trial ongoing in idiopathic pulmonary fibrosis (IPF). Calliditas read out positive topline data from a Phase 2 proof-of-concept trial with setanaxib in head and neck cancer in May 2024 and positive topline data from the Phase 2b trial in Primary Biliary Cholangitis (PBC) in July 2024.

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

Our values

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

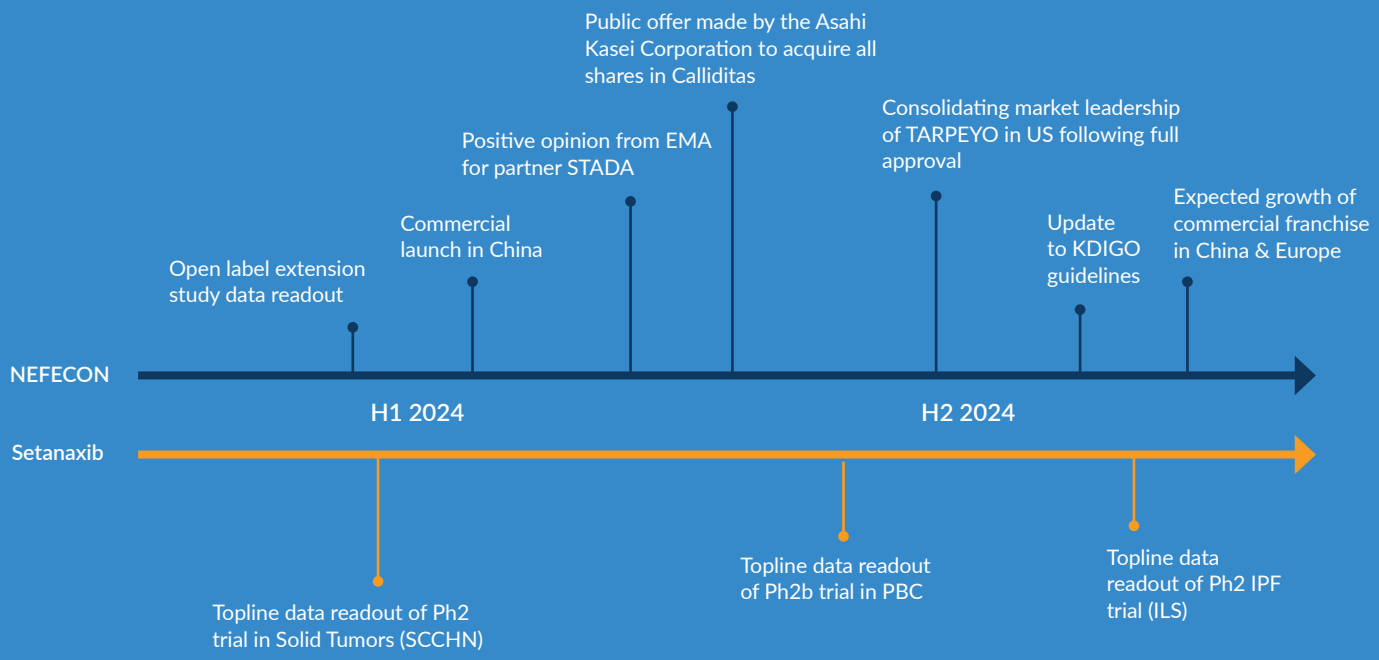
EXPERTISE
We leverage our strong internal experience and competencies while complementing our strengths through knowledge sharing and external collaborations as needed.

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

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

Investment highlights

RECENT AND ANTICIPATED DRIVERS



Key figures

	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
SEK in thousands, except per share amount or as otherwise indicated	**2024**	**2023**	**2024**	**2023**	**2023**
Net sales	559,780	269,384	855,261	460,735	1,206,888
Of which TARPEYO product sales	493,356	259,239	771,632	449,931	1,075,829
Operating income (loss)	(31,503)	(75,172)	(235,329)	(255,246)	(373,055)
Income (loss) before Income tax for the period	(42,661)	(70,660)	(289,985)	(278,679)	(457,017)
Earnings (loss) per share before and after dilution (SEK)	(0.88)	(1.71)	(5.47)	(5.21)	(8.69)
Cash flow from (used in) operating activities	(7,043)	(163,031)	(205,248)	(394,971)	(434,655)

	June 30,		December 31,
(SEK in thousands, except per share amount or as otherwise indicated)	**2024**	**2023**	**2023**
Total reg. shares, incl outstanding shares and shares held by Calliditas, end of the period	59,918,583	59,580,087	59,580,087
Equity attributable to equity holders of the Parent Company at the end of the period	106,789	504,367	334,806
Equity ratio at the end of the period in %	6%	30%	18%
Cash at the end of the period	797,278	866,181	973,733

Record Revenues and Achievement of Profitability Target

Following on from the record quarter of Q1 with regards to enrolments as well as new prescribers, the success of Q2 is a consequence of our consistent corporate priorities and investment strategy, reflected by investment decisions taken in Q3 of 2023 in expectation of full approval of TARPEYO by the FDA in December of 2023. In Q2, we saw a record 750 new enrolments for TARPEYO in the US and we generated record revenues of SEK 560 million for the quarter, out of which net product revenues from TARPEYO represented SEK 493 million ($46.3m), which represents a 90% growth over Q2, 2023 and 77% over Q1, 2024. With the combination of our significant, but judicious investments into a broader field presence in the US, additional marketing and market access infrastructure combined with experienced and senior US leadership resources, we clearly achieved our stated long-term goals for the company this quarter. We cemented our clear market leadership position and delivered on continued significant revenue growth. In the quarter we had expenses related to the Asahi Kasei offer, and expenses related to provisions for social security contribution for incentive programs, totaling 101.7 MSEK. Excluding these expenses our adjusted operational profitability was SEK 70 million for the quarter. This brings Nefecon franchise related revenues for the first 6 months of 2024 to around $80 million, with an additional EUR 10 million milestone payment from STADA secured in Q3 related to the full approval of Kinpeygo, announced on July 26th.

As previously disclosed, our interactions with payors were intense over the first several months of the year and as of the end of June we had seen the vast majority of the major insurance plans adjust their rules based on the new TARPEYO indication. This has continued in July and August and we are nearly through the update cycle related to the new label with the vast majority of plans providing updates in line with the new label.

In addition to these very significant commercially related achievements, we also saw the validation of our pipeline in Q2, based on the positive topline data readout from our Phase 2 Head and Neck cancer trial. With statistically significant results both in terms of PFS (progression free survival) and OS (overall survival) in combination with a statistically significant fourfold increase in tumor infiltrating lymphocytes in the treatment arm, it clearly supports the presumed anti fibrotic mode of action of setanaxib and we are very excited about the potential of this proprietary and unique platform.

This was further supported in the post reporting period, when we reported out topline data from our Phase 2b PBC (Primary Biliary Cholangitis) trial which showed statistically significant improvement versus placebo of the primary endpoint of Alkaline Phosphatase (ALP) for both doses; 1200 mg/day and 1600 mg/day. This was particularly exciting as the study population was a heavily treated population, with over 40% on the standard of care of UDCA as well as one additional medication, either Ocaliva, or Bezafibrate, a PPAR agonist. In addition, 13% of the study population was on all three medications, reflecting the very different composition of the placebo arm, versus all earlier Phase 2 or 3 trials in PBC. We are therefore very excited about the outcome in this highly non responder population and we look forward to the read out of the other ongoing Phase 2 trials with setanaxib in IPF and Alport syndrome, and we will review the data and competitive environment to assess in which rare disease it would be most appropriate to potentially conduct a pivotal trial.

It is with great pride that I look back at what the team at Calliditas has achieved over the last 4 years, since the successful read out of the interim data of the NefIgArd Phase 3 trial in December of 2020. These regulatory, commercial and development successes were accomplished against a backdrop of highly challenging capital markets environment for biotech companies, as well as an extremely volatile macro situation. I am struck by how far we have come as an organization and extremely grateful for the amazing contribution of each and every employee of Calliditas, who have enabled the company to achieve this outcome.

