



# 2023

ANNUAL REPORT

**calliditas**  
THERAPEUTICS

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The Annual Report of Calliditas Therapeutics AB (publ), 556659-9766, is comprised of directors report, the Group's and the Parent Company's financial statements with notes and audit report (pages 32-87).

# Calliditas – pioneering new treatments for rare diseases

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

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

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

IgA nephropathy is the most common primary glomerulonephritis worldwide, so the market potential for Nefecon is substantial, as evidenced by our early commercial success and out-licensing deals with potential payments exceeding USD 300 million, encompassing upfront payments and predefined milestones, as well as ongoing royalty obligations.

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

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

# Significant Events

## March 2023, Positive topline results

Calliditas announced positive topline results from the global, randomized, double-blind, placebo-controlled Phase 3 clinical trial NeflgArd, which investigated the effect of Nefecon (TARPEYO®/Kinpeygo® (budesonide) delayed release capsules) versus placebo in patients with primary IgA nephropathy (IgAN).

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

## August 2023, FDA priority review

The FDA granted priority review for the application for full approval of TARPEYO (budesonide) delayed release capsules for the treatment of IgA nephropathy.

## August 2023, Lancet publication

Full data from the Phase 3 NeflgArd study with Nefecon® (TARPEYO®/Kinpeygo®) was published in The Lancet.

## February 2023, UK conditional approval

Calliditas announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom granted Conditional Marketing Authorisation (CMA) for Kinpeygo® for the treatment of IgA nephropathy in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$ g/gram. Kinpeygo became the first and only approved treatment for IgAN in the UK.

## June 2023, ERA Congress

At the European Renal Association (ERA) Congress in Milan, Italy, Calliditas had two oral presentations and two abstracts reflecting top line data and analyses from the NeflgArd Phase 3 Study, evaluating Nefecon in patients with IgA nephropathy.

## June 2023, Seeking full TARPEYO approval

Calliditas submitted a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) seeking full approval of TARPEYO (budesonide) delayed release capsules (developed under the project name Nefecon) for the entire study population evaluated in the Phase 3 NeflgArd study.

**November 2023, Conditional Nefecon approval in China**  
Calliditas' partner Everest Medicines announced that China's National Medical Products Administration (NMPA) approved Nefecon for the treatment of primary IgA nephropathy in adults at risk of disease progression.

**November 2023, Alport study initiation**  
Calliditas announced the initiation of a Phase 2 clinical study to evaluate setanaxib in Alport syndrome.

**November 2023, ASN Kidney Week**  
Scientific progress was noted when Calliditas' researchers presented additional analyses of the Phase 3 NeflgArd study which underlined the statistically significant and clinically meaningful treatment benefit of TARPEYO. A total of seven abstracts, including a scientifically reviewed publication of biomarker data for Nefigan was presented in meetings with key opinion leaders, nephrologists and patient organizations.

**December 2023, US patent approval**  
Calliditas received approval (Notice of Allowance) regarding a US patent application for TARPEYO®. In the first quarter of 2024 the patent, which provides patent protection in the US through 2043, was issued and listed in the Orange Book.

**December 2023, Full approval of TARPEYO®**  
The FDA granted Calliditas full approval of TARPEYO® for reduction of kidney loss in adult IgAN patients at risk of disease progression.

**September 2023, Seeking full Kinpeygo approval**  
STADA and Calliditas announced the filing of the application for full marketing authorisation of Kinpeygo in the EU.

2024

## Financial summary for the Group

(SEK in thousands, except per share amount or as otherwise indicated)	2023	2022	2021	2020	2019
Net sales (SEK in thousands)	1,206,888	802,879	229,347	874	184,829
Loss before income tax (SEK in thousands)	(457,017)	(409,417)	(513,373)	(436,151)	(32,501)
Total assets (SEK in thousands)	1,859,245	1,952,973	1,459,910	1,463,908	845,200
Average number of employees	181	86	56	23	14



## A Year filled with Success

In March 2023 we announced that the global NeflgArd Phase 3 trial successfully met its primary endpoint, estimated glomerular filtration rate (eGFR), with statistical significance of  $p < 0.0001$ . Achieving this highly clinically relevant endpoint of kidney filtration capability was a fantastic feeling after well over fifteen years of pioneering work for patients with IgA nephropathy!

The clinical trial showed both an immediate stabilizing effect on eGFR and an enduring impact on proteinuria, with the treatment effect remaining intact even after 15 months off drug. These benefits were observed across the entire study population, irrespective of UPCR levels, and resulted in a difference of 3ml/min/year, reflecting an approximate 50% reduction in the decline of eGFR compared with placebo over the 2-year period. We believe that the highly differentiated approach of targeting the origin of the disease by focusing on modulating B cell production of secretory galactose deficient IgA1 (Gd-IgA1) is ground-breaking. We maintain that these results support the thesis that the drug has the potential to provide a clinically meaningful delay in the need for dialysis or transplantation.

In June we submitted a supplementary New Drug Application (sNDA) to the FDA for full approval of TARPEYO. Also in June, we had the pleasure of attending the ERA EDTA conference, where we had two oral presentations and 2 posters, allowing us to share the exciting long-term Phase 3 data with the nephrology community for the first time.

In August we were excited to see the full data set from our global, randomized, placebo controlled, double-blind Phase 3 clinical trial, NeflgArd, published in *The Lancet*. This marked the beginning of a peer-to-peer scientific dialogue with US physicians, offering opportunities to interact with the nephrology community about the results of the trial and discuss appropriate treatment paradigms.

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

In November the American Society of Nephrology had its annual Kidney Week meeting in Philadelphia, which provided us with numerous opportunities to meet and engage with nephrologists across the country. At the conference we presented several posters, including the modelling of the 2-year eGFR slope from the Neflgard Phase 3 trial predicting long term clinical benefit in a real-world population, adding to the already substantial scientific evidence supporting the disease modifying impact of TARPEYO. We also had the opportunity to meet with well over 100 nephrologists who provided valuable insight into IgAN treatment paradigms and how TARPEYO is being used in practice. It was incredibly rewarding to hear all of the positive stories about patient outcomes and the difference that this medication is making for young adults previously facing an uncertain future and the risk of ending up in dialysis. It was also clear that the publication of the RaDaR registry data and similar longitudinal data from the southern California IgAN cohort of Kaiser Permanente had a profound impact on how the nephrology community was starting to think about this patient population. The data reflected faster progression than expected and significantly higher observed risk for progression amongst patients previously considered "stable" or "controlled". This data, in combination with recently published clinical trial data showing significant eGFR decline amongst patients on optimized RAS blockade, was clearly reflecting a more serious outlook for patients with this condition than previously thought. Nephrologists are therefore really starting to focus on the pathophysiology and on treating the underlying condition, in addition to controlling proteinuria.

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

On December 20th 2023 we were granted full approval by the FDA for TARPEYO, our targeted treatment for primary IgA nephropathy. This was a fantastic achievement after many years of efforts to bring an approved medication to patients with this rare disease. Our label now reflects reduction of

kidney loss and enables us to address the full adult IgAN population at risk of disease progression, a welcome broadening for both patients and physicians.

For 2023 we reported total revenues of SEK 1.2bn, out of which net product revenues from TARPEYO amounted to SEK 1.1bn (\$102m), representing growth of 190% compared to 2022. This very strong growth we believe reflects the underlying unmet medical need and the compelling clinical data of TARPEYO, propelling it to become the cornerstone of the new standard of care for IgAN. The growth in unique prescribing nephrologists also accelerated, reaching 301 in Q4 alone, a growth of over 50% over Q3 2023. Prescriptions also continued to grow over the year, reaching 555 for Q4, a growth of over 50% over Q3. Driven by this significant revenue growth, Q4 was cashflow positive and the last 9 months of the year saw a net use of cash from operations of SEK 203m. Our cash position therefore remains strong with SEK 974m on the balance sheet, which we believe will be sufficient to take us to profitability, assuming continued revenue growth of TARPEYO.

Regarding our pipeline, we reported out supportive biomarker data of the setanaxib head and neck cancer trial in July, with 6 out of the 7 patients that reported progression free survival belonging to the treatment arm. Transcriptomic analysis supported modulation of the hepatic fibrotic pathway and the IPF fibrotic pathway, which is supportive of our ongoing trials in these rare diseases. In Q4 we started a Phase 2 proof-of-concept trial in Alport syndrome, a renal orphan disease where there is a substantial unmet medical need, with nothing approved today. We look forward to reading out three out of the four ongoing Phase 2 trials with setanaxib throughout 2024.

2023 was an eventful and very positive year for Calliditas. A journey that started in 2008 with a Phase 2a POC trial in IgAN now saw the full approval of this medicine in the US, generating over \$100m of revenue in its first full year of commercialization. Approval across other geographies was achieved and, with an experienced and robust organization in Europe and the US, we are well on our way to achieve our goal of creating a successful, sustainable and profitable rare disease company. We have a strong, highly talented and purposeful team at Calliditas who brought about this success. I want to thank each and every person in this team for all of the hard work, agility, ingenuity and perseverance you brought to bear during this amazing year of execution. I also want to thank all of the patients, caregivers, KOLs and investigators who supported us, especially those who participated in the Neflgard study during all of these years and thus made it possible to deliver an approved medication to patients with this rare disease. We could never have done any of this without you.

THANK YOU!

Renée Aguiar-Lucander, CEO

\*KOL: Key Opinion Leaders

# Pipeline to Build a Rare Disease Franchise

Evaluating setanaxib across three rare disease indications, with three Phase 2 data readouts expected in 2024.

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

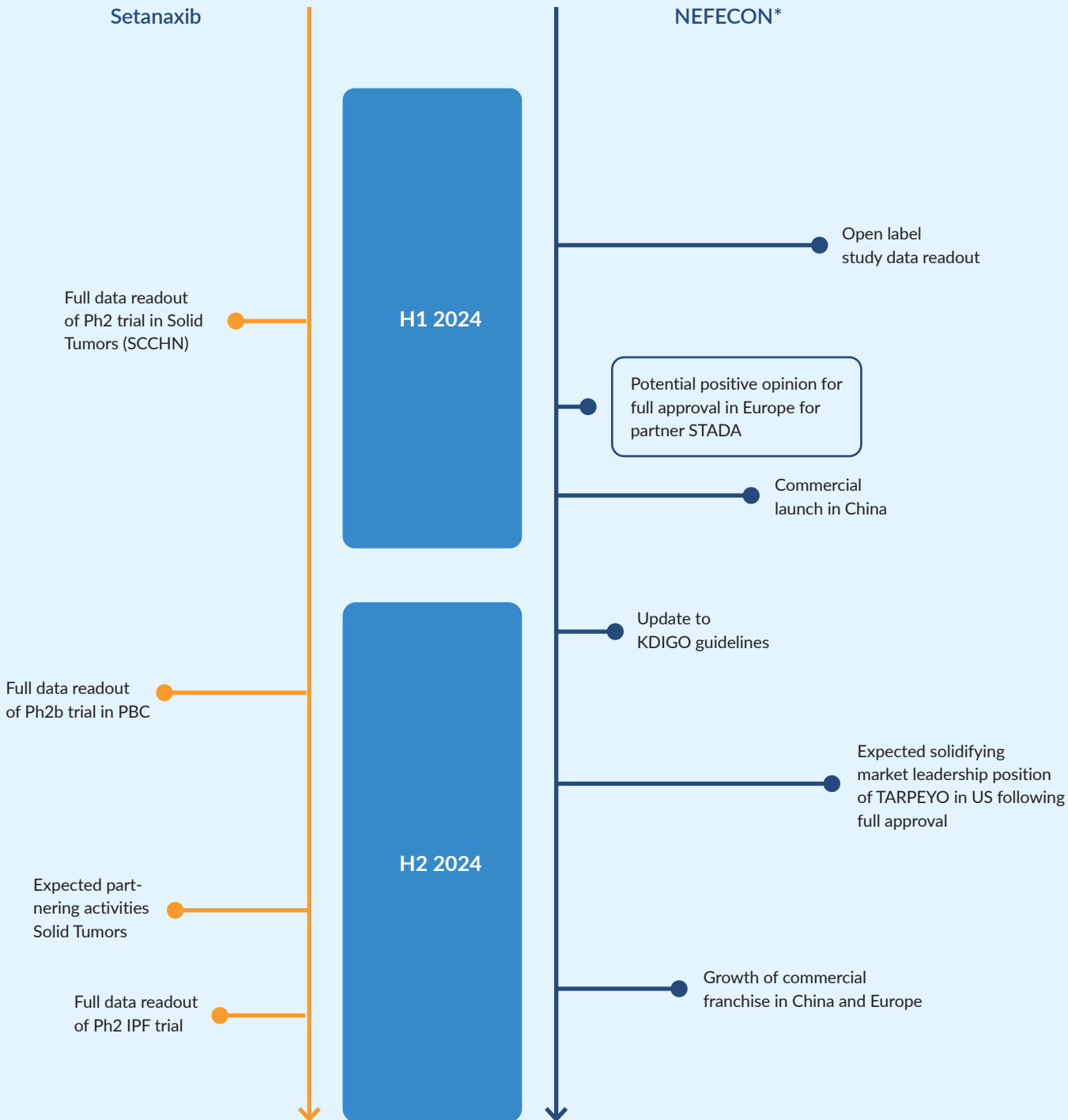
	Phase 1	Phase 2	Phase 3	Approved	Status	Notes
NEFECON*	Immunoglobulin A Nephropathy (IgAN)				Commercial	US (TARPEYO) Europe (KINPEYGO) China (NEFECON)
	Immunoglobulin A Nephropathy (IgAN)				Pre Commercial	Japan
Setanaxib	Primary Biliary Cholangitis				Ongoing	
	Idiopathic Pulmonary Fibrosis				Ongoing	Investigator Led study
	Alport Syndrome				Ongoing	
	Solid Tumors (SCCHN)				Ongoing	Partnering focus

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



# Expected Key Events

Exciting year ahead with global commercial ramp up and three ph2 data readouts expected from our pipeline.