On May 28th Asahi Kasei announced a public take-over bid for the company, recommended by the Calliditas Board of directors and supported by major shareholders representing 44.65% of the shares. The tender offer documents were published on July 17th with the tender offer period started on July 18th and is expected to close on August 30th, 2024. The result is expected to be announced on or about September 2nd, 2024. If over 90% of the shares are tendered, we expect a subsequent squeeze out and delisting of the shares.

Our cash position remains strong with SEK 797 million ($75m) on the balance sheet at the end of the quarter, reflecting the very limited cash burn in the quarter. We believe that the remaining quarters of 2024 will deliver positive operating profitability for the business operating in the ordinary course, based on the continued revenue growth of TARPEYO and the overall development of the Nefecon franchise. We adjust our guidance to $165 – 185 million of net revenues from the Nefecon franchise for 2024.

Renée Aguiar-Lucander, CEO

Our pipeline

Calliditas' lead product has been fully approved in the US and EU and has conditional approval in China. Our pipeline consists of development programs derived from a first-in-class NOX inhibitor platform. The lead compound, setanaxib, was designed to be a selective NOX 1 and NOX 4 inhibitor and is the first product candidate to reach the clinical stage. Calliditas read out topline data from its trial with setanaxib in squamous cell carcinoma of the head & neck (SCCHN) in May 2024 and from its Phase 2b trial in primary biliary cholangitis (PBC) in July 2024. Calliditas is also presently running a trial with setanaxib in 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. Approved in the EEA and granted conditional marketing authorization UK under the tradename Kinpeygo® for the treatment of primary IgAN in adults at risk of rapid disease progression, and granted conditional approval in China under the tradename Nefecon®.

Exciting journey ahead

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

TARPEYO's expected inclusion in updated KDIGO guidelines

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 full approval in July 2024, and conditional approval by the MHRA for the UK in February 2023. Nefecon received conditional approval in China by the China NMPA in November 2023.

Disease background

Although IgAN manifests in the kidney, the evidence indicates that it is a disease that starts in the distal part of the intestine, specifically in the ileum. Peyer's patches, which are concentrated within the gut-associated lymphoid tissue in the ileum, have been identified as a major source of mucosal-type IgA antibodies. Patients with IgA nephropathy have elevated levels of mucosal-type IgA, which – in contrast to the majority of the IgA in the blood – are predominately dimeric or polymeric and are galactose-deficient. In IgAN patients, a combination of a genetic predisposition and environmental, bacterial and dietary factors is presumed to lead to an increased production of these galactose-deficient IgA antibodies. This increased production, potentially in conjunction with increased intestinal permeability, leads to these secretory antibodies appearing in the blood.

Successful Phase 3 trial readout

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

The full Phase 3 NefIgArd trial consisted of a total of 364 patients, including 200 patients from the interim analysis, based upon which Calliditas successfully filed for accelerated approval with the FDA and for conditional approval with the European Commission, UK MHRA, and China NMPA. The full trial included 9 months of treatment and a 15-month post-treatment observational period for all study participants to confirm long-term renal protection. The endpoint of the full Phase 3 trial assessed the difference in kidney function between treated and placebo patients, as measured by eGFR, over a two-year period from the start of dosing of each patient. The data read-out took place in March 2023, and in August 2023 was published in *The Lancet*.

The primary endpoint of the Phase 3 trial was a time-weighted average of eGFR observed at each time point over two years. The primary endpoint was successfully met with a highly statistical p value of <0.0001. At 9 months the absolute difference in eGFR of the treatment arm was an improvement of 0.7 mL/min/1.73 m^2 versus a loss of 4.6 mL/min/1.73 m^2 for the placebo arm. The treatment benefit was preserved during the period of observation, reflected by a loss of kidney function at two years in the placebo arm of 12.0 mL/min/1.73 m^2 versus 6.1 mL/min/1.73 m^2 for the treatment arm. This was also confirmed by a difference in slope of 3 mL/min/year in favor of TARPEYO.

There was a cumulative improvement in proteinuria in patients treated with Nefecon versus placebo during the 9-month treatment period, which continued to significantly improve after end of treatment, resulting in a decline of over 50% at 12 months. At month 24, proteinuria levels in patients who had received Nefecon were still at a reduced level, similar to that observed at the 9-month time point, reflecting the durability of the proteinuria reduction of a 9-month course of treatment.

Regulatory approvals

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

Calliditas' partner STADA received a full approval from the European Commission for Kinpeygo in July 2024. Kinpeygo has also received conditional approval from the UK MHRA, and is awaiting regulatory review for full approval. Nefecon received conditional approval in China in November 2023 and has also approvals in Macau, Singapore and Hong Kong. Calliditas' partner Everest Medicines will be commercialising this product in these territories.

IgA nephropathy - a significant market opportunity

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

Our commercial partnerships

Europe

Nefecon® was granted full marketing authorisation by the European Commission in July 2024, and hold a conditional marketing authorisation 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. Kinpeygo is marketed in the European Economic Area (EEA), the UK and Switzerland, if approved in this jurisdiction, exclusively by STADA Arzneimittel AG, with whom Calliditas entered into a license agreement in July 2021 to register and commercialize Kinpeygo in Europe. STADA launched Kinpeygo in Germany in September 2022, with additional European countries to follow.

Greater China

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

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

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

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

Japan

At the end of 2022, Calliditas entered into a partnership to commercialize Nefecon in Japan with Viatris Pharmaceuticals Japan, a subsidiary of Viatris Inc. (Nasdaq: VTRS). In July, 2024, Viatris initiated a phase III clinical trial in Japan with Nefecon in Japanese patients with IgA nephropathy.

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

TARPEYO: Moving from supportive care to treating IgAN

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

Mechanism of action

Targeted B cell immunomodulator designed to locally target origin of disease

Patient focus

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

Efficacy

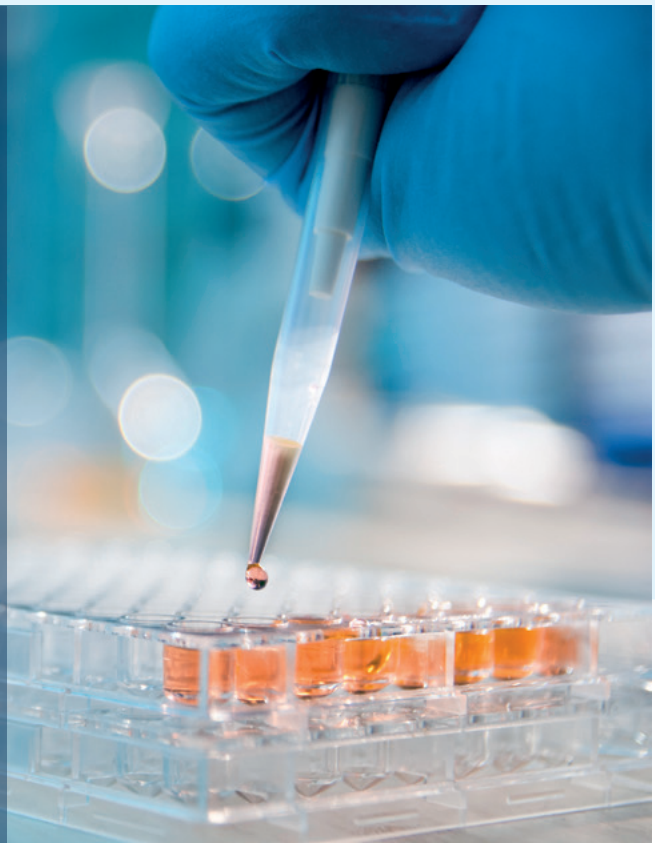
Durable eGFR benefit and sustained proteinuria disease-modifying effects in IgAN

Safety

Well characterized active ingredient and safety profile

IgAN Patients:

- A genetic predisposition is required but not sufficient; most patients are diagnosed in their 20s and 30s
- More than 50% are at risk of developing ESRD within 10-20 years, leading to kidney transplant
- The treatment goal is to preserve eGFR – kidney function
- Recently published longitudinal data imply that disease progression is faster and outlook worse than previously thought[1]



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

Continued Strong Demand for TARPEYO in Q2

During the second quarter, the US team continued to build on the momentum from the previous quarter, focusing on leveraging the full FDA approval of TARPEYO to inform and engage nephrology healthcare professionals, payors, and patient communities about TARPEYO's clinical data and its pivotal role in treating IgAN.

In the second quarter of 2024, TARPEYO achieved another quarterly record with 750 new patient enrolments, demonstrating continued quarter-over-quarter growth. We added 343 new prescribers this quarter, bringing the total number of prescribers to 2,336, underscoring the growing market acceptance and demand for TARPEYO. This positive momentum is expected to continue throughout 2024, supported by the new label and indication, further reinforcing TARPEYO's positioning as a cornerstone treatment in IgAN. We have also made significant progress with payers in Q2, with over 80% of commercial lives covered in alignment with the updated label. We are continuing to educate the payer community to promote open access.

In the second quarter, our medical and commercial teams had a robust presence at major nephrology conferences, such as the National Kidney Foundation (NKF) and European Renal Association (ERA). At ERA, the presented efficacy analysis using a matching-adjusted indirect comparison (MAIC) methodology of Nefecon and sparsentan, showed that treatment with Nefecon was associated with estimated glomerular filtration rate (eGFR) benefit compared with continuous treatment with sparsentan. Additionally, a real-world analysis highlighted the challenges associated with conventional systemic glucocorticoids (SGC), such as prednisone. This analysis demonstrated significant side effects and costs for IgAN patients treated with conventional SGC compared to those not treated with SGC.

In Q2 we also presented initial data from the open-label extension study, which showed positive results and a treatment response consistent with the NeflgArd study across the endpoints of UPCR and eGFR at 9 months for all patients, including those who previously received TARPEYO treatment in the NeflgArd study.

2024 Q2 KEY METRICS

750
New Patients enrolled in Q2
6% QoQ growth

343
New Prescribers in Q2
LTD Prescribers: 2,336

46.3M
Net sales in USD of TARPEYO
in Q2 2024

Q2 HIGHLIGHTS

Full Approval Promotional Campaign Launch.

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

Patient Education and Patient Ambassador Programs

Scientific Congresses and Peer-to-Peer Engagement

NATIONAL KIDNEY FOUNDATION
SPRING CLINICAL MEETINGS
61st ERA CONGRESS
STOCKHOLM & VIRTUAL
MAY 23-26, 2024
Inspiring Kidney Care

EXCITING JOURNEY AHEAD

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

Participating in ASN annual congress and driving scientific exchange and data dissemination.

Leverage KDIGO guidelines expected in 2H 2024.

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

Pipeline: NOX Inhibitor platform

Calliditas' pipeline consists of development programs based on a first-in-class NOX inhibitor platform. Calliditas has been running clinical trials with lead compound setanaxib in squamous cell carcinoma of the head & neck (SCCHN), which read out positive topline data in May 2024, as well as in primary biliary cholangitis (PBC), and is running a clinical trial in Alport syndrome. Setanaxib is also being evaluated in an investigator-led study in idiopathic pulmonary fibrosis (IPF).

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 and in July, 2024, Calliditas announced positive topline data where the trial met its primary endpoint, showing statistically significant improvement in ALP for both doses tested versus placebo.

Pipeline: NOX Inhibitor platform

Setanaxib in squamous cell carcinoma of the head and neck

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

This trial built on promising in vivo preclinical data from Professor Gareth Thomas' research at the School of Cancer Sciences at the University of Southampton. The response to immuno-oncology therapies can be affected by the tumor microenvironment, in particular by the numbers of tumor-infiltrating lymphocytes (TILs) and cancer-associated fibroblasts (CAFs) in the tumor. A relationship between CAFs and prognosis in SCCHN has been established. NOX4 is highly over-expressed in CAFs and drives myofibroblastic activation within tumors, shielding them from CD8+ TILs.

There is increasing use of pembrolizumab as 1st line monotherapy in patients with relapsed or metastatic SCCHN, although response rates are low (ORR approx. 20%). Using a CAF-rich tumor model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in improved penetration of TILs into the centre of the tumor, slowing of tumor growth and improved survival.

Expanded patent protection

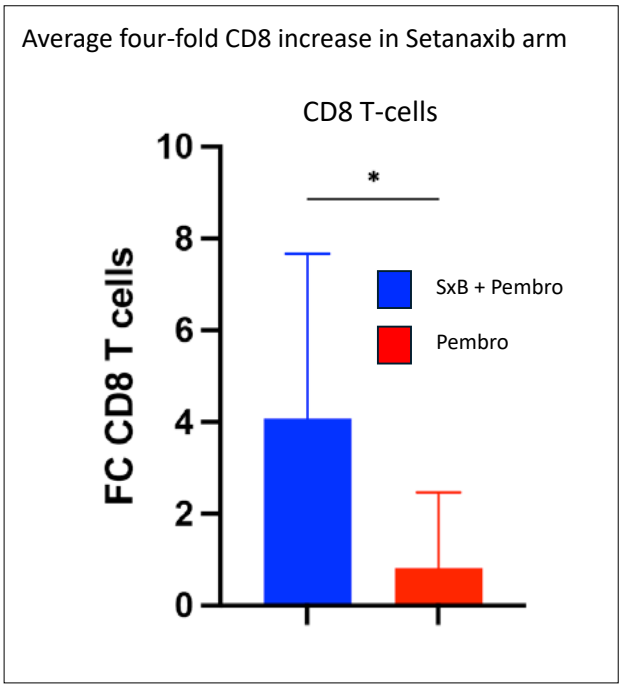
In April 2024, Calliditas received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application no. 16/760,910 entitled "Use of NOX Inhibitors for Treatment of Cancer". This Notice of Allowance resulted in the issuance of a U.S. patent in June 2024 covering a method of treating a solid tumor presenting resistance to PD-1 inhibitor immunotherapy by administering setanaxib in combination with a PD-1 inhibitor. The patent will have an expiration date in 2039.

Phase 2 data readout

The treatment groups were well-balanced with no clinically relevant differences between the groups observed at baseline. Patients treated with pembrolizumab and setanaxib showed statistically significant improvements in the key secondary endpoints of progression-free survival, (PFS median 5 months versus 2.9 months; Hazard ratio= 0.58) and overall survival (OS at 6 months 92% vs 68%; OS at 9 months 88% vs 58%; Hazard ratio=0.45) compared to patients treated with pembrolizumab and placebo.

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

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



Calliditas Head of Marketing Teona Johnson

Q2 has been the strongest quarter yet in terms of enrollments. What have been the key initiatives that have helped to drive this result in 2024?

The full approval of TARPEYO at the end of December 2023, based on our confirmatory endpoint of eGFR, was a significant milestone. This eGFR data, crucial to nephrologists as it measures kidney function, has been met with overwhelmingly positive feedback from the nephrology community. The recognition of TARPEYO's ability to reduce the loss of kidney function has led to increased demand and utilization of TARPEYO for patients diagnosed with IgAN.

Our key initiatives across all functions have been around educating healthcare professionals, payers, and the patient community on TARPEYO's clinical value proposition through targeted programs and tactics. These efforts aim to drive not just awareness of the new indication but also a thorough understanding of the entire clinical data of TARPEYO and its position as a cornerstone treatment in IgAN.

Since the full approval of TARPEYO, what has been the focus of the marketing team?

Our marketing team has been laser-focused on engaging with healthcare professionals (HCPs), as well as patient and advocacy groups. We've recognized the critical role of peer-to-peer education and have intensified our efforts to facilitate speaker programs and other peer-to-peer educational initiatives. Our approach is customer-centric and comprehensive, ensuring that our customers can interact with Calliditas and TARPEYO in their preferred ways of communication. We've implemented surround-sound promotional campaigns across various channels, delivering consistent messaging that effectively communicates the clinical value of TARPEYO.