# The Share

## Share Performance

### Nasdaq Stockholm

Calliditas was listed on Nasdaq Stockholm Mid-Cap, on June 29, 2018. As of December 31, 2023, the closing rate was SEK 127.10. The highest closing rate during the year was SEK 141.90 and the lowest SEK 81.85.

### Nasdaq USA

Calliditas was listed on Nasdaq Global Select Market in the U.S., on June 5, 2020. An ADS listed in the U.S. corresponds to two ordinary shares. On December 31, 2023, the closing price was USD 25.74. The highest closing price during the year was USD 28.99 and the lowest was USD 15.68.

## Turnover

### Nasdaq Stockholm

A total of 74.9 million shares were traded during 2023, with a total value of SEK 7,823 million. On average, 298,093 shares were traded each day.

### Nasdaq USA

During the period January-December 2023, a total of 2.9 million ADSs were traded. On average, 11,626 ADSs were traded per day.

## Shareholders

As of December 31, 2023, Calliditas had 18,784 share-holders. The 20 largest shareholders controlled

65.96% of the capital at year-end. The three largest shareholders were BVF Partners, Linc AB and Stiftelsen Industrifonden. Foreign shareholders accounted for 30.44% of capital.

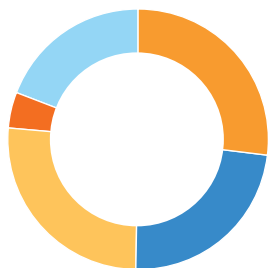
## Share Capital

As of December 31, 2023, share capital in Calliditas amounted to SEK 2,383 thousand. The number of shares was 59,580,087 corresponding to a quotient value per share of SEK 0.04. In accordance with the Articles of Association, the share capital must be not less than SEK 1,000 thousand and not more than SEK 4,000 thousand. The number of shares shall be not less than 25,000,000 and not more than 100,000,000. The proportion of shares available for trade (free float) amounted approximately to 66,25% at year-end.

## Investor Relations Work

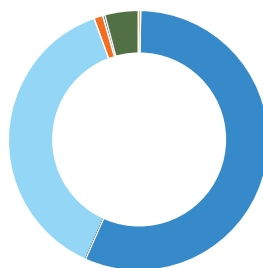
Investor Relations work in 2023 has focused on the continued establishment of Calliditas in the capital market in the Nordic region, Europe and the USA. The management has participated in a number of sector-specific conferences that during the year were both in person and virtual. Calliditas has also conducted a large number of in person and virtual meetings on both the sales and buying side to educate the market and ensure that there is a broad knowledge of the company in the market.

Ownership per category, %



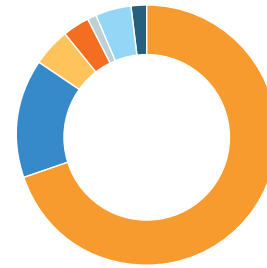
Swedish institutional owners	27,08%
Foreign institutional owners	23,45%
Swedish private individuals	25,94%
Other	18,90%
Unknown owner type	4,62%

Trading platforms, %



ITG Posit	0,32%
Nasdaq	56,40%
Instinet Blockmatch Europe	0,09%
Cboe	37,82%
Aquis Stock Exchange	1,04%
Sigma x	0,29%
Liquidnet EU Limited Equity MTF	0,01%
London Stock Exchange	4,03%

Ownership per country, %



Sweden	69,90%
USA	14,73%
Great Britain	4,60%
France	3,51%
Norway	0,94%
Unkown country	4,63%
Other	1,69%

Source: Monitor by Modular Finance AB

## Analysts

Calliditas is monitored by Bryan Garnier & Co, Carnegie, Citi, Guggenheim, H.C Wainwright & Co, Jefferies, Kempen & Co, Kepler Cheuvreux, LifeSci Capital, Pareto Securities, SEB and Stifel.

## Outlook 2024

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

## CALTX share data 2023

Average daily turnover (SEK)	31,167,394
Average daily turnover rel. mcap	0.50%
Average daily shares traded	298,093
Number of shares traded	74,821,405
Average trades per day	1890
Number of trades	474,507
Average value per trade	16,487
High	141.90
Low	80.80
Volume-Weighted Average Price (VWAP)	104.56

## The 15 largest shareholders as of December 31, 2023

Shareholders	Total number of shares	Holding, %	Votes, %
BVF Partners LP	6,260,311	10,51%	11,67%
Linc AB	5,962,312	10,01%	11,11%
Calliditas Therapeutics AB	5,908,018	9,92%	0,00%
Stiftelsen Industrifonden	3,145,440	5,28%	5,86%
Avanza Pension	2,096,247	3,52%	3,91%
Polar Capital	2,000,000	3,36%	3,73%
Unionen	1,971,692	3,31%	3,67%
Handelsbanken Fonder	1,773,542	2,98%	3,30%
Fourth Swedish National Pension Fund	1,754,603	2,94%	3,27%
Sofinnova Partners	1,408,078	2,36%	2,62%
Öhman Fonder	1,329,142	2,23%	2,48%
The Invus Group	1,068,115	1,79%	1,99%
Hans Edvin Öhman	885,554	1,49%	1,65%
Renée Aguiar-Lucander	643,000	1,08%	1,20%
BlackRock	606,741	1,02%	1,13%
<b>Top 15 largest shareholders</b>	<b>36,812,795</b>	<b>61,79%</b>	<b>57,58%</b>
Other shareholders	22,767,292	38,21%	42,42%
<b>Total share</b>	<b>59,580,087</b>	<b>100,00%</b>	<b>100,00%</b>

## Size classes as of December 31, 2023

Size classes	No. of known shareholders	No. of shares	Holding, %	Votes, %	Proportion of known shareholders
1 - 100	9,418	353,517	0,59%	0,59%	50,08%
101 - 200	2,395	375,309	0,63%	0,63%	12,73%
201 - 300	1,363	351,258	0,59%	0,59%	7,25%
301 - 400	840	304,475	0,51%	0,51%	4,47%
401 - 500	817	388,031	0,65%	0,65%	4,34%
501 - 1,000	1,707	1,328,955	2,23%	2,23%	9,08%
1,001 - 2,000	1,046	1,579,325	2,65%	2,65%	5,56%
2,001 - 5,000	711	2,285,700	3,84%	3,84%	3,78%
5,001 - 10,000	260	1,925,868	3,23%	3,23%	1,38%
10,001 - 20,000	111	1,606,124	2,70%	2,70%	0,59%
20,001 - 50,000	75	2,392,718	4,02%	4,02%	0,40%
50,001 - 100,000	26	1,754,164	2,94%	2,94%	0,14%
100,001 - 500,000	21	4,323,482	7,26%	7,26%	0,11%
500,001 - 1,000,000	5	3,174,197	5,33%	5,33%	0,03%
1,000,001 - 5,000,000	9	16,546,859	27,77%	27,77%	0,05%
5,000,001 - 10,000,000	3	18,130,641	30,43%	30,43%	0,02%
10,000,001 - 50,000,000	0	0	0,00%	0,00%	0,00%
50,000,001 -	0	0	0,00%	0,00%	0,00%
Unknown holding size	0	2,759,464	4,63%	4,62%	0,00%
<b>Total</b>	<b>18,807</b>	<b>59580087</b>	<b>100,00%</b>	<b>100,00%</b>	<b>100,00%</b>



## TARPEYO: the first ever fully approved treatment for IgAN

Calliditas' lead product was granted full approval by the US Food and Drug Administration (FDA) in December 2023, becoming the first and only fully FDA-approved treatment for the autoimmune kidney disease IgA nephropathy (IgAN).

This product, which was developed under the name Nefecon<sup>®</sup>, is approved under the brand name TARPEYO<sup>®</sup> in the United States. TARPEYO was initially granted accelerated approval by the FDA in December 2021, becoming the first ever approved product in IgAN. Nefecon has also been granted conditional approval in China and in Europe, where it is approved under the brand name Nefecon and Kinpeygo<sup>®</sup>, respectively. Calliditas and its partner STADA have filed for full approval of Kinpeygo in Europe, and are expecting a decision on opinion from the Committee for Medicinal Products for Human Use in the first half of 2024.

### *The NeflgArd Trial*

Calliditas' regulatory filings for full approval with the FDA and European Medicines Agency (EMA) were based on positive data from the NeflgArd Phase 3 study. The trial read out positive topline data in March

2023, meeting its primary endpoint by demonstrating a highly statistically significant benefit in eGFR of Nefecon over placebo after 9-months of treatment and 15-months of follow-up off drug.

We were delighted to be able to publish our Phase 3 data trial in a peer-reviewed article in *The Lancet*. The full article, which can be accessed here, was published in August, prior to the International Symposium on IgA Nephropathy (IIgANN) in September and the largest annual meeting for nephrologists, the American Society of Nephrology's (ASN's) Kidney Week, in early November. We were extremely encouraged by the positive feedback we received from the countless interactions with physicians during these conferences. The strong kidney protective effect of Nefecon across the entire study population, which was sustained even after 15 months off drug, was commented on as being highly impressive and differentiated from all other drug candidates. Our updated label following the FDA granting full approval in December 2023 reflects these results, and we are excited for our sales force to be able to engage with nephrologists on the basis of our strong eGFR data.

### *NeflgArd Trial Design*

The NeflgArd trial was a pivotal, global Phase 3 trial

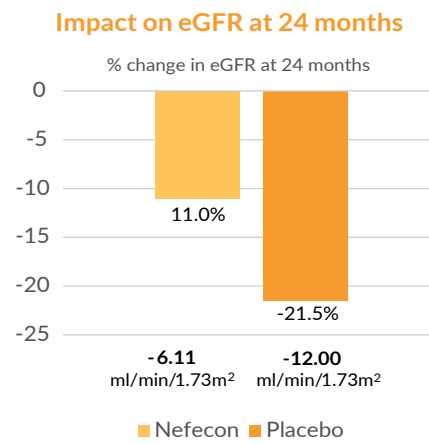
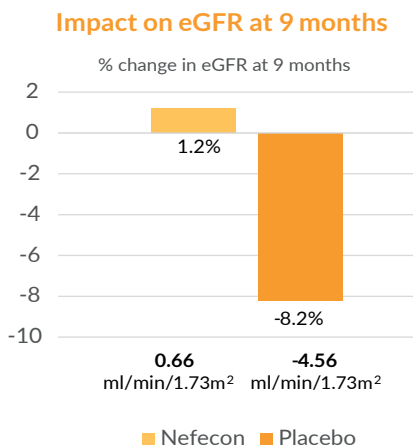
consisting of two readouts. An interim readout of efficacy and safety was conducted after 200 patients had been treated for 9 months. The primary endpoint was the effect of Nefecon on urine protein creatinine ratio (UPCR, otherwise known as proteinuria) over 9 months compared to placebo, and a key secondary endpoint was changes in estimated glomerular filtration rate (eGFR), a true measure of kidney function.

The final readout was conducted once a total of 364 patients had been treated for 9 months and then observed for an additional 15 months off drug. This post approval, confirmatory portion of the 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. All patients were on a background of optimized and stable renin-angiotensin system (RAS) inhibitor therapy. The patients were randomized in a 1:1 ratio into one of two treatment groups – Nefecon 16 mg/day orally or placebo

– and treated for nine months daily, and then monitored for 15 months off-drug.