On the patient side, our focus has been on empowering patients with knowledge about TARPEYO as a treatment option. We want them to feel confident advocating for a disease-specific treatment and discussing TARPEYO with their doctors. The TARPEYO Ambassador program, in particular, has been a resounding success, providing a platform for patients to hear from others who have first-hand experience with TARPEYO. This peer support has been instrumental in increasing patient acceptance of TARPEYO.

The Thought Leader Liaison Team has expanded recently. What are the team's objectives, and what impact have they had?

The Thought Leader Liaison (TLL) team is a strategic field marketing team with the key objective of driving product and disease advocacy with Key Opinion Leaders (KOLs) and key customers. TLLs excel at understanding our key customers' needs and concerns and help identify and partner with them and their institutions on opportunities to educate on the product and the disease. In addition, it is crucial for the marketing team to develop strategies rooted in true insights. The TLL team plays a critical role in ensuring that marketing strategies and tactical initiatives reflect customer and market insights and feedback.

You have been at Calliditas for over three years. How has your role and work evolved throughout this time?

We have undergone significant changes and growth as a team over the past three years, driven by developments in this therapeutic area and by the growth of the company. Three years ago, there were no approved therapies in IgAN. With the very first approval of TARPEYO, there is now an established regulatory pathway for drug approvals, with more therapies in the pipeline for this rare disease. Emerging longitudinal data now indicates that this disease is more severe and faster progressing than previously thought, which hopefully leads to much earlier diagnosis and treatment. Consequently, the treatment goals for IgAN are also changing; the ambitious goal of preventing patients with this rare disease from needing dialysis or kidney transplantation in their lifetime is now within reach based on approved medications, which may also be complemented by other approaches as development efforts continue.

This evolution in this therapeutic area is closely tied to our marketing strategy and the changing needs of our customers. Nephrologists want to understand how they should be thinking about evolving their treatment approach of IgAN and we are committed to truly understanding our customers' needs and have been developing programs and initiatives to address them. For me it's both an obligation and a privilege to be at the forefront of this evolution, and I take this leadership role leading and evolving the marketing organization very seriously.

What key events and milestones are you and the marketing team looking forward to for the rest of 2024?

This has been an exciting year for us. In the second half of the year, we are looking forward to continuing to deliver quality programs and educational initiatives for IgAN patients and HCPs based on our fully approved cornerstone treatment for IgAN. We also plan to expand our efforts with new and innovative digital programs launching in the second half, to drive continued engagement with customers at ASN, and utilize the updated KDIGO guidelines once they are published, all with the aim of continuing driving the uptake and adoption of TARPEYO as a disease modifying, cornerstone treatment in IgAN.

The next step in the long-term sustainability work

With a double materiality assessment completed and a roadmap for the implementation of CSRD, Calliditas now has important fundamental elements for its sustainability work in place. During the second quarter, Calliditas continued the development of policies and to develop processes for data collection.

Going forward the results of the completed double materiality assessment will guide Calliditas' long-term sustainability work and sustainability reporting. The purpose of the assessment is to determine Calliditas' significant positive and negative impact on people and the environment, as well as the financial risks and opportunities that can be linked to the same aspects. The sustainability issues identified in the double materiality assessment as material for Calliditas can be grouped into seven main areas. With the aim of gaining momentum and initiating a future follow-up within the framework of ESRS, several key performance indicators have been selected (see matrix). The selection has been made in light of the metrics and targets included in a number of the ESRS that Calliditas is required to report from FY 2025.

Continued focus on policies and process development

To develop Calliditas' long-term sustainability work, the next step is to develop policies and set up processes for collecting information and data. The ambition is also to gradually add additional key figures to ensure a progressive sustainability work in accordance with the implementation of CSRD.

CALLIDITAS' MATERIAL SUSTAINABILITY AREAS	KEY FIGURES FOR ONGOING FOLLOW-UP
Environment	
• Climate change mitigation and adaptation • Circular economy and waste	• Share of all purchased electricity from renewable sources
Social	
• Employee health and safety • Access to products • End-user health and safety	• Number of incidents linked to work-related injuries, ill health cases and fatalities • Number of days lost due to work-related ill health • Number of employees who left Calliditas/ Employee turnover
Business ethics	
• Anti-corruption and anti-bribery • Animal protection	• Percentage of employees trained in Calliditas' Code of Conduct • Percentage of business partners who have signed Calliditas' Code of Conduct

January – June 2024

Revenue

Net sales amounted to SEK 559.8 million and SEK 269.4 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the net sales amounted to SEK 855.3 million and SEK 460.7 million, respectively. Net sales primarily originated from net sales of TARPEYO® in the US, which amounted to SEK 493.4 million and SEK 259.2 million for the three months ended June 30, 2024 and 2023 respectively, and SEK 771.6 million and SEK 444.9 million for the six months ended June 30, 2024 and 2023 respectively.

Royalty income from our partnerships amounted to SEK 38.9 million and SEK 8.8 million for the three months ended June 30, 2024 and 2023 respectively, and SEK 51.8 million and SEK 13.2 million for the six months ended June 30, 2024 and 2023 respectively. For additional information see Note 4.

Cost of Sales

Cost of sales amounted to SEK 53.4 million and SEK 14.2 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the cost of sales amounted to SEK 67.5 million and SEK 23.2 million. The change in cost of sales in the periods relates to increased sales volumes.

Total Operating Expenses

Total operating expenses amounted to SEK 537.8 million and SEK 330.3 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the total operating expenses amounted to SEK 1,023.1 million and SEK 692.7 million. Expenses of SEK 31.2 million referred to advisor fees related to the offer from Asahi Kasei Corporation and SEK 70.5 million referred to the provisions for social security contribution for incentive programs as a result of an increase in Calliditas' share price in the second quarter, totaling SEK 101.7 million, were included in the three and six months ending June 2024.

Research and Development Expenses

Research and development expenses amounted to SEK 120.7 million and SEK 89.0 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the research and development expenses amounted to SEK 271.3 million and SEK 215.6 million, respectively. The change in the periods referred to increased costs related to incentive programs due to the increase in Calliditas share price in the second quarter, and in addition, increased cost for Nefecon manufacturing scale-up as well as higher Pharmacovigilance costs due to increased volume of patients in the US market.

Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 253.0 million and SEK 191.5 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the marketing and selling expenses amounted to SEK 493.1 million and SEK 358.7 million, respectively. The increased costs in the periods were mainly originated from intensified marketing activities of TARPEYO and increased US salesforce due to the TARPEYO full approval in the US, together with increased costs related to incentive programs due to the increase in Calliditas share price in the second quarter,

Administrative Expenses

Administrative expenses amounted to SEK 166.8 million and SEK 77.2 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the administrative expenses amounted to SEK 268.8 million and SEK 149.7 million, respectively. The change in the periods referred to increased costs related to incentive programs due to the increase in Calliditas share price in the second quarter and advisor fees related to the public offer from Asahi Kasei, and in addition, increased costs from a larger organization and increased regulatory requirements.

Other Operating Incomes/Expenses, net

Other operating income (expenses), net amounted to SEK 2.7 million and SEK 27.3 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the other operating income (expenses) amounted to SEK 10.2 million and SEK 31.3 million, respectively.
The decrease in income 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 11.2 million) and SEK 4.5 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the net financial income (expenses) amounted to (SEK 54.7 million) and (SEK 23.4 million), respectively.
The change in the net amount of was primarily derived from interest expenses and currency effects primarily related to translation effects.

Tax

Total income tax (expense) amounted to (SEK 4.8 million) and (SEK 21.3 million) for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024

and 2023, the total income tax (expense) amounted to (SEK 3.7 million) and (SEK 0.8 million), respectively. The tax expenses in the periods were primarily explained by taxable profit in 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 June 30, 2024 and 2023, the loss for the period amounted to SEK 47.5 million and SEK 91.9 million and the corresponding loss per share before and after dilution amounted to SEK 0.88 and SEK 1.71. For the six months ended June 30, 2024 and 2023, the loss amounted to SEK 293.6 million and SEK 279.5 million, respectively, and the corresponding loss per share before and after dilution amounted to SEK 5.47 and SEK 5.21, respectively.

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 7.0 million and SEK 163.0 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the cash flow used in operating activities amounted to SEK 205.2 million and SEK 395.0 million, respectively.

Cash flow used in investing activities amounted to SEK 0.1 million and SEK 1.1 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, cash flow used in investing activities amounted to SEK 4.0 million and SEK 4.0 million, respectively. The investing activities are mainly related to acquisition of equipment.

Cash flow used in financing activities amounted to SEK 4.0 million and SEK 3.0 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, cash flow used in financing activities amounted to SEK 9.5 million and SEK 6.0 million, respectively.

Net decrease in cash amounted to SEK 11.2 million and SEK 167.1 million for the three months periods ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the net decrease in cash amounted to SEK 218.7 million and SEK 404.9 million, respectively. Cash amounted to SEK 797.3 million and SEK 866.2 million as of June 30, 2024 and 2023, respectively.

Personnel

The average number of employees were 224 and 174 for the three months ended June 30, 2024 and 2023, respectively, and 222 and 169 employees for the six months ended June 30, 2024 and 2023, respectively.

Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 106.8 million and SEK 504.4 million as of June 30, 2024 and 2023, respectively. The number of registered shares, including shares held by Calliditas and ongoing issuance of shares of 338,496, amounted to 59,918,583 and 59,580,087 as of June 30, 2024 and 2023, respectively.

Treasury Shares

As of June 30, 2024, Calliditas had 5,908,018 ordinary shares held as treasury shares by the Parent Company. At the Annual General Meeting 2024, authorization was given that Calliditas can transfer (sell) these ordinary shares with the purpose to finance an acquisition of operations, to procure capital to finance the development of projects, repayment of loans or to commercialize Calliditas' products. No transfer (sale) of treasury shares have occurred as of June 30, 2024. See Note 7 and 8 for further information.

Incentive Programs

During the three months ended June 30, 2024, no options have been allocated. For the same period 829,564 options have been exercised. As of June 30, 2024, the group´s provision includes social security contribution of SEK 70.5 million attributable to incentive programs related to the increase in Calliditas share price. For more information regarding the Incentive programs, see Note 9.

Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 413.1 million and SEK 105.6 million for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the net sales amounted to SEK 551.3 million and SEK 274.0 million, respectively.

Operating income (loss) amounted to SEK 5.2 million and (SEK 118.1 million) for the three months ended June 30, 2024 and 2023, respectively. For the six months ended June 30, 2024 and 2023, the operating loss amounted to SEK 168.7 million and SEK 164.7 million, respectively. The increased operating income in the three month period were primarily related to increased revenue from TARPEYO sales in the US.

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, Senior Vice President Regulatory Affairs Frank Bringstrup, Vice President Technical Operations Lars Stubberud and Vice President Human Resources Sandra Frithiof.

Annual General Meeting 2024

The 2024 Annual General Meeting was held 17 June in Stockholm, Sweden. All documentation are published on the company's website. The annual general meeting resolved to adopt the income statement and the consolidated income statement for the financial year 2023 as well as the balance sheet and consolidated balance sheet as of 31 December 2023. The members of the Board of Directors and the CEO were discharged from liability for the financial year 2023.

The Share

As of 30 June 2024, the number of shares amounted to 59,918,583 ordinary shares, of which, 5,908,018 are held as treasury shares by the Parent Company. As of 28 June, 2024, the closing price for the Calliditas Therapeutics share CALTX was SEK 205.6. The total number of shareholders as of June 30, 2024 was approximately 11,200.

Public offer by Asahi Kasei Corporation

A public cash offer has been made by Asahi Kasei Corporation, to acquire all shares in Calliditas for SEK 208 in cash per Share. The offer includes a concurrent offer by the Asahi Kasei Corporation to acquire all American Depositary Shares, each representing two Shares in Calliditas, for SEK 416 in cash per ADS, which will be conducted pursuant to the securities rules of the United States. The total value of the offer corresponds to approximately SEK 11,164 million. The acceptance period of the offer commenced on July 18, 2024 and expire on August 30, 2024, subject to any extensions. For more information, see information published on Calliditas website: https://www.calliditas.se/en/recommended-offer/.

Updated Outlook 2024

For 2024, Calliditas expects continued revenue growth: Total net sales from the Nefecon franchise, including milestones, are estimated to be USD 165-185 million for the year ending 31 December, 2024, adjusted from USD 150-180 million previously communicated.

Shareholder Structure

Ten largest shareholders as of 30 June, 2024	%
BVF Partners LP	10,51
Linc AB	10,01
Asahi Kasei Corporation	9,01
Stiftelsen Industrifonden	5,28
Polar Capital	4,20
Sofinnova Partners	3,03
Fourth Swedish National Pension Fund	3,03
Unionen	2,69
Öhman Fonder	2,25
Handelsbanken Fonder	2,01
Subtotal, 10 largest shareholders	**52,01**
Treasury shares	**9,92**
Other shareholders	**38,07**
Total	**100.00**

Auditor's Review

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

Declaration by the Board of Directors

The Board of Directors and CEO declare that the interim report for the six months ended June 30, 2024 gives a fair view of the business development, financial position and result of operation of the Parent Company and the Group and describes significant risks and uncertainties that the Parent Company and its subsidiaries are facing.

Stockholm 13 August, 2024

Board of Directors

Elmar Schnee
Chairman of the board

Henrik Stenqvist
Board member

Diane Parks
Board member

Hilde Furberg
Board member

Frederick Driscoll
Board member

Elisabeth Björk
Board member

Renée Aguiar-Lucander
CEO

Significant Events

Significant Events During the Period 1 January – June 30, 2024

- On 7 January, Calliditas announced that Maria Törnsén was appointed to the position of President North America. Ms. Törnsén is responsible for all US based operations and reports to the CEO.
- On 13 February, Calliditas announced that the United States Patent and Trademark Office (USPTO) issued patent no. 11896719, entitled "New Pharmaceutical Compositions", on 24 January, 2024 with validity 13 February, 2024. This is Calliditas' second patent for TARPEYO in the United States, and provides product protection until 13 February 2043.
- On 6 March, Calliditas announced that the FDA granted an orphan drug exclusivity period of seven years for TARPEYO®, expiring in December 2030, based on when the company obtained full approval with an expanded indication for this drug product.
- On 24 April, Calliditas announced that the global open-label extension (OLE) study to the Phase 3 NefIgArd study showed a treatment response consistent with the NefIgArd study across endpoints of urine protein to creatinine ration (UPCR) and estimated glomerular filtration rate (eGFR) at 9 months across all IgAN patients, including those who had previously received Nefecon in the NefIgArd study.
- On 6 May, Calliditas announced topline data from the proof-of-concept Phase 2 trial evaluating setanaxib, its lead NOX enzyme inhibitor, in combination with pembrolizumab, in patients with squamous cell carcinoma of the head and neck (SCCHN). The analysis showed statistically significant improvements in progression-free survival (PFS), as well as in overall survival (OS), with statistically significant changes in tumor biology consistent with the mechanism of action of setanaxib.
- On 14 May, Calliditas announced that its partner Everest Medicines launched Nefecon® in China, which is estimated to have up to 5 million patients suffering from the progressive autoimmune disease.
- On 28 May, Calliditas announced Statement by the Board of Directors of Calliditas Therapeutics AB (publ) in relation to the public offer by Asahi Kasei Corporation. The Board of Directors of Calliditas Therapeutics AB (publ) unanimously recommends that the shareholders and holders of American Depositary Shares ("ADS") of Calliditas Therapeutics AB (publ) (jointly the "Securityholders")
accept the public tender offer by Asahi Kasei Corporation.
- On June 17, Calliditas published the Bulletin from the annual general meeting of Calliditas Therapeutics AB (publ). The annual general meeting resolved to adopt the income statement and the consolidated income statement for the financial year 2023 as well as the balance sheet and consolidated balance sheet as of 31 December 2023. The members of the Board of Directors and the CEO were discharged from liability for the financial year 2023.
- On June 18 ,Calliditas announced that the United States Patent and Trademark Office (USPTO) has issued a new patent for setanaxib for the treatment of cancer. The patent will have an expiration date in 2039.