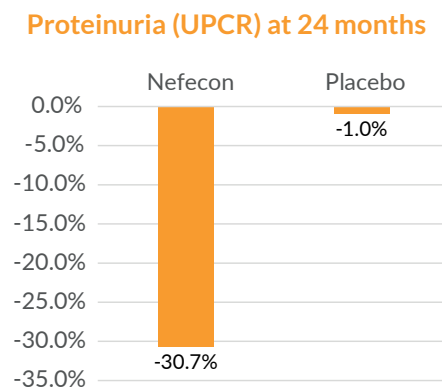
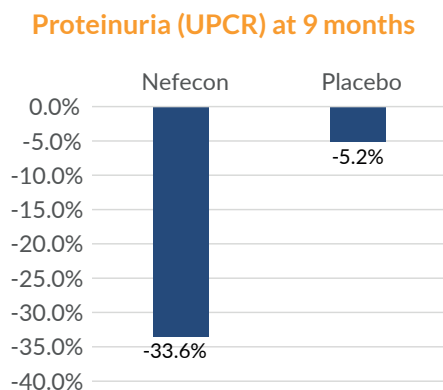
#### eGFR Data

The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in eGFR over the two-year period of nine months of treatment with Nefecon or placebo and 15 months of follow-up off drug. On average, eGFR over 2 years was 5.05 mL/min/1.73 m<sup>2</sup> higher with Nefecon compared to placebo (p<0.0001). Mean change in eGFR over the 2-year period was -2.47 mL/min/1.73 m<sup>2</sup> for Nefecon 16 mg versus -7.52 mL/min/1.73 m<sup>2</sup> for placebo. Supportive 2-year total slope analyses were statistically significant and clinically meaningful, reflecting a sustained treatment benefit. The eGFR benefit was observed across the entire study population, irrespective of UPCR baseline.



#### UPCR (Proteinuria) Data:

UPCR reductions observed were durable, reflecting a long lasting treatment effect during the 15 month follow-up period off treatment.



#### Safety Profile:

The results indicated that Nefecon was generally well-tolerated, and treatment-emergent adverse events were mostly mild to moderate in severity and reversible.

# TARPEYO's Commercial Journey

In 2023, Calliditas reached a pivotal milestone with the FDA approval of TARPEYO on December 20th. This approval established TARPEYO as the first and only approved treatment to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN), irrespective of proteinuria levels and with the potential to become a cornerstone for IgAN treatment.

In the US, TARPEYO achieved significant year-over-year growth in patient enrollments and new prescribers, with 1,753 patients enrolled for TARPEYO treatment and 997 new prescribers, signaling a strong demand for the product.

An essential facet of our work to bring TARPEYO to IgAN patients is our patient support service, TARPEYO Touchpoints, which aims to make TARPEYO accessible to patients in a timely fashion and offers a personalized experience for IgAN patients. The TARPEYO Touchpoints team comprises reimbursement specialists who navigate the insurance process alongside a group of nurses and pharmacists, all dedicated to guiding patients and physicians through the process of accessing TARPEYO.

In 2023, we increased our efforts in patient education and engagement around IgAN disease and TARPEYO, underscoring our strategic priorities. We continue to work with and support initiatives by recognized advocacy organizations, including the IgA Nephrology Foundation, NephCure, National Kidney Foundation, American Association of Kidney Patients, and American Kidney Fund.

Notably, in July, for the second consecutive year, Calliditas was a lead sponsor at the IgA Nephropathy Foundation's SPARK 2023 patient conference. Our long-standing support underscores our commitment to amplifying the foundation's mission of educating, empowering, and engaging the IgAN patient and caregiver community. Moreover, this year marked the introduction of our patient ambassador programs. Through this initiative, we strive to empower patients and enrich their understanding of their treatment options.

## 2023 KEY METRICS



**1753**

New Patients enrolled in 2023,  
69% YoY growth



**997**

New Prescribers in 2023  
LTD Prescribers: 1,637  
55% YoY growth



**\$101.4 M**

Annual net revenues for TARPEYO  
in 2023

Our medical and commercial teams made a significant impact by exhibiting and presenting at prominent nephrology conferences, including the International Society of Nephrology (ISN), National Kidney Foundation (NKF), European Renal Association (ERA), and American Society of Nephrology (ASN). These platforms provided Calliditas with invaluable opportunities to introduce new data and foster meaningful scientific discussions.

Furthermore, our data presentations were well-received, as evidenced by their acceptance and publication in leading scientific journals. These achievements underscore our commitment to advancing the treatment landscape for IgA nephropathy (IgAN) and reinforcing TARPEYO's role as a potentially disease-modifying therapy for IgAN.

In addition to the comprehensive data presented on TARPEYO, findings from RaDaR, a national registry of the UK rare kidney diseases, as well as data presented at ASN by Kaiser Permanente, one of the US's largest health plans, have shed light on the disease progression of IgA nephropathy. These studies highlight that nearly all patients with IgAN are at risk of kidney failure in their lifetime, irrespective of proteinuria levels.

This reinforces the need for effective treatments like TARPEYO. As the only approved immunomodulating therapy, TARPEYO is uniquely designed to address the production of pathogenic Gd-IgA1, yielding significant eGFR benefit. TARPEYO's integration as a cornerstone therapy, alongside standard supportive care, is critical to addressing the underlying autoimmune mechanisms driving IgAN.

## SCIENTIFIC HIGHLIGHTS

Full Results from the NeflgArd Phase 3 trial published in The Lancet

THE LANCET

7 Presentations at IIGaNN with analysis from NeflgArd Phase 3 trial and biomarker data



Biomarker Data from Phase 2 NEFIGAN trial published in KI

Targeted-release budesonide modifies key pathogenic biomarkers in immunoglobulin A nephropathy: insights from the NEFIGAN trial



7 abstracts presented at ASN. Peer-reviewed publication on Nefigan biomarker data and comparative dissolution of TARPEYO



## AN EXCITING JOURNEY AHEAD



KDIGO Guidelines Update expected in 2024



Ability to promote full approval label with recently increased field organisation



Open Label Extension (OLE) data from patients with a second 9 month treatment

Readout expected in H1 2024



## A Conversation with Cathrin, a TARPEYO Patient

### **When were you initially diagnosed with IgAN? How did you feel when you received this diagnosis?**

I was shocked by my IgAN diagnosis. I am from the UK, but now I live with my husband and our foster dogs in Alabama. When I was planning my move to the US, I had to complete a Visa health assessment. Through those routine medical exams, it was discovered that I had increased protein levels in my urine, which ultimately led to my diagnosis. In retrospect, I had identified blood in my urine a few times before, but I never really thought anything of it because I always felt healthy.

At the time of my diagnosis, I was devastated. I was diagnosed with IgAN in 2011. This was years ago, so the research and treatment options available at the time were way behind what they are now. The thought of being on medication for the rest of my life when I was only 25 was scary. My dad had struggled with his renal health, so I saw what this type of journey could entail.

### **How has living with IgAN impacted you?**

Because of the pandemic and my travel schedule, I lost

access to my treatment for a while. I immediately started seeing blood in my urine again. Seeing something like that is so frightening, I can't even begin to explain. What is more frightening though, is the impact that IgAN could have on my life.

Trying to preserve my kidney health so my disease doesn't progress to the point of me needing dialysis or a transplant is very important to me. I am an astrophotographer, which means I am lucky enough to help share the beauty of the universe with others through my paintings and exploration trips. I also love music; I used to DJ regularly across the world. I live a fast and full life with lots of travel and spontaneity, so it is very important to me that my IgAN is well managed.

### **What has your treatment journey been?**

I worked with a nephrologist who recommended taking ACE inhibitors. My kidney function at the time was just below normal. However, despite the efforts to treat my IgAN with some medicines, as well as changing my diet, I didn't see the results I wanted. My husband and I have been talking about trying to start a family, so I knew it wasn't enough to just watch and wait for my disease to progress—it was time to take control of the process.



“After years of being told there was no medicine for IgAN, hearing about a treatment that targeted the potential source of my disease felt like I had a path forward again.”

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### **What is your relationship with your nephrologist like?**

Where I live, there aren't many experts in this disease, so I prioritized finding someone who could help me. My doctor was actually one of my painting clients and it was by accident that we got talking. He mentioned he was a nephrologist, and we went from there. I travel to him out of state, and we've built a great relationship. He said that the goal of my treatment was to keep my eGFR in the normal range as an indicator to help keep my kidneys were functioning properly.

### **How did you feel when your doctor told you about TARPEYO as a treatment option?**

After my diagnosis, I worked with a nephrologist who recommended taking ACE inhibitors. My kidney function at the time was just below normal.

When my nephrologist told me about TARPEYO, he mentioned that the studies looked promising, specifically the long-term data once treatment had ended. I read pretty much everything I could online including looking at all the studies. The videos online explaining how TARPEYO works even taught me a lot about the condition.

After years of being told there was no medicine for IgAN, hearing about a treatment that targeted the potential source of my disease felt like I had a path forward again.

Because TARPEYO is a 9-month course, I feel like I'm doing what I can now and then will start trying for kids when my 9-month treatment cycle is complete, and my doctor is comfortable with that plan.

### **How did TARPEYO work for you?**

My doctor and I are happy with the results we have seen so far! My kidney function is relatively unchanged

and the protein and blood in my urine has decreased significantly. At first, I experienced a few minor side effects, but my nephrologist worked with me to find a solution. I was grateful that my doctor worked with me the whole time to make sure I was well-prepared for the experience.

He warned me that I would likely not see results immediately. But fortunately, I did see positive results on my labs at my first appointment after three months of treatment. He also let me know that TARPEYO may keep impacting my results even after I had completed my nine months on the treatment.

I've also been paying attention to my health while taking TARPEYO and I'm happy to say that I'm feeling really good.

### **How was your experience with the TARPEYO Touchpoints program?**

After I was prescribed TARPEYO, I worked with the TARPEYO Touchpoints team. They walked me through the process. Initially my insurance actually denied my claim, but after a follow-up, they accepted the appeals letter. My treatment with TARPEYO is completely covered and I have a \$0 copay.

Within a few weeks, TARPEYO was mailed straight to my home and each month it is shipped to me directly.

### **How do you feel about your disease now that you've been able to use TARPEYO as a treatment option?**

In just a few months, I will finish my treatment with TARPEYO. I am feeling really good, and I am excited to build my family. Now I can confidently say, my IgAN is in my hands.

# Overview of the disease

IgA nephropathy (IgAN) – also known as Berger’s disease – is the most common form of glomerulonephritis, a chronic inflammatory condition of the kidney, in the Western world.

## IgAN Disease Background

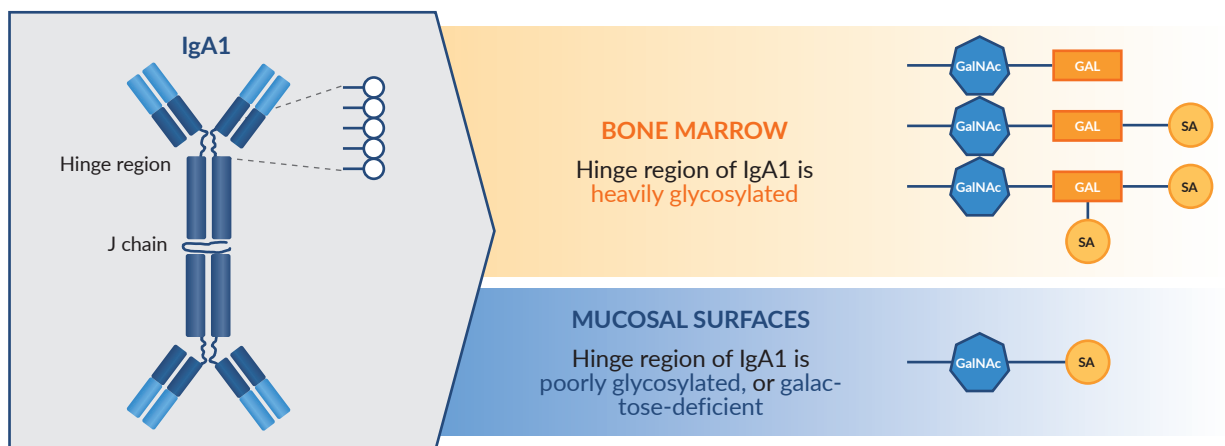
IgAN is a serious progressive autoimmune disease of the kidney. A recently published registry analysis<sup>1</sup> showed that most patients with IgAN progress to kidney failure within 10–15 years, irrespective of age at diagnosis, with a median time to kidney failure of approximately 10 years. Even patients with relatively low levels of proteinuria, previously considered “benign”, have been shown to be at significant risk of kidney failure in the long-term, underscoring the need for disease-modifying treatments for the disease.

IgAN is an orphan disease that we estimate affects up to 130,000 – 150,000 people in the US and up to 200,000 people in Europe. A significantly higher prevalence of IgAN has been observed in Asia, including in Greater China, where it has historically been a leading cause of ESRD and where it is estimated that IgAN affects approximately 5,000,000 people.