Significant Events After the end of the Period

- On July 26, Calliditas announced that the European Commission has granted a full marketing authorization for Kinpeygo for the treatment of adults with primary immunoglobulin A nephropathy (IgAN).
- On July 26, Calliditas announced positive TRANSFORM Phase 2b topline data in primary biliary cholangitis. The Phase 2b TRANSFORM trial met its primary endpoint, showing statistically significant improvement in ALP for both doses tested versus placebo. The trial evaluated setanaxib, a NOX enzyme inhibitor, in patients with primary biliary cholangitis (PBC) and elevated liver stiffness.

Supplemental Information

Presentation to investors, analysts and press

- Calliditas invites investors, analysts and press to a presentation of the Q2 Report 2024 at 14:30 p.m. CET on 13 August, 2024. The report was published on 13 August at 7:00 a.m. CET.
- Calliditas' CEO Renée Aguiar-Lucander will present the report together with CFO Fredrik Johansson, CMO Richard Philipson and President North America Maria Törnsén. The presentations will be given in English.
- Time for presentation: Tuesday 14:30 p.m. CET on 13 August, 2024
- Link to webcast
  https://ir.financialhearings.com/calliditas-therapeutics-q2-report-2024
- To participate via conference call register via this link:
  https://conference.financialhearings.com/teleconference/?id=50049712
  After registration, you will receive a phone number and a conference ID to log in to the conference call. There will be no Q&A session.

Upcoming events

INTERIM REPORT Q3
January – September 2024
11 November 2024

YEAR END REPORT Q4
January – December 2024
20 February 2025

For further information please contact

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Forward looking statements

This Interim Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans, revenue and other financial projections, and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this Interim Report are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this Interim Report, including, without limitation, any related to Calliditas' business, operations, commercialization of TARPEYO, Kinpeygo and Nefecon, clinical trials, supply chain, strategy, goals and anticipated timelines for development and potential approvals, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts, including 2024 total net sales guidance and cash runway, all statements regarding the public offer by Asahi Kasai Corporation, profitability 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

Calliditas Therapeutics AB
Kungsbron 1
SE 111 22 Stockholm, Sweden

calliditas.com / ir@calliditas.com

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

The information in the report is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Market Act. The information was sent for publication, through the agency of the contact persons set out above, on August 13, 2024, at 7:00 a.m. CET.

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Year Ended December 31, 2023
Net sales	4	559,780	269,384	855,261	460,735	1,206,888
Cost of sales		(53,448)	(14,214)	(67,460)	(23,242)	(60,463)
Gross income		**506,332**	**255,169**	**787,801**	**437,493**	**1,146,425**
Research and development expenses		(120,715)	(88,986)	(271,328)	(215,639)	(502,223)
Marketing and selling expenses		(252,985)	(191,472)	(493,132)	(358,696)	(727,740)
Administrative expenses		(166,831)	(77,151)	(268,849)	(149,698)	(332,991)
Other operating income/(expenses), net		2,696	27,267	10,179	31,294	43,473
Operating income (loss)		**(31,503)**	**(75,172)**	**(235,329)**	**(255,246)**	**(373,055)**
Net financial income/(expenses)		(11,158)	4,512	(54,656)	(23,433)	(83,962)
Income (loss) before income tax		**(42,661)**	**(70,660)**	**(289,985)**	**(278,679)**	**(457,017)**
Income tax		(4,817)	(21,274)	(3,653)	(780)	(9,168)
Net income (loss) for the period		**(47,478)**	**(91,934)**	**(293,638)**	**(279,459)**	**(466,185)**
Attributable to:						
Equity holders of the Parent Company		(47,478)	(91,934)	(293,638)	(279,459)	(466,185)
		(47,478)	**(91,934)**	**(293,638)**	**(279,459)**	**(466,185)**
Loss per share before and after dilution (SEK)	8	(0.88)	(1.71)	(5.47)	(5.21)	(8.69)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Year Ended December 31, 2023
Net income (loss) for the period	(47,478)	(91,934)	(293,638)	(279,459)	(466,185)
Other comprehensive income					
Other comprehensive income (loss) that may be reclassified to income or loss in subsequent periods:					
Exchange differences on translation of foreign operations	482	(4,040)	16,833	(2,881)	(14,538)
Other comprehensive income (loss) that may be reclassified to income or loss in subsequent periods	**482**	**(4,040)**	**16,833**	**(2,881)**	**(14,538)**
Other comprehensive income (loss) that will not be reclassified to income or loss in subsequent periods:					
Remeasurement gain (loss) on defined benefit plans	(336)	(556)	(324)	(1,218)	(3,071)
Other comprehensive income (loss) that will not be reclassified to income or loss in subsequent periods	**(336)**	**(556)**	**(324)**	**(1,218)**	**(3,071)**
Other comprehensive income (loss) for the period	**146**	**(4,596)**	**16,509**	**(4,099)**	**(17,609)**
Total comprehensive income (loss) for the period	**(47,332)**	**(96,530)**	**(277,129)**	**(283,558)**	**(483,794)**
Attributable to:					
Equity holders of the Parent Company	(47,332)	(96,530)	(277,129)	(283,558)	(483,794)
	(47,332)	**(96,530)**	**(277,129)**	**(283,558)**	**(483,794)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	June 30, 2024	June 30, 2023	December 31, 2023
ASSETS				
Non-current assets				
Intangible assets		423,864	466,083	430,754
Goodwill		47,807	48,945	48,584
Equipment		16,685	9,222	16,053
Right-of-use assets		42,671	32,271	38,186
Non-current financial assets		27,207	16,617	24,201
Deferred tax assets		34,507	22,423	26,315
Total non-current assets		**592,741**	**595,560**	**584,093**
Current assets				
Inventories		40,164	17,697	20,428
Current receivables		222,586	146,365	196,666
Prepaid expenses and accrued income		94,436	83,343	84,324
Cash		797,278	866,181	973,733
Total current assets		**1,154,464**	**1,113,587**	**1,275,152**
TOTAL ASSETS		**1,747,205**	**1,709,147**	**1,859,245**
EQUITY AND LIABILITIES				
Equity				
Equity attributable to equity holders of the Parent Company		106,789	504,367	334,806
Total equity	*7,8,9*	**106,789**	**504,367**	**334,806**
Non-current liabilities				
Provisions	*9*	87,794	15,146	36,116
Contingent consideration	*6*	58,477	69,290	56,561
Deferred tax liabilities		36,698	41,950	41,641
Non-current interest-bearing liabilities		982,487	759,052	939,508
Lease liabilities		25,785	20,512	27,088
Other non-current liabilities		19,397	8,521	16,381
Total non-current liabilities		**1,210,638**	**914,471**	**1,117,295**
Current liabilities				
Accounts payable		151,015	72,037	100,564
Other current liabilities		26,619	30,742	25,953
Accrued expenses and deferred revenue		252,144	187,531	280,627
Total current liabilities		**429,778**	**290,309**	**407,144**
TOTAL EQUITY AND LIABILITIES		**1,747,205**	**1,709,147**	**1,859,245**

Condensed Consolidated Statements of Changes in Equity

	Six Months Ended June 30,		Year Ended December 31,
(SEK in thousands)	2024	2023	2023
Opening balance equity attributable to equity holders of the Parent Company	**334,806**	**766,264**	**766,264**
Loss for the period	(293,638)	(279,459)	(466,185)
Other comprehensive income/(loss)	16,509	(4,099)	(17,609)
Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company	**(277,129)**	**(283,558)**	**(483,794)**
Transactions with owners:			
New share issue	14	-	-
Share-based payments	49,098	21,661	52,337
Total transactions with owners	**49,112**	**21,661**	**52,337**
Closing balance equity attributable to equity holders of the Parent Company	**106,789**	**504,367**	**334,806**
Closing balance equity	**106,789**	**504,367**	**334,806**

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Year Ended December 31, 2023
Operating activities					
Operating loss	(31,503)	(75,172)	(235,329)	(255,246)	(373,055)
Adjustment for non-cash-items	95,770	(7,266)	112,029	19,876	102,478
Interest received	3,280	724	5,796	732	32,905
Interest paid	(24,749)	(17,915)	(51,283)	(33,376)	(94,497)
Income taxes paid	(17,435)	(13,839)	(17,679)	(15,175)	(22,747)
Cash flow from (used in) operating activities before changes in working capital	**25,363**	**(113,468)**	**(186,466)**	**(283,189)**	**(354,915)**
Cash flow from (used in) changes in working capital	(32,406)	(49,564)	(18,782)	(111,782)	(79,740)
Cash flow from (used in) operating activities	**(7,043)**	**(163,031)**	**(205,248)**	**(394,971)**	**(434,655)**
Cash flow from (used in) investing activities	**(102)**	**(1,060)**	**(3,960)**	**(3,973)**	**(13,745)**
New share issue	14	-	14	-	-
New borrowings	-	-	-	-	962,889
Costs attributable to new loans	-	-	-	-	(26,625)
Repayment of borrowing	-	-	-	-	(724,479)
Repayment of lease liabilities	(4,060)	(3,015)	(9,527)	(5,984)	(12,134)
Cash flow from financing activities	**(4,046)**	**(3,015)**	**(9,513)**	**(5,984)**	**199,650**
Net increase (decrease) in cash	**(11,191)**	**(167,107)**	**(218,721)**	**(404,928)**	**(248,750)**
Cash at the beginning of the period	**810,317**	**1,013,600**	**973,733**	**1,249,094**	**1,249,094**
Net foreign exchange gains (loss) in cash	(1,848)	19,688	42,266	22,015	(26,611)
Cash at the end of the period	**797,278**	**866,181**	**797,278**	**866,181**	**973,733**

Condensed Parent Company Statements of Income

(SEK in thousands)	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Year Ended December 31, 2023
Net sales	413,071	105,617	551,270	273,987	805,551
Cost of sales	(53,361)	(14,199)	(67,337)	(23,211)	(60,399)
Gross income	**359,710**	**91,419**	**483,933**	**250,776**	**745,151**
Research and development expenses	(102,227)	(77,820)	(239,871)	(196,609)	(456,970)
Marketing and selling expenses	(133,395)	(107,068)	(243,065)	(195,739)	(402,436)
Administrative expenses	(151,660)	(61,848)	(235,820)	(121,033)	(273,359)
Other operating income/(expenses), net	32,797	37,229	66,083	97,882	219,818
Operating income (loss)	**5,225**	**(118,088)**	**(168,740)**	**(164,723)**	**(167,796)**
Net financial income/(expenses)	(13,639)	(3,984)	(3,236)	(22,318)	(105,722)
Loss before income tax	**(8,414)**	**(122,072)**	**(171,976)**	**(187,041)**	**(273,518)**
Income tax	-	-	-	-	-
Loss for the period	**(8,414)**	**(122,072)**	**(171,976)**	**(187,041)**	**(273,518)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Year Ended December 31, 2023
Loss for the period	(8,414)	(122,072)	(171,976)	(187,041)	(273,518)
Other comprehensive income (loss)	-	-	-	-	-
Total comprehensive income (loss)	**(8,414)**	**(122,072)**	**(171,976)**	**(187,041)**	**(273,518)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	June 30, 2024	June 30, 2023	December 31, 2023
ASSETS				
Non-current assets				
Intangible assets		-	32,132	-
Equipment		2,062	455	342
Non-current financial assets		1,223,814	1,049,716	1,125,186
Total non-current assets		**1,225,876**	**1,082,303**	**1,125,528**
Current assets				
Inventories		40,164	17,697	20,428
Current receivables		449,745	71,974	223,700
Prepaid expenses and accrued income		73,160	64,648	67,603
Cash		469,114	754,802	817,871
Total current assets		**1,032,183**	**909,121**	**1,129,602**
TOTAL ASSETS		**2,258,059**	**1,991,423**	**2,255,130**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Total restricted equity		5,489	5,475	5,475
Total non-restricted equity		781,421	960,101	904,299
Total shareholders' equity	*7,9*	**786,910**	**965,577**	**909,774**
Non-current liabilities				
Provisions	*9*	63,648	10,685	25,924
Non-current interest-bearing liabilities		982,487	759,052	939,508
Other non-current liabilities		19,501	8,626	16,486
Total non-current liabilities		**1,065,636**	**778,363**	**981,918**
Current liabilities				
Accounts payable		112,497	31,210	62,562
Other current liabilities		153,318	119,076	113,685
Accrued expenses and deferred revenue		139,698	97,197	187,191
Total current liabilities		**405,513**	**247,483**	**363,438**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**2,258,059**	**1,991,423**	**2,255,130**

Notes to Condensed Consolidated Financial Statements

Note 1 - Description of Business

Calliditas Therapeutics AB (publ) ("Calliditas" or the "Parent Company"), with corporate registration number 556659-9766, and its subsidiaries (collectively, the "Group") conducts commercial and development activities in pharmaceuticals. These interim condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the six months ended June 30, 2024 and 2023. Calliditas is a Swedish public limited company registered in and with its registered office in Stockholm. The registered address of the corporate headquarters is Kungsbron 1, D5, Stockholm, Sweden. Calliditas is listed at Nasdaq Stockholm in the Mid Cap segment with ticker "CALTX" and, in the form of ADSs, on the Nasdaq Global Select Market in the United States with the ticker "CALT". These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on August 13, 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.

Public offer by Asahi Kasei Corporation

A public cash offer is made by Asahi Kasei Corporation, to acquire all shares in Calliditas for SEK 208 in cash per Share. The offer includes also a concurrent offer by the Asahi Kasei Corporation to acquire all American Depositary Shares, each representing two Shares in Calliditas, for SEK 416 in cash per ADS, which will be conducted pursuant to the securities rules of the United States. The total value of the offer corresponds to SEK 11,164 million. The acceptance period of the offer was set to July 18, 2024 and expire on or around August 30, 2024, subject to any extensions. For more information, see pressrelease published on Calliditas website May 28, 2024 08:30 CET.

Note 2 - Accounting Policies

These interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting". The Parent Company applies the Swedish Financial Reporting Board recommendation RFR2, Accounting for legal entities. The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Annual Report for 2023. None of the new or amended standards and interpretations that became effective January 1, 2024, have had a significant impact on the Group's financial reporting. Significant accounting policies can be found in the Annual Report 2023, from pages 45 and onwards including disclosures at respective note.
The ESMA (European Securities and Markets Authority) guidelines on alternative key performance ratios are applied, which means disclosure requirements regarding financial measures that are not defined in accordance with IFRS. For key ratios not defined by IFRS, see the Definitions and reconciliations of alternative performance measures on page 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 in the EU under the brand name Kinpeygo. The product has also received conditional marketing authorization in the UK under the brand name Kinpeygo, and in China under the brand name Nefecon, and are dependent on renewal of the conditional marketing authorizations. There is a risk that commercialization will not go according to plan or that the uptake of prescribing physicians will be worse than planned or that the drug will not have sufficient effect, or show unwanted side effects, which may affect the sales negatively. The impact on the financial statements is described in the Financial overview.