## IgAN Pathophysiology

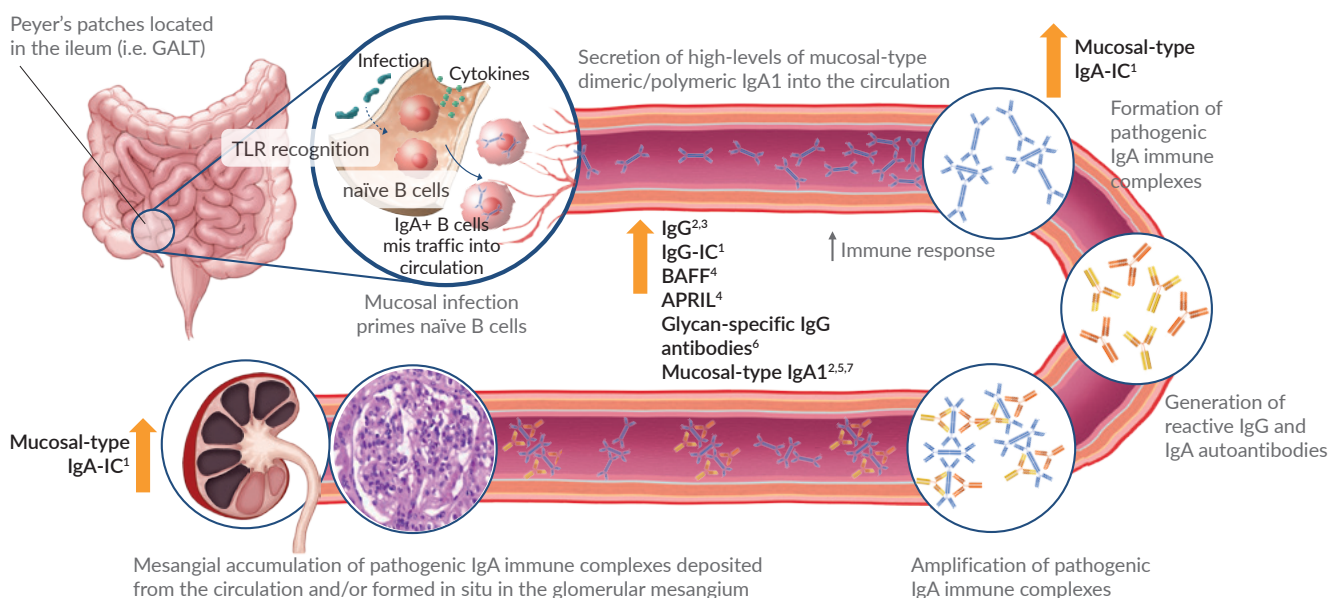
Although IgAN manifests in the kidney, the evidence indicates that it is a disease that starts in the distal part of the intestine, specifically in the ileum. Peyer’s patches, which are concentrated within the gut-associated lymphoid tissue in the ileum, have been identified as a major source of mucosal-type IgA1 antibodies. IgA1 antibodies play a key role in the immune system, protecting the body from foreign substances such as food-derived factors, bacteria and viruses. Patients with IgA nephropathy have elevated levels of mucosal-type IgA, and studies have shown that the type of IgA that deposits in the glomeruli in patients with IgAN is identical to the mucosal-type IgA produced in the gut.

The majority of the IgA in the blood circulation is monomeric, heavily O-galactosylated and is derived from bone-marrow-residing plasma cells. In contrast, the mucosal-type IgA antibodies produced by the Peyer’s patches are predominately dimeric or polymeric and are galactose deficient. In IgAN patients, a combination of a genetic predisposition and of environmental, bacterial and dietary factors is presumed to lead to an increased production of these galactose-deficient IgA



The structure of IgA antibodies varies depending on where they are produced

<sup>1</sup> CJASN 18: 727–738, 2023



antibodies. This increased production, potentially in conjunction with increased intestinal permeability, leads to these antibodies appearing in the blood.

The galactose-deficient spot at the hinge region of the IgA antibodies is immunogenic when found in the circulation. It therefore generates an autoimmune response, attracting autoantibodies in the form of IgG or IgA and forming pathogenic immune complexes that deposit in the glomeruli, the kidney's filtration apparatus. The trapped immune complexes initiate an inflammatory response which damages the kidney and ultimately destroys its filtration mechanism. This leads to slow, progressive deterioration of renal function, which in many patients ultimately results in the need for dialysis or kidney transplant.

### Treatment landscape for IgAN patients

Kidney Disease Improving Global Outcomes 2012 (KDIGO) recommended the use of blood pressure lowering agents that inhibit or block the renin-angiotensin system (RAS) using either angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs). RAS blockade became the standard

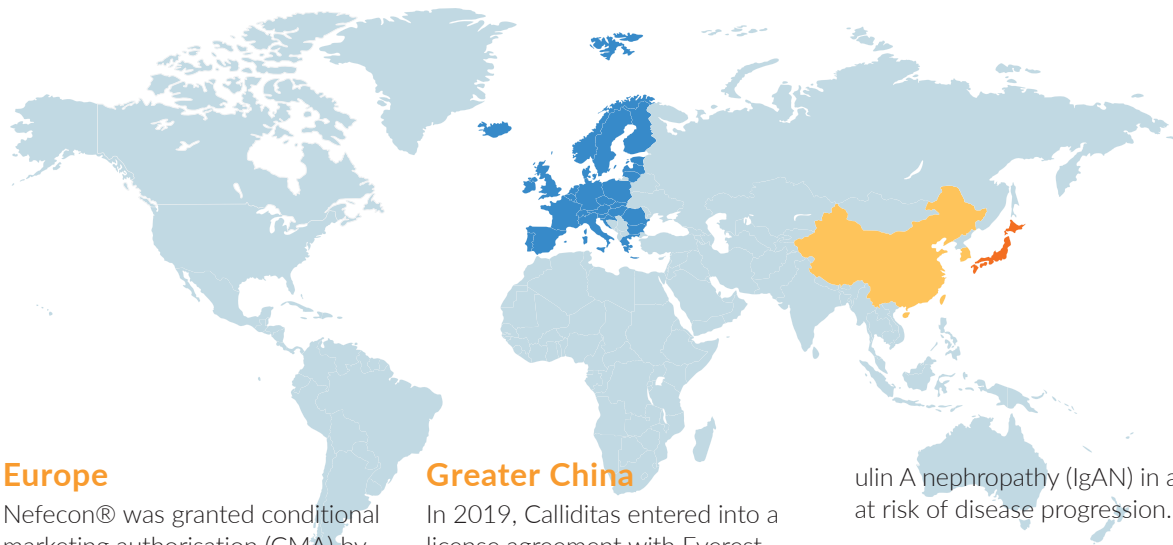
of care for IgAN. This treatment reduces the pressure in the kidney glomeruli, thereby reducing leakage and protein excretion in urine. However, treatment via RAS inhibition is primarily supportive and does not address the underlying cause of IgAN.

The KDIGO guidelines are currently being revised, and we anticipate the inclusion of TARPEYO into the Guideline for the Management of Glomerular Diseases when an update is made in 2024.

### Nefecon is designed to target the origin of the disease

Nefecon is an oral, delayed release formulation of budesonide, an immunomodulator with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism (90%), resulting in limited systemic exposure. It was designed as a delayed release capsule with an enteric coating so that it remains intact until it reaches the ileum. Each capsule contains beads coated with various polymers and budesonide designed to target the area with the highest concentration of Peyer's patches, with the intention of having a disease-modifying effect.

# Our Commercial Partnerships



## Europe

Nefecon® was granted conditional marketing authorisation (CMA) by the European Commission in July 2022, and subsequently by the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom in February 2023, under the brand name Kinpeygo® for the treatment of IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) >1.5 g/gram, becoming the first approved treatment for IgAN in the EU.

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

Following the positive data readout from the full NeflgArd trial and the submission of an sNDA to the FDA, Calliditas is collaborating with STADA to seek full approval of Kinpeygo by the European Commission and the MHRA in the full study population. An opinion from the CHMP is expected in the first half of 2024.

## Greater China

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

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

In October 2023, Everest received approval for Nefecon in IgAN patients at risk of disease progression from the Pharmaceutical Administration Bureau of the Macau Special Administrative Region, making it the first region in Everest territories that received Nefecon approval. On November 24 2023, Everest announced that China's National Medical Products Administration (NMPA) conditionally approved Nefecon® for the treatment of primary immunoglob-

ulin A nephropathy (IgAN) in adults at risk of disease progression.

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 NeflgArd 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 Viartis Pharmaceuticals Japan, a subsidiary of Viartis Inc. (Nasdaq: VTRS). Viartis is a global healthcare company which is headquartered in the United States and has a presence in over 165 countries and territories, and also operates approximately 40 manufacturing facilities.



## Interview with Mr Rogers Luo, CEO Everest Medicines

### **The conditional approval of Nefecon by the NMPA was a great milestone for IgAN patients in China. What was the process like to bring about this approval?**

The approval is a great collaboration between different departments such as regulatory affairs, clinical development as well as our partner Calliditas to provide Chinese patients with first-in-disease treatment option for IgAN. There are estimated 5 million IgAN patients in China. Due to our teams' joint efforts, Nefecon® was the first non-oncology medicine to receive Breakthrough Therapy Designation in China and was also granted Priority Review status, which helped facilitate the NDA approval. Because of Nefecon, the CDE has started to accept the surrogate endpoint as the basis for accelerated drug approval in the field of nephrology, which will benefit the research and development of new drugs in this field in the future.

### **What kind of feedback has the Everest team received from the early access patient program in Hainan?**

The success of the early access program exceeded our expectations. Without any sales representatives and despite the inconvenience of flying out to Hainan's Boao, there were approximately 700 patients signed up for the program. This strong demand underscores the urgent and significant unmet medical needs among the large IgAN patient base in China.

### **What has the reaction been to Nefecon's approval?**

Chinese doctors and patients have been very excited about Nefecon's approval as they finally have an approved drug with an IgAN indication to treat the disease. Unfortunately, current treatment options for IgAN, such as renin-angiotensin system (RAS) inhibitors, are non-targeted and cannot fundamentally alter disease progression. Additionally, Chinese IgAN patients are at risk of faster disease progression under conventional treatment, and the Phase 3 clinical study showed that 9 months of Nefecon® treatment can lead to approximately 66% less deterioration in kidney function in the Chinese subgroup at 24 months vs. 50% in the global IgAN population. Patients treated with Nefecon® in China also showed a 43% greater reduction in UPCR compared with placebo at 24 months, compared to 30% greater reduction in UPCR in the global population. The proportion of Chinese patients without micro-hematuria in the Nefecon® group increased from 26.9% at baseline to 57.7% during observational follow-up, according to the subgroup analysis. These data support more urgent need for Nefecon® in China.

### **What kind of feedback have you received from nephrologists in China?**

Nephrologists in China are very excited about Nefecon's approval. As a B-cell immunomodulator targeting the origin of the disease and

reducing the production of Gd IgA1 antibodies, nephrologists in China all agree that Nefecon's clinical data and sales overseas in 2022 and 2023 have shown significant benefits for IgAN patients. The treatment will open a new chapter for IgAN treatment in China. In addition, due to its targeted nature and high first-pass metabolism, Nefecon® can avoid the adverse effects of systemic glucocorticoids with limited suppression of the immune system.

### **How has the Everest team prepared for the launch of Nefecon on the Chinese market?**

Since Hainan Bo'ao EAP program start in April 2023, we have been educating both patients and doctors on IgAN. With approximately 700 patients signed up for EAP, we have already established Nefecon® as a go-to treatment for IgAN patients in China. With about 20,000 patients registered in an IgAN program funded through a charity foundation, we understand there is significant patient demand. Everest already has an integrated central commercial platform ready for Nefecon's launch in China. We have started building out the front-line sales team and is accelerating supply chain preparations to launch Nefecon® in the Chinese market soon.

### **How many sales people are you planning to deploy initially for the launch?**

We will gradually build up the sales team for Nefecon® launch in China over 2024, with up to 120 sales representatives by end of the year, covering core hospitals. We have already established a centralized commercial platform including medical affairs, marketing and market access that is also essential to the launch.

### **What are the key components of a successful commercial launch of Nefecon?**

Everest Medicines is committed to adopting the best commercialization practices in the industry to benefit the most patients quickly and efficiently. We have built an efficient and focused commercial infrastructure that includes highly experienced and capable teams in channel and commercial operations, marketing, market access, medical affairs, and sales, as well as logistics and quality control to ensure all perspectives are well covered for successful commercial launch of our products. We will also accelerate commercialization through strategic partnerships and enhance patient access through patient access programs, commercial insurance coverage and national reimbursement drug listing, and national reimbursement drug listing.



## Expanding TARPEYO's Intellectual Property

**In December 2023, United States Patent and Trademark Office (USPTO) issued a notice of allowance for Calliditas' patent application.**

The USPTO subsequently issued patent no. 11896719, entitled "New Pharmaceutical Compositions", on January 24, 2024 with validity as of February 13, 2024. This became Calliditas' second patent for TARPEYO in the United States, and provides product protection until 2043.

The patent covers a method of treating IgA nephropathy with a composition that encompasses TARPEYO® (budesonide) delayed release capsules, developed under the name "NEFECON®". The patent has been listed in The Orange Book.

Calliditas intends to file corresponding patent applications in additional territories around the world, including Europe and China.

Following TARPEYO's full approval in December 2023, the FDA has also granted a seven year orphan drug exclusivity period for TARPEYO, which will expire in December 2030.

Following full approval in December 2023, TARPEYO® (budesonide) is indicated "to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression". The orphan drug exclusivity period reflects the new indication, which covers all adult patients with primary IgAN at risk of disease progression based on a confirmed reduction of kidney loss reflecting a clinical benefit on kidney function for adult patients with primary IgAN.

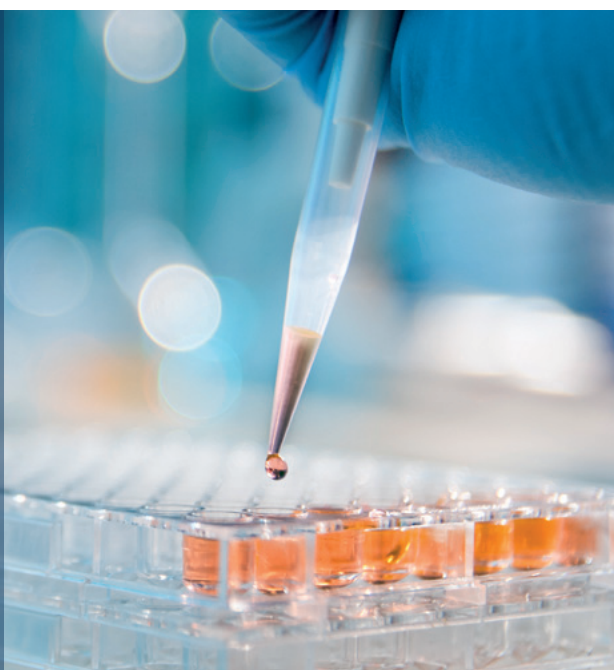
# IgA nephropathy - a significant market opportunity

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.

- 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.<sup>1</sup>
- 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.<sup>2</sup>
- 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.

## 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



<sup>1</sup>Veeva OpenData for 2023, including all active HCPs where the primary specialty is Nephrology  
<sup>2</sup>Spherix RealWorld Dynamix

# Pipeline: NOX Inhibitor Platform

Calliditas' pipeline consists of development programs based on a first-in-class NOX inhibitor platform. Calliditas is presently running clinical trials with lead compound setanaxib in squamous cell carcinoma of the head & neck (SCCHN), which read out interim data in July 2023, as well as in primary biliary cholangitis (PBC) and Alport syndrome. There is also an investigator-led trial investigating setanaxib in idiopathic pulmonary fibrosis (IPF).

## NOX Enzyme Inhibitors

NOX enzyme inhibitors are a set of promising novel experimental drugs in a new therapeutic class, recognized by the WHO since 2019 when it approved "naxib" as a new stem. Nicotinamide adenine dinucleotide phosphate (NADPH) oxidases, otherwise known as NOX enzymes, are the only known enzymes that are solely dedicated to producing reactive oxygen species (ROS) as their primary function. They are transmembrane enzymes that transfer electrons from NADPH in the cytoplasm across the cell membrane, which results in the formation of ROS.

At appropriate concentrations, ROS have essential functions in cellular signaling processes, but disruption of the redox homeostasis has been implicated

in multiple disease pathways. When a cell is injured, excess NOX activity is triggered and redox homeostasis becomes unbalanced, leading to activation of pro-fibrogenic pathways. Cancer-associated fibroblasts in the tumor microenvironment also express NOX enzymes, which can result in tumors with low immunological activity and relative resistance to the effects of immuno-oncologic agents, such as checkpoint inhibitors. Setanaxib, which is the first drug candidate to reach the clinic from the NOX platform, is designed to specifically reduce ROS, which is implicated in fibrosis and inflammation pathways.

## Lead Compound Setanaxib, First NOX Inhibitor to Reach Clinical Stage, with Milestones Expected within 12 Months

### PHASE 2 STUDY IN H&N CANCER

Proof of concept study in SCCHN cancer with positive CAF level

50-patient study with setanaxib + pembrolizumab or placebo + pembrolizumab

Supportive interim readout

Final Phase 2 data expected in Q2 2024

### TRANSFORM TRIAL IN PBC

Ongoing Phase 2b Primary Biliary Cholangitis (PBC) trial

Protocol to be amended to enable data readout after Phase 2b portion

Data readout expected in Q3 2024

FDA Fast Track designation

### ADDITIONAL INDICATIONS

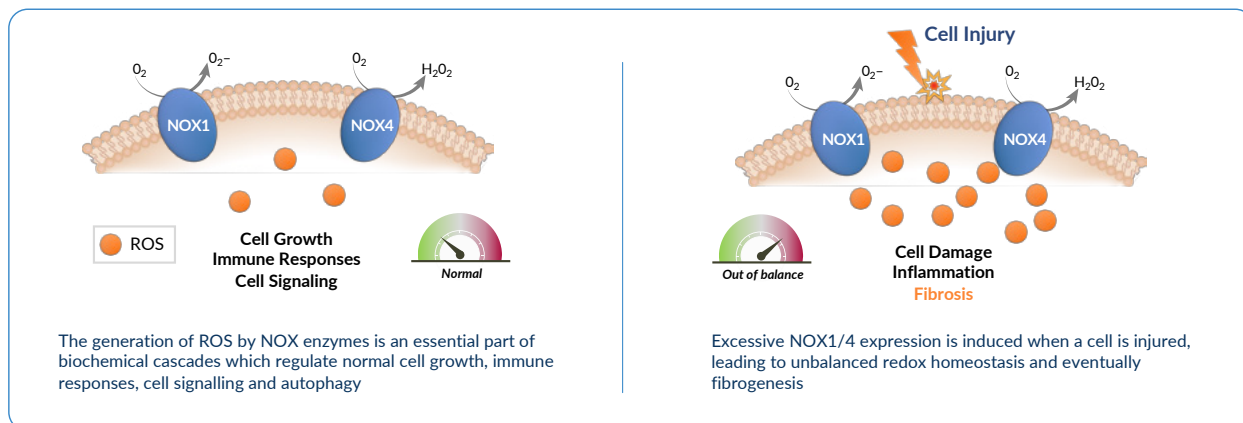
Setanaxib evaluated in a Phase 2 trial in IPF (Investigator-led trial).

Data expected in Q4 2024

Phase 2 trial initiation in Alport Syndrome in November 2023



## NOX (NADPH OXIDASE) ENZYMES CATALYZE THE CONVERSION OF OXYGEN INTO REACTIVE OXYGEN SPECIES (ROS)



### Alport Syndrome

Alport syndrome is a genetic disorder arising from the mutations in the genes that code for type 4 collagen. The type 4 collagen alpha chains are primarily located in the kidneys, eyes, and cochlea, and thus the condition is characterized by kidney disease, loss of hearing, and eye abnormalities. Eventually, patients present with proteinuria, hypertension, progressive loss of kidney function (gradual decline in GFR), and end-stage renal disease (ESRD).

It is estimated that approximately 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 in vivo pre-clinical work, Calliditas launched a randomized, placebo-controlled clinical trial in Alport syndrome including around 20 patients, evaluating overall safety as well as impact on proteinuria. The study was initiated in November 2023, and on the basis of the data readout Calliditas 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

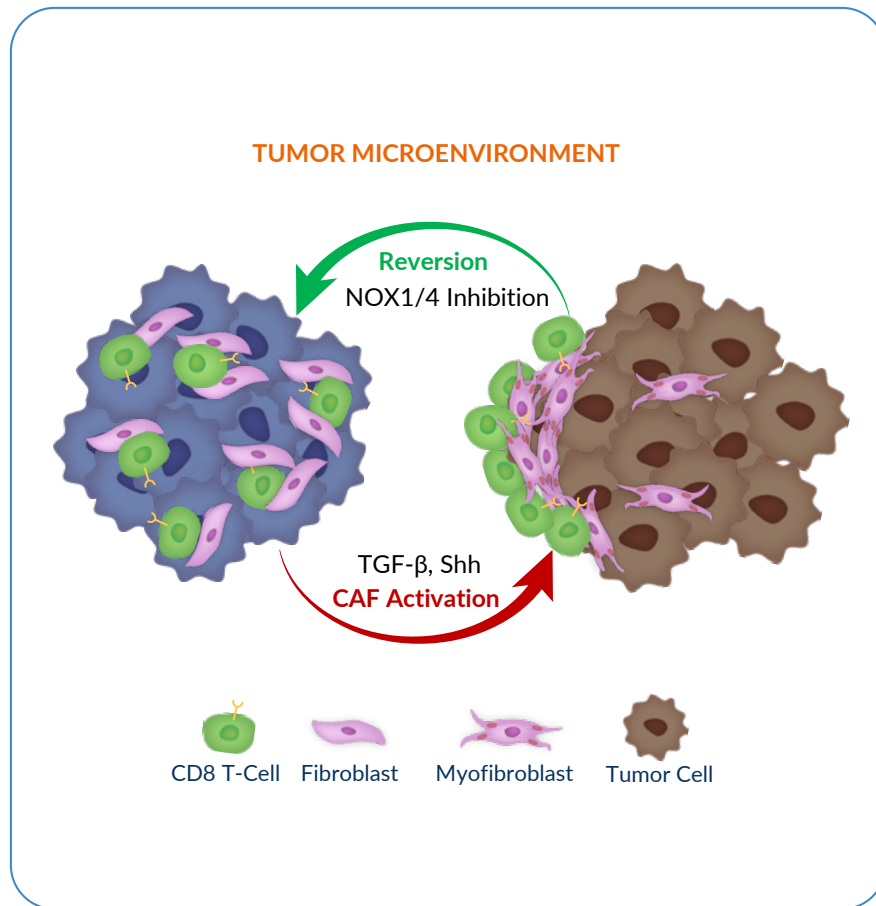
PBC is a progressive and chronic autoimmune disease of the liver that causes a cycle of immune injury to biliary epithelial cells, resulting in cholestasis and fibrosis. It is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 140,000 patients in the US, where the annual incidence ranges from 0.3 to 5.8 cases per 100,000. Calliditas received FDA Fast Track Designation for setanaxib in PBC in August 2021.

Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, known as Ocaliva, are the only treatments for PBC approved by the FDA and the European Commission. However, despite these treatment options, there is still an unmet medical need among PBC patients, in particular when it comes to important quality of life outcomes.

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

Calliditas is conducting a randomized, placebo-controlled, double-blind Phase 2b trial in PBC patients with elevated liver stiffness. We are expecting to read out data in Q3 2024.

<sup>4</sup> Watson S, Padala SA, Hashmi MF, et al. Alport Syndrome. [Updated 2023 Aug 14]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK470419/>



## Setanaxib in head and neck cancer

A patient's response to immunotherapy can be affected by the tumor microenvironment, especially by the number of tumor-infiltrating lymphocytes (TILs) and cancer-associated fibroblasts (CAFs). The relationship between CAFs and prognosis in squamous cell carcinoma of the head and neck (SCCHN) has been established, with NOX4 highly overexpressed in CAFs. This overexpression drives myofibroblastic activation within tumors and shields them from CD8+ TILs. Calliditas is evaluating setanaxib in a clinical study in head and neck cancer, building on promising in vivo preclinical data that suggests that setanaxib could significantly enhance the effects of immune-oncology therapies.

We are conducting a double-blind, randomized, placebo-controlled, proof-of-concept Phase 2 study, which is investigating the effect of setanaxib 800mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks, in at least 50 patients with relapsed or metastatic SCCHN and tumors with moderate or high levels of cancer-associated fibroblasts.

A tumor biopsy is taken prior to randomization and again after approximately 9 weeks of treatment. Treatment will continue until unacceptable toxicity or disease progression, in keeping with standard practice for oncology trials. Calliditas read out interim data from the study in July 2023, and expects to read out final trial data in Q2 2024.

### Interim Readout

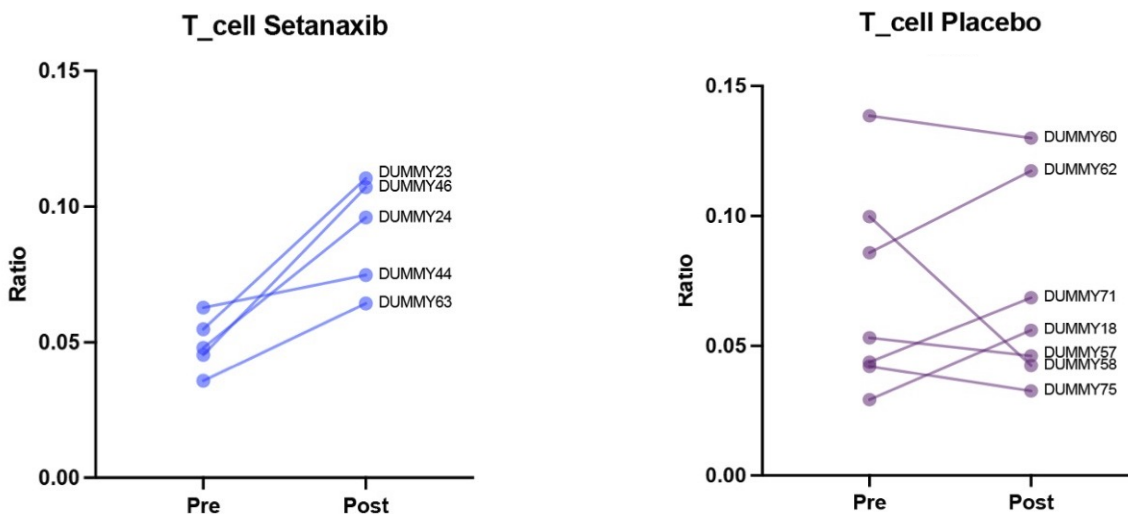
In July 2023, Calliditas read out interim data from the trial, which reflected encouraging early clinical progression-free survival (PFS) results and supports the presumed anti-fibrotic mode of action of setanaxib. The basis for the analysis consisted of a data set of 20 patients with recurrent or meta-static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

The transcriptomic analysis showed that the two top pathways impacted by the treatment were fibrosis related signalling pathways (the Idiopathic Pulmonary Fibrosis Signaling Pathway and Hepatic Fibrosis/Hepatic Stellate Cell Activation Pathway), providing support for the presumed mode of action on activated cancer associated fibroblasts in head and neck cancer,

as well as a potential anti-fibrotic effect in Calliditas' other ongoing clinical programs. Pathology analysis showed preliminary evidence of an increase in immunological activity within tumors of patients treated with setanaxib, with favorable changes in Foxp3 and PDL-1 CPS.