Financial Risks

Calliditas' financial policy governing the management of financial risks has been designed by the Board of Directors and represents the framework of guidelines and rules in the form of risk mandated and limits for financial activities. The Group is primarily affected by foreign exchange risk, since the development costs for Nefecon and setanaxib are mainly paid in USD and EUR. Further, the Group holds account receivables in USD and EUR and cash in USD and EUR to meet future expected costs in USD and EUR in connection with commercialization of TARPEYO in the US and the clinical development programs. Regarding the Group and the Parent Company's financial risk management, the risks are essentially unchanged compared with the description in the Annual Report for 2023.
For more information and full disclosure regarding the operational and financial risks, reference is made to the Annual Report for 2023 and the Annual Report on Form 20-F, filed with the SEC in April 2024.

Note 4 - Revenue from Contracts with Customers

(SEK in thousands)	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023	Year Ended December 31, 2023
Type of goods or services					
Product sales	520,907	260,632	803,437	447,571	1,087,418
Outlicensing of product	-	-	-	-	82,712
Royalty income	38,873	8,752	51,824	13,164	36,758
Total	**559,780**	**269,384**	**855,261**	**460,735**	**1,206,888**
Geographical markets					
USA	493,356	259,238	771,632	444,931	1,075,829
Europe	18,836	10,146	35,697	15,804	39,614
Asia	47,588	-	47,932	-	91,445
Total	**559,780**	**269,384**	**855,261**	**460,735**	**1,206,888**

Net sales for the periods primarily originate from net sales of TARPEYO in the US, which amounted to SEK 493.4 million and SEK 259.2 million for the three months ended June 30, 2024 and 2023. For the six month ended June 30, 2024 and 2023, net sales of TARPEYO amounted to SEK 771.6 million and SEK 444.9 million, respectively. Royalty income from our partnerships amounted to SEK 38.9 million and SEK 8.8 million for the second quarter of 2024 and 2023. For the six months ended June 30, 2024 and 2023, royalty income amounted to SEK 51.8 million and SEK 13.2 million, respectively. For the second quarter and the six months ended June 30, 2024 and 2023, no milestones were recognized. For 2023, outlicensing of product consisted of milestone fees from Everest Medicines.

The total liability for expected returns and rebates amounts to SEK 48.1 million and SEK 46.1 million as of June 30, 2024 and 2023, respectively, which are recognized in other current liabilities.

Note 5 - Related-Party Transactions

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

Note 6 - Financial Instruments

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

Contingent consideration is recognized at fair value, measured at Level 3 of the IFRS value hierarchy. The fair value of the contingent consideration has been estimated in accordance with the present value method and the probability has been taken into account if and when the various milestones will occur. The calculations are based on a discount rate of 13.4 percent. The most significant input affecting the valuation of the contingent consideration is the Group's estimate of the probability of the milestones being reached.

Calliditas holds a credit agreement that contains customary affirmative and negative covenants for a senior secured loan, such as minimum cash liquidity and minimum product revenue. The fair value for the loan at the end of the period amounts to SEK 1,005.8 million.

Note 7 - Treasury Shares

As of June 30, 2024, Calliditas had 5,908,018 ordinary shares held as treasury shares by the Parent Company. At the Annual General Meeting 2024, 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 (sell) of treasury shares have occurred as of June 30, 2024. The total number of issued shares as of June 30, 2024, is disclosed in Note 8.

Note 8 - Shareholders' Equity

	June 30,		December 31,
(SEK in thousands, except per share amounts and number of shares)	2024	2023	2023
Total registered shares at the beginning of the period	59,580,087	59,580,087	59,580,087
Issuance of shares during the period	338,496	-	-
Total registered and subscribed but not registered shares at the end of the period	**59,918,583**	**59,580,087**	**59,580,087**
Shares			
Ordinary shares	59,918,583	59,157,587	59,580,087
Total	**59,918,583**	**59,157,587**	**59,580,087**
- of which shares are held by Calliditas	*5,908,018*	5,908,018	5,908,018
Total registered and subscribed but not registered shares at the end of the period, net of shares held by Calliditas	**54,010,565**	**53,249,569**	**53,672,069**
Share capital at the end of the period	2,397	2,383	2,383
Equity attributable to equity holders of the Parent Company	106,789	504,367	334,806
Total equity at the end of the period	**106,789**	**504,367**	**334,806**

	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
(SEK in thousands, except per share amounts and number of shares)	2024	2023	2024	2023	2023
Loss per share before and after dilution, SEK	(0.88)	(1.71)	(5.47)	(5.21)	(8.69)
Weighted-average number of ordinary shares outstanding for the period, before and after dilution	53,686,948	53,672,069	53,679,550	53,672,069	53,672,069

Reserves for translation from foreign operations amounted to SEK 11.6 million and SEK 6.4 million which are included in retained earnings in equity as of June 30, 2024 and 2023, respectively.

Note 9 - Incentive Programs

	June 30, 2024			June 30, 2023		
	Options Outstanding	Share Awards Outstanding	Total Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding
Incentive Programs						
Board LTIP 2021	-	22,882	22,882	-	22,882	22,882
Board LTIP 2022	-	37,136	37,136	-	37,136	37,136
Board LTIP 2023	-	40,957	40,957	-	40,957	40,957
ESOP 2020	535,166	-	535,166	1,364,730	-	1,364,730
ESOP 2021	1,386,163	-	1,386,163	1,468,500	-	1,468,500
ESOP 2022	1,814,166	-	1,814,166	1,961,000	-	1,961,000
ESOP 2023	1,865,000	-	1,865,000	-	-	-
Total Outstanding	**5,600,495**	**100,975**	**5,701,470**	**4,794,230**	**100,975**	**4,895,205**

Board LTIP 2021:

This is a performance-based long-term incentive program for Calliditas Board members. The share awards are subject to performance-based earnings, which are dependent on the development of Calliditas' share price from the date of the 2021 Annual General Meeting to July 1, 2024.

Board LTIP 2022:

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

Board LTIP 2023:

This is a performance-based long-term incentive program for Calliditas Board members. The share awards are subject to performance-based earnings, which are dependent on the development of Calliditas' share price from the date of the 2023 Annual General Meeting to July 1, 2026.

ESOP Programs

Calliditas implements option programs for employees and key consultants in Calliditas. The options are granted free of charge to participants of the program. The options have a three-year vesting period calculated from the grant date, provided that, with customary exceptions, the participants remain as employees of, or continue to provide services to, Calliditas. Once the options are vested, they can be exercised within a one-year period. Each vested option entitles the holder to acquire one share in Calliditas at a predetermined price. The price per share is to be equivalent to 115% of the weighted average price that the company's shares were traded for on Nasdaq Stockholm during the ten trading days preceding the grant date. The options have, at the time of each issue, been valued according to the Black-Scholes valuation model.

Definitions and Reconciliations of Alternative Performance Measures

Definitions of Alternative Performance Measures

Alternative Key Performance Indicator	Definitions	Reason for Inclusion
Adjusted operating profit (loss)	Adjustment for items in the operating profit includes costs from such events in the company's operations that interfere with comparisons with other periods' results.	Costs that have a significant impact on comparability and are of importance as supplementary information for trend analyzes to investors and the company's management.
Equity ratio at the end of the period in %	The ratio at the end of respective period is calculated by dividing total shareholders' equity by total assets.	The equity ratio measures the proportion of the total assets that are financed by shareholders.

Reconciliations of Alternative Performance Measures

	June 30,		December 31,
(SEK in thousands or otherwise indicated)	2024	2023	2023
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	106,789	504,367	334,806
Total assets at the end of the period	1,747,205	1,709,147	1,859,245
Equity ratio at the end of the period in %	**6%**	**30%**	**18%**

Adjusted operating profit/loss

	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
(SEK in thousands)	2024	2023	2024	2023	2023
Operating income (loss)	**(31,503)**	**(75,172)**	**(235,329)**	**(255,246)**	**(373,055)**
Adjustments in the operating result:					
Provisions social security contribution for incentive programs	70,532	-	70,532	-	-
Advisor fees for Asahi Kasei public offer	31,218	-	31,218	-	-
Adjusted operating profit (loss)	**70,247**	**(75,172)**	**(133,579)**	**(255,246)**	**(373,055)**