As SMA levels at baseline were not balanced between the groups, and tumor biopsy samples were generally small, it was not possible to draw any conclusions regarding setanaxib's impact on SMA reduction. In terms of PFS, 7 out of the 16 evaluable patients were progression-free with either stable disease or partial response, of which 6 were in the setanaxib arm and 1 was in the placebo arm. 6 of the 7 patients were still on the study drug at the time of the data readout, with the longest period on drug being reported as 21 weeks, related to a patient in the setanaxib arm.

## Increased Number of T-Cells Penetrating Tumor in Patients on Setanaxib Treatment





## Calliditas Vice President Regulatory Affairs Frank Bringstrup

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


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

Considerations from a commercial perspective based on the data were included and implemented in the storyline for the high-level documents, so that the turn-around for the submission was fast, and at the same time we could ensure that the dossier would be

optimised for negotiations for a competitive label. A request for Priority Review was included with the filing for full approval and was granted by FDA, and this, in combination with the early submission, enabled an approval date in December 2023.

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

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



“My primary focus has been to get fast to the market with first cycle approvals and competitive labelling. It is critical for patients, as well as for Calliditas’ success.”

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

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

From the outset of the China NDA review process, an internal Calliditas-Everest pre-defined ‘Q&A’ process was put in place, so as to ensure that we could collaborate on an optimal response strategy for any questions from the regulatory authority to effectively manage the response preparations. This regulatory ‘Q&A phase’

was managed successfully, and in November 2023 the NMPA approved Nefecon® for the treatment of primary IgAN in adults at risk of disease progression.

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

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



# Future-proofing our sustainability work

The most important thing Calliditas does, from both a business and a sustainability perspective, is to develop and offer medicines that improve the quality of life for patients with rare kidney and liver diseases. The fact that our core business contributes to improving people's lives is of great value in itself. But we do not settle for that. Proactive sustainability work means considering all perspectives: impacts, risks, and opportunities – both for the environment and our people throughout our local and global value chain as well as for Calliditas as a company.

### **Greater focus on sustainability**

During the year, we stepped up our sustainability work and worked purposefully and with a long-term approach to set focus areas and targets to increase the understanding of our footprint, including where and what we impact and how this in turn impacts us. This in-depth knowledge enables us to focus on where we can have the greatest positive impact.

One of the driving forces behind our work has been the upcoming EU sustainability reporting requirements – the Corporate Sustainability Reporting Directive (CSRD) and the European Sustainability Reporting Standards (ESRS). These mandatory requirements will place demands on our work with and the reporting of our most material sustainability matters.

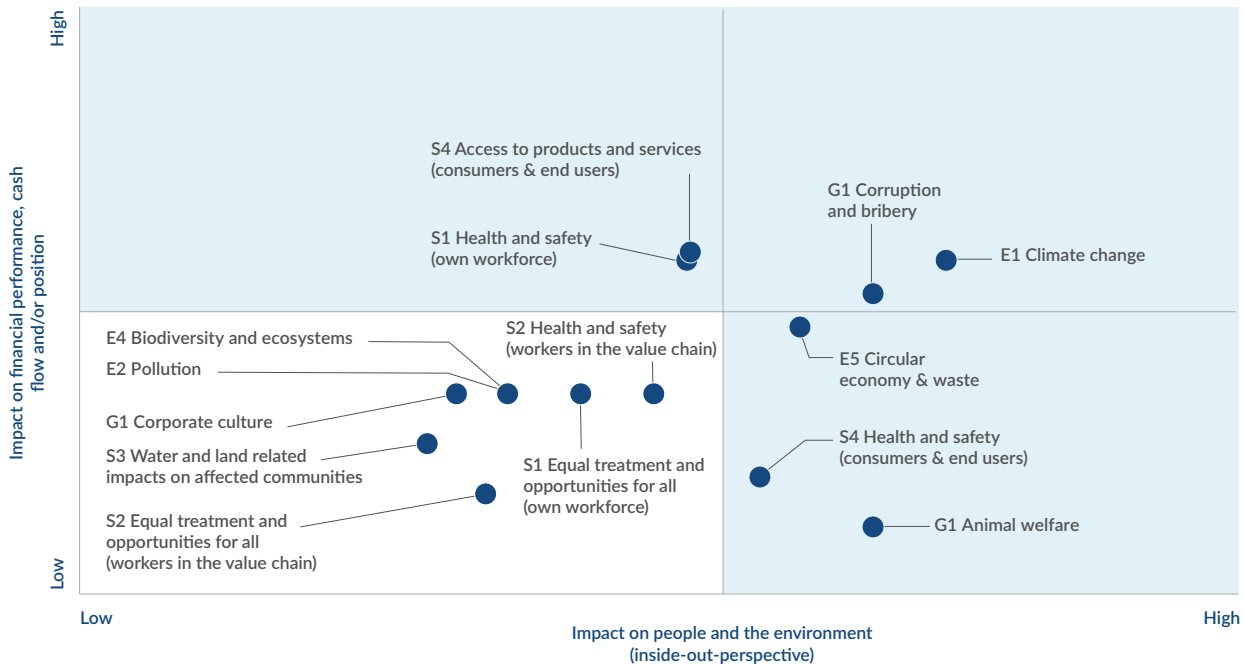
### **Management involvement is becoming increasingly important**

Change management in a company has the greatest impact when the management team and board are actively involved. This is why our management and board were trained in the CSRD and ESRS requirements during the year. In addition, some of the management team were actively involved in further developing our sustainability approach during the year.

### **Double materiality assessment**

To drive Calliditas' sustainability work forward, a double materiality assessment was conducted in 2023. Double materiality involves considering both the impact on people and the environment, and the impact on the company's financial performance.

The line intersection in the matrix represents the materiality threshold. The sustainability matters in the blue shaded area are considered to be material



The first step in the assessment was to define and understand Calliditas’ context from a sustainability perspective. This involved understanding which sustainability matters Calliditas’ operations have an impact on, and which sustainability matters Calliditas in turn is impacted by. Based on internal and external sources, such as internal policies and competitor analyses, a list of potential material sustainability matters was created.

Each sustainability matter on the list was then assessed based on its impact on people and the environment as well as the impact on Calliditas’ financial performance. The assessment covered both positive and negative impact, whether it is actual or potential, and where in the value chain the impact occurs. Furthermore, consideration was given to the scale and scope, irremediable character, and probability of each sustainability matter.

Each sustainability matter was mapped in a matrix and then validated by a group of Calliditas managers with relevant expertise. The threshold to determine which matters are considered to be material were defined and validated by the group and approved by the CEO.

**Calliditas’ material sustainability matters**

The methodical double materiality assessment concluded that Calliditas’ sustainability impact is in seven main areas, which in turn are divided based on whether the impact is related to environmental, social or governance. These material sustainability matters will

guide Calliditas’ strategic sustainability work and sustainability reporting going forward.

**Environmental**

- Climate change
- Circular economy and waste

**Social**

- Health and safety of own workforce
- Provide access to Calliditas’ products for customers and end-users
- Health and safety of the end-users of Calliditas’ products

**Governance**

- Corruption and bribery
- Animal welfare

**A forward-looking perspective**

The completion of the double materiality assessment ensures that Calliditas will focus on the sustainability matters where Calliditas’ impact is greatest and where activities are necessary to future-proof the company.

In 2024, we will take further steps towards reporting in accordance with CSRD and ESRS to prepare the organization and ensure that data collection processes are in place. Calliditas can expect to be subject to the new legal requirements from the 2025 financial year

# Board of Directors' Report

The Board of Directors and the CEO of Calliditas Therapeutics AB (publ), with its registered office, in Stockholm, Sweden and Corporate Registration Number 556659-9766, hereby submit the Annual Report and consolidated financial statements for the fiscal year 2023. All amounts are expressed in SEK millions unless otherwise stated.

## Multi-Year Summary, Group

	2023	2022	2021	2020	2019
Net sales (SEK in thousands)	1,206,888	802,879	229,347	874	184,829
Loss before income tax (SEK in thousands)	(457,017)	(409,417)	(513,373)	(436,151)	(32,501)
Total assets (SEK in thousands)	1,859,245	1,952,973	1,459,910	1,463,908	845,200
Average number of employees	181	86	56	23	14

## Multi-Year Summary, Parent Company

	2023	2022	2021	2020	2019
Net sales (SEK in thousands)	805,551	548,977	229,347	874	184,829
Loss before income tax (SEK in thousands)	(273,518)	(208,548)	(354,405)	(407,363)	(36,186)
Total assets (SEK in thousands)	2,255,130	2,173,639	1,528,439	1,318,525	838,249
Average number of employees	58	45	29	15	13

## Operations

Calliditas Therapeutics is a commercial stage biopharma company based in Stockholm, Sweden focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs.

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

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

IgA nephropathy is the most common primary glomerulonephritis worldwide, so the market potential for Nefecon is substantial, as evidenced by our early commercial success and out-licensing deals with potential payments exceeding USD 300 million, encompassing upfront payments and predefined milestones, as well as ongoing royalty obligations.

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



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

The group consists of the parent company Calliditas Therapeutics AB, the American subsidiaries Calliditas NA Enterprises Inc, Calliditas Therapeutics US Inc, the French subsidiary Calliditas Therapeutics France SAS, the Swiss subsidiary Calliditas Therapeutics Suisse S.A. The Swedish subsidiary Nefecon AB, had no ongoing operations.

## Significant Events During the Year

### First Quarter

In February 2023, Calliditas announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom granted Conditional Marketing Authorisation (CMA) for Kinpeygo® for the treatment of immunoglobulin A (IgA) nephropathy in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$ g/gram. Kinpeygo became the first and only approved treatment for IgAN in the UK.

In March 2023, Calliditas announced positive topline results from the global, randomized, double-blind, placebo-controlled Phase 3 clinical trial NeflgArd, which investigated the effect of Nefecon (TARPEYO®/Kinpeygo® (budesonide) delayed release capsules) versus placebo in patients with primary IgA nephropathy (IgAN).

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

### Second Quarter

In June 2023, Calliditas announced the submission of a supplemental New Drug Application (sNDA) to the US Food and Drug Administration (FDA) seeking full approval of TARPEYO (budesonide) delayed release capsules (developed under the project name Nefecon)

for the entire study population evaluated in the Phase 3 NeflgArd study. The sNDA submission was based on the full data set from the Phase 3 NeflgArd clinical trial, a randomized, double-blind, multicenter study which assessed the efficacy and safety of Nefecon dosed at 16 mg once daily versus placebo on a background of optimized RASi therapy in adult patients with primary IgAN.

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

### Third Quarter

In August, full data from the Phase 3 NeflgArd study with Nefecon® (TARPEYO®/Kinpeygo®) was published in The Lancet.

In September STADA and Calliditas announced the filing of the application for full marketing authorisation of Kinpeygo in the EU.

### Fourth Quarter

In November, Calliditas' partner Everest Medicines announced that China's National Medical Products Administration (NMPA) had conditionally approved Nefecon for the treatment of primary immunoglobulin A nephropathy (IgAN) in adults at risk of disease progression.

In November, Calliditas announced the initiation of a Phase 2 clinical study to evaluate setanaxib in Alport syndrome.

In December, Calliditas received approval (Notice of Allowance) regarding a US patent application for TARPEYO®. In the first quarter of 2024, notice was issued regarding the patent, which provides patent in the US through 2043.

In December, the United States (US) Food and Drug Administration (FDA) granted Calliditas full approval of TARPEYO® for reduction of kidney loss in adult IgAN patients at risk of disease progression.

## BOARD OF DIRECTORS' REPORT

### Sales and Earnings

The Group's revenue amounted to SEK 1,206.9 million and SEK 802.9 million for the year ended December 31, 2023 and 2022, respectively and derived mainly from net sales of TARPEYO in the U.S. and milestones from our partnerships in Europe, China and Japan. Total net sales from TARPEYO amounted to SEK 1,075.8 million and SEK 372.2 million for the year ended December 31, 2023 and 2022, respectively. Milestones and royalties from our partnerships amounted to SEK 119.5 million and SEK 427.4 million for the year ended December 31, 2023 and 2022, respectively.

### Cost of Sales

Cost of sales amounted to SEK 60.5 million and SEK 15.2 million for the year ended December 31, 2023 and 2022, respectively.

### Research and development expenses

Research and development expenses amounted to SEK 502.2 million and SEK 414.7 million for the year ended December 31, 2023 and 2022, respectively. The increase of SEK 87.5 million was primarily due to clinical activities for the setanaxib platform, including the ongoing setanaxib trials, compared to the prior year.

### Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 727.7 million and SEK 515.2 million for the year ended December 31, 2023 and 2022, respectively. The increase of SEK 212.5 million was primarily related to the costs for sales and marketing of TARPEYO in the U.S.

### Administrative Expenses

Administrative expenses amounted to SEK 333.0 million and SEK 259.5 million for the year ended December 31, 2023 and 2022, respectively. The increase of SEK 73.5 million was primarily related to general cost increases due to a larger organization and increased regulatory requirements compared to the prior year.

### Other operating Income/Expenses, net

Other operating income/(expenses), net amounted to SEK 43.5 million and (SEK 20.2 million) for the year ended December 31, 2023 and 2022, respectively. The improvement was primarily attributable to movements in exchange rates related to operating receivables and liabilities.

### Financial Income/Expenses

Financial income amounted to SEK 30.4 million and SEK 50.2 million for the year ended December 31, 2023 and 2022, respectively and mainly pertains unrealized currency gains. Financial expenses amounted to SEK 114.3 million and SEK 37.7 million for the year ended December 31, 2023 and 2022, respectively and the increase consisted mainly of interest expenses and fees related to borrowing and currency effects primary from translation effects.

### Tax

Total income tax/(expense) amounted to (SEK 9.2 million) and (SEK 2.9 million) for the year ended December 31, 2023 and 2022, respectively. The increase was primarily explained by recognized taxable profit for the U.S. subsidiaries. The Group's tax losses carried-forward have not been recognized as deferred tax assets, other than to the extent such tax losses can be used to offset temporary differences.

### Earnings

For the year ended December 31, 2023 and 2022, the Group had a net loss of SEK 466.2 million and SEK 412.3 million, respectively and the corresponding loss per share before and after dilution amounted to SEK 8.69 and SEK 7.78.

### Liquidity and Financial Position

Cash amounted to SEK 973.7 million and SEK 1,249.1 million as of December 31, 2023 and 2022, respectively. Shareholders' equity related to the shareholders of the Parent Company amounted to SEK 334.8 million and SEK 766.3 million as of December 31, 2023 and 2022, respectively.

### Cash Flow

Cash flow used in operating activities amounted to SEK 434.7 million and SEK 311.4 million for the year ended December 31, 2023 and 2022, respectively. The decrease was mainly attributable to the change in current receivables.

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

Cash flow from financing activities amounted to SEK 199.7 million and SEK 576.0 million for the year ended December 31, 2023 and 2022, respectively.

The decrease is mainly attributable to reduced net borrowing compared to the same period previous year.

Net increase/(decrease) in cash amounted to (SEK 248.8 million) and SEK 259.5 million for the year ended December 31, 2023 and 2022, respectively.

### Personnel

The number of employees in the Group were 195 and 102 employees as of December 31, 2023 and 2022, respectively. The total number of full-time equivalent (FTE), including the consultants, were 217 and 178 as of December 31, 2023 and 2022, respectively. The average number of employees were 181 and 86 for the year ended December 31, 2023 and 2022, respectively of which 58% were women and 42% were men.

### Environment

Calliditas works proactively to reduce its adverse environmental impact and to evolve as a sustainable company. Calliditas' products have limited impact on the environment. Instead, environmental impact is in the areas of purchasing of products and services, energy consumption and travel. Calliditas aims to contribute to sustainable development and is therefore endeavoring to actively improve environmental performance as far as it is economically viable.

### Long-Term Incentive Programs

The Group has three outstanding option programs currently vesting, ESOP 2021, ESOP 2022 and ESOP 2023. The options will be granted to the participants free of charge. The options have a three-year vesting period from the grant date, provided, with the usual exceptions, that the participant is still employed by/still provides services to Calliditas. Once the options have been exercised, they can be exercised over a one-year period. Each vested option entitles the holder to acquire one share in the company at a predetermined price. The price per share shall correspond to 115% of a weighted average price at which the company's shares are traded on Nasdaq Stockholm during the ten trading days preceding the grant date. Exercise of options from ESOP 2021 can take place at the earliest during the second quarter of 2024. Exercise of options from ESOP 2022 can take place at the earliest during the third quarter of 2025. Exercise of options from ESOP 2023 can take place at the earliest during the third quarter of 2026. At the end of the year 6,098,730 options were allocated.

Calliditas also has three long-term incentive programs for board members of Calliditas, LTIP 2021, LTIP 2022 and

LTIP 2023. Participants in the programs will be allocated performance-based share awards free of charge. The share awards in LTIP 2021 are subject to performance-based earnings based on the development of Calliditas's share price from the date of the Annual General Meeting 2021 through July 1, 2024. The share awards in LTIP 2022 are subject to performance-based earnings based on the development of Calliditas's share price from the date of the Annual General Meeting 2022 through July 1, 2025. The share awards in LTIP 2023 are subject to performance-based earnings based on the development of Calliditas's share price from the date of the Annual General Meeting 2023 through July 1, 2026. In total, there were share awards outstanding corresponding to 100,975 shares at full vesting at the end of the year. For further information about the warrants program, refer to Note 10 Share-Based Payments.

### Share Capital and Shareholders

The share capital at the end of the year amounted to SEK 2.4 million, divided into 59,580,087 shares with a quotient value of SEK 0.04. All shares are ordinary shares and have an equal right to the company's profit and each share has one vote at the Annual General Meeting, excluding shares held by Calliditas. Since June 29, 2018, Calliditas share has been admitted to trading on Nasdaq Stockholm in the Mid Cap segment and since June 5, 2020, US depository receipts have been admitted to trading on Nasdaq Global Select in the US.

At the end of 2023, Calliditas had 19,000 (18,585) shareholders and the ten largest shareholders owned 47.4 (48.3) % of all outstanding shares, excluding shares held by Calliditas. As of December 31, 2023, BVF Partners LP, Linc AB and Stiftelsen Industrifonden were the single largest shareholders in the company, with a total of 6,260,311, 5,962,312 and 3,145,440 shares, respectively, corresponding to 10.5%, 10.0% and 5.3%, respectively, of the votes and capital.

For further information regarding the share, please see pages 10-11.

### Work of the Board of Directors

Calliditas' Board of Directors consists of six Board members including the Chairman, who is elected for the period until the 2024 AGM. The Board of Directors follows a written procedure that is revised on an annual basis and determined at the first regular Board meeting every board year. Among other things, the rules of procedure govern the function of the Board of Directors as well as the functions and division of work between the

members of the Board of Directors and the CEO. In connection with the Board meeting, the Board of Directors also establishes the instructions for the CEO, including financial reporting. The Board meets in accordance with an annual schedule. In addition to these board meetings, additional board meetings may be convened to address issues that may not be referred to the regular board meeting. In 2023, the board met 13 times. In addition to the board meetings, the chairman of the board and the CEO have a continuous dialogue about the company's management.

For additional information of the work of the Board of Directors, please see the Corporate Governance Report on pages 88-93.

### **Current Guidelines for Executive Remuneration**

The executive management for the Group falls within the provisions of these guidelines. Executive management refers to the CEO and other members of the executive management, as well as board members. The guidelines are forward-looking, i.e. they are applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the guidelines by the Annual General Meeting 2020. These guidelines do not apply to any remuneration decided or approved by the general meeting.

### ***The guidelines' promotion of Calliditas' business strategy, long-term interests and sustainability***

Calliditas' business strategy is to progress its lead candidate Nefecon through Phase 3 clinical development and towards regulatory approval and subsequent commercialization and licensing. Calliditas has after accelerated approval, started to commercialize Nefecon for IgA nephropathy on a standalone basis in the United States, branded as TARPEYO, through partnership with STADA in Europe branded as Kinpeygo and has also signed partnerships in other regions such as China and Japan.

Calliditas will also selectively explore line extensions for Nefecon and setanaxib, and other drug candidates in the pipeline, in other diseases where there is a strong scientific and clinical rationale and attractive commercial opportunities, such as in certain kidney and liver diseases. Calliditas may also selectively consider leveraging the Group's capabilities through accessing additional product candidates with a strong strategic and commercial fit with Nefecon for development and commercialization. Calliditas' business strategy and safeguarding of its long-term interests, including its sustainability, presumes that Calliditas is able to recruit and retain

qualified personnel. To this end, it is necessary that Calliditas offers competitive remuneration. These guidelines enable Calliditas to offer the executive management a competitive total remuneration.

### ***Types of remuneration, etc.***

Calliditas shall offer remuneration in accordance with market practice which enables the recruitment and retention of qualified executives. Remunerations within the Group shall be based on principles of performance, competitiveness, and fairness.

The remuneration to the executive management may consist of fixed remuneration, variable remuneration, share and share-price related incentive programs, pension and other benefits. If local conditions justify variations in the remuneration principles, such variations may occur.

The fixed remuneration shall reflect the individual's responsibility and experience level. The fixed remuneration shall be reviewed annually.

The variable cash remuneration covered by these guidelines shall aim at promoting Calliditas' business strategy and long-term interests, including its sustainability, by for example being clearly linked to the business strategy or promote the executive's long-term development. The satisfaction of criteria for awarding variable cash remuneration shall be measured over a period of one year. Variable remuneration paid in cash may not exceed 60 percent of the annual fixed cash salary. Variable remunerations shall be connected to predetermined and measurable criteria, designed with the aim of promoting the Group's long-term value creation. To which extent the criteria for awarding variable cash remuneration has been satisfied shall be evaluated/determined when the measurement period has ended. The Remuneration Committee is responsible for the evaluation so far as it concerns variable remuneration to the CEO and to other executives. For financial objectives, the evaluation shall be based on the latest financial information made public by the Group.

Pension shall be premium based. Variable cash remuneration shall not qualify for pension benefits. For the CEO and other executives, the premium may, in situations where premium-based pension is applicable, amount to a maximum of 30 percent of the annual fixed cash salary. Notwithstanding the above, the Board of Directors is entitled to offer other solution, which in terms of cost, are equivalent to the above.

Executives may be awarded customary other benefits, such as company car, occupational health service, etc. Such other benefits may amount to not more than 15 percent of the fixed annual cash salary.

Long-term share-related incentive plans for employees, consultants and board members have been implemented in Calliditas. Such plans have been resolved by the general meeting and are therefore excluded from these guidelines. For more information regarding these incentive plans, including the criteria on which the outcome depends on, please see <https://www.calliditas.se/en/governance/remuneration/>.

Between Calliditas and the CEO, the notice period shall be 12 months upon notice by the company. Upon notice by the CEO, the notice period is 6 months. For other members of the executive management, notice periods of 3 to 12 months apply. During the notice period, normal cash salaries shall be paid. In addition, remuneration may be paid for non-compete undertakings. Such remuneration shall compensate for loss of income and shall only be paid in so far as the previously employed executive is not entitled to severance pay. The remuneration shall amount to not more than 60 percent of the fixed cash salary at the time of termination of employment and be paid during the time the non-compete undertaking applies, however not for more than 12 months following termination of employment.

To the extent a board member conducts work for Calliditas, in addition to the board work, consulting fees and other compensation for such work may be payable. For employments governed by rules other than Swedish, pension benefits and other benefits may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of these guidelines.

#### **Salary and employment conditions for employees**

In the preparation of the Board of Directors' proposal for these remuneration guidelines, salary and employment conditions for employees of Calliditas have been taken into account by including information on the employees' total income, the components of the remuneration and increase and growth rate over time, in the Remuneration Committee's and the Board of Directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable.

#### **The decision-making process to determine, review and implement the guidelines**

The Board of Directors has established a Remuneration Committee. The committee's tasks include preparing the Board of Directors' decision to propose guidelines for executive remuneration. The Board of Directors shall prepare a proposal for new guidelines at least every fourth year and submit it to the general meeting. The guidelines shall be in force until new guidelines are adopted by the general meeting. The Remuneration Committee shall also monitor and evaluate programs for variable remuneration for the executive management, the application of the guidelines for executive remuneration as well as the current remuneration structures and compensation levels in the Group. The members of the Remuneration Committee are independent to Calliditas and its executive management. The CEO and other members of the executive management do not participate in the Board of Directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

#### **Derogation from the guidelines**

The Board of Directors may temporarily resolve to derogate from the guidelines, in whole or in part, if in a specific case there is special cause for the derogation and a derogation is necessary to serve Calliditas' long-term interests, including its sustainability, or to ensure the Group's financial viability. As set out above, the Remuneration Committee's tasks include preparing the Board of Directors' resolutions in remuneration-related matters. This includes any resolutions to derogate from the guidelines.

#### **Risk Management**

Calliditas' board of directors and management work continuously to identify and assess risks for the company's operations and take measures to reduce the effect of these. A risk management strategy is drawn up for every material risk. This work involves support from expertise in areas such as commercialization, regulatory strategies and the design and implementation of clinical trials.

#### **Risks and Uncertainties**

Calliditas' operations are impacted by a number of factors that affect the Group's earnings and financial position and that in certain respects cannot be controlled, in part or in full, by Calliditas. When assessing Calliditas' future development, it is important alongside opportunities for profit growth to also consider these risks. The most important material risks and uncertainties in terms of the Group's future development are listed below, without any order of precedence.

### Operational risks

Calliditas main activities are research and development and commercialization of pharmaceuticals, which is an area that is to a large extent both risky and capital-intensive. Calliditas has a product in the commercial phase, Tarpeyo/Kinpeygo/Nefecon, which has been approved for marketing in the USA, China and Europe. There is a risk that commercialization will not go according to plan and that the uptake of treating doctors will be worse than planned or that the drug will not have sufficient effect or show unwanted side effects, which may affect sales negatively. Calliditas has two product candidates in clinical development, Nefecon and setanaxib, for the treatment of IgA nephropathy and primary biliary cholangitis and head and neck cancer, respectively, and there is a risk that the projects will never reach market registration or get full approval due to the risk that the drugs do not have sufficient effect or show unwanted side effects. Even after a drug has been launched, market registration can be withdrawn if serious side effects occur.

Calliditas conducts clinical studies regarding its product candidates. Clinical studies are time-consuming and costly and involve risks such as difficulties in finding clinics, difficulties in recruiting suitable patients, that the cost per patient exceeds budget and shortcomings in the performance of the studies by the clinics participating in the study. Both Nefecon and setanaxib are drug candidates with orphan drug classification in IgA nephropathy and primary biliary cholangitis, respectively. The number of suitable patients for clinical trials is thus lower than for common diseases and it may be a challenge for Calliditas to recruit patients for the implementation of the Phase 2b study for the treatment of primary biliary cholangitis and the Phase 2 studies for the treatment of head and neck cancer and Alport Syndrome.

If competing drugs take market shares or competing research projects achieve a better effect and reach the market faster, the future value of the product portfolio may be lower than expected. Patent applications filed by Calliditas may never be approved and approved patents may be annulled, which may result in Calliditas losing patent protection. The business is also affected by government decisions such as approvals and price changes. There is an ongoing political debate on perceived overpricing of orphan drugs, especially in the United States. There is a risk that new rules will have a negative impact on orphan drug prices in the future. There are also risks regarding the manufacture of the product where the selected manufacturer may have

problems delivering sufficient quality and / or quantity or lose the necessary permits to manufacture. Part of Calliditas strategy is to investigate the possibility of developing products in other indications. Calliditas, however, has not yet finished any clinical trials in other indications. Conducting clinical trials is always associated with risks related to the implementation of the study, the results and the approval of regulatory authorities, and as a result it is currently uncertain whether Calliditas ambition to develop products for treatment for other indications will be realized.

The risk of the war in Ukraine and the EU sanctions imposed on Russia and Belarus is expected to be limited and not directly impact the Group since there is no direct link or exposure to these countries or entities listed by the EU restrictive measures. Any future enforced sanctions or development of the situation will be monitored and addressed.

### Liquidity risks

Calliditas manages liquidity risks by continuously monitoring cash flow so that it can reduce liquidity risk and ensure its solvency. Calliditas has earnings capacity, but it doesn't currently cover its costs, therefore Calliditas may be dependent on external financing and there is a risk external financing will not be available to Calliditas if and when it is needed.

### 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. In addition to the liquidity risk stated above, 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 accounts receivable in USD and cash in USD and EUR to meet future expected costs in USD and EUR in connection with commercialization of TARPEYO in the U.S. and the clinical development programs. The Group currently has no variable interest rate on the external loan and therefore no significant risk of increased interest costs.

### Parent Company

Calliditas Therapeutics AB is focused on the administration of the Group, research and development, to own and manage subsidiaries and to support commercial subsidiaries and commercial partners. Net sales for the Parent Company amounted to SEK 805.6 million and

SEK 549.0 million for the year ended December 31, 2023 and 2022, respectively. The increase was primarily derived sales of TARPEYO compared to the prior year. Operating loss amounted to SEK 167.8 million and SEK 215.4 million for the year ended December 31, 2023 and 2022, respectively. The improvement of the operating loss was primarily derived from the increase in revenues compared to the prior year. Non-current financial assets amounted to SEK 1 125.2 million and SEK 887.5 million as of December 31, 2023 and 2022, respectively. The increase of SEK 237.7 million was primarily derived from intercompany transactions.

The Parent Company had cash of SEK 817.9 million and SEK 1,059.7 million as of December 31, 2023 and 2022, respectively.

### Outlook

Callidita's drug Nefecon commercialized under the name TARPEYO in the USA, has a large market potential and on December 20, 2023, reached a verdict milestone with the historic FDA approval. The drug then became the first and only complete approved treatment to reduce loss of kidney function in adults with primary IgAN. The FDA approval applies to adults with primary IgAN at risk of disease progression, regardless of proteinuria levels, and sets a new standard for the treatment of IgAN. In 2022, Kinpeygo received conditional approval in the European Cooperation Area (EEA) and during 2023 Nefecon received conditional approval in China. These approvals thus marking the transition of Calliditas to one biopharmaceutical company in commercial phase.

Callidita's strong presence in the scientific arena in nephrology together with critical stakeholders reflects the strategic work of continuing to operate on the scientific exchange. With the commercial operations in USA and clinical R&D studies ongoing, operations are capital intensive and until Nefecon/TARPEYO/Kinpeygo will bring in revenues that exceed costs, external financing may be required. The Group's cash position of SEK 973.7 million as of December 31, 2023 and subject to continued successful commercialization of Tarpeyo in the US, is currently considered sufficient until an operationally positive cash flow is achieved.

### Proposed Appropriation of the Company's Earnings

#### Proposed appropriation of earnings

The following earnings (TSEK) are at the disposal of the Annual General Meeting,

Share premium reserve	2,521,419
Retained earnings	(1,343,602)
<b>Net loss for the year</b>	<b>(273,518)</b>
	<b>904,299</b>

The Board of Directors proposes that SEK 904,299 thousand is carried forward.

### Dividend Policy

Any future dividend and the size thereof, will be determined based on long-term growth, earnings trends and capital requirements of Calliditas. It is the view of the Board of Directors that Calliditas should prioritize progression of the development program, and until the future revenues substantially exceeds the cost of operation, financial resources should mainly be used to finance Calliditas' development programs.

In view of company's financial position and negative earnings, the Board of Directors does not intend to propose any dividend before the company generates long-term sustainable profits and positive cash flow. Dividends shall, as far as a dividend is proposed, be balanced with regard to the business risk.

The Board of Directors proposes, in view of dividend policy, that no dividend be paid for the 2023 financial year.

For more information on the Group and Parent Company's earnings and financial position, refer the following statements of income and financial position, changes in shareholders' equity and cash flows with accompanying supplementary disclosures.

## Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31,		
		2023	2022	2021
Net sales	3	1,206,888	802,879	229,347
Cost of sales		(60,463)	(15,201)	-
<b>Gross profit</b>		<b>1,146,425</b>	<b>787,678</b>	<b>229,347</b>
Research and development expenses	7,8,9,10	(502,223)	(414,749)	(357,485)
Marketing and selling expenses	7,8,9,10	(727,740)	(515,190)	(179,603)
Administrative expenses	6,7,8,9,10	(332,991)	(259,469)	(210,630)
Other operating income	4	44,608	2,862	259
Other operating expenses	5	(1,135)	(23,074)	(6,344)
<b>Operating loss</b>	7	<b>(373,055)</b>	<b>(421,943)</b>	<b>(524,456)</b>
Financial income	11	30,387	50,195	20,336
Financial expenses	12	(114,349)	(37,669)	(9,253)
<b>Loss before income tax</b>		<b>(457,017)</b>	<b>(409,417)</b>	<b>(513,373)</b>
Income tax expense	13	(9,168)	(2,851)	3,836
<b>Loss for the year</b>		<b>(466,185)</b>	<b>(412,268)</b>	<b>(509,537)</b>
Attributable to:				
Equity holders of the Parent Company		(466,185)	(412,268)	(500,293)
Non-controlling interests		-	-	(9,244)
		<b>(466,185)</b>	<b>(412,268)</b>	<b>(509,537)</b>
<b>Loss per share</b>				
Before and after dilution to ordinary equity holders of the Parent Company	14	(8.69)	(7.78)	(9.84)



## Consolidated Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31,		
		2023	2022	2021
<b>Loss for the year</b>		<b>(466,185)</b>	<b>(412,268)</b>	<b>(509,537)</b>
<b>Other comprehensive income</b>				
<i>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:</i>				
Exchange differences on translation of foreign operations	20,25	(14,538)	36,287	(20,111)
<b>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods</b>		<b>(14,538)</b>	<b>36,287</b>	<b>(20,111)</b>
<i>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:</i>				
Remeasurement gain/(loss) on defined benefit plans	28	(3,071)	2,763	1,993
<b>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods</b>		<b>(3,071)</b>	<b>2,763</b>	<b>1,993</b>
<b>Other comprehensive income/(loss) for the year</b>		<b>(17,609)</b>	<b>39,050</b>	<b>(18,118)</b>
<b>Total comprehensive loss for the year</b>		<b>(483,794)</b>	<b>(373,218)</b>	<b>(527,655)</b>
<b>Attributable to:</b>				
Equity holders of the Parent Company		(483,794)	(373,218)	(519,189)
Non-controlling interests		-	-	(8,466)
		<b>(483,794)</b>	<b>(373,218)</b>	<b>(527,655)</b>

## Consolidated Statements of Financial Position

(SEK in thousands)	Note	December 31,	
		2023	2022
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	15	430,754	438,057
Goodwill	15	48,584	45,784
Equipment	16	16,053	7,468
Right-of-use assets	8	38,186	24,452
Non-current financial assets	17,19,32	24,201	11,210
Deferred tax assets	18	26,315	13,799
<b>Total non-current assets</b>		<b>584,093</b>	<b>540,770</b>
<b>Current assets</b>			
Inventories	21	20,428	3,647
Accounts receivable	20	180,892	78,703
Other current assets	19	15,774	10,018
Prepaid expenses and accrued income	22	84,324	70,741
Cash	23	973,733	1,249,094
<b>Total current assets</b>		<b>1,275,152</b>	<b>1,412,204</b>
<b>TOTAL ASSETS</b>		<b>1,859,245</b>	<b>1,952,973</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
	25		
Share capital		2,383	2,383
Additional paid-in capital		2,643,227	2,590,890
Reserves		(5,231)	9,307
Retained earnings including net loss for the year		(2,305,573)	(1,836,317)
<b>Total equity attributable to equity holders of the Parent Company</b>		<b>334,806</b>	<b>766,264</b>
<b>Non-current liabilities</b>			
Provisions	26	32,595	11,792
Contingent consideration	27	56,561	75,880
Pension liabilities	28	3,521	884
Deferred tax liabilities	18	41,641	39,752
Non-current interest-bearing liabilities	20	939,508	713,030
Non-current lease liabilities	8,19	27,088	15,792
Other non-current liabilities	19,29	16,381	4,350
<b>Total non-current liabilities</b>		<b>1,117,295</b>	<b>861,479</b>
<b>Current liabilities</b>			
Accounts payable	19,20	100,564	160,404
Current tax liabilities		6,167	5,684
Other current liabilities	8,19	19,786	22,697
Accrued expenses and deferred revenue	30	280,627	136,446
<b>Total current liabilities</b>		<b>407,144</b>	<b>325,231</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>1,859,245</b>	<b>1,952,973</b>

## Consolidated Statements of Changes in Equity

(SEK in thousands)	Note	Attributable to the Equity Holders of the Parent Company					Total	Non-Controlling Interests	Total Equity
		Share Capital	Additional Paid-in Capital	Translation Reserve	Retained Earnings incl. Net Loss for the Year				
<b>Opening equity January 1, 2021</b>		<b>1,998</b>	<b>2,133,179</b>	<b>(6,090)</b>	<b>(918,596)</b>	<b>1,210,491</b>	<b>45,809</b>	<b>1,256,300</b>	
Loss for the year		-	-	-	(500,293)	(500,293)	(9,244)	(509,537)	
Other comprehensive income/(loss) for the year		-	-	(20,889)	1,993	(18,896)	778	(18,118)	
<b>Total comprehensive loss for the year</b>		<b>-</b>	<b>-</b>	<b>(20,889)</b>	<b>(498,300)</b>	<b>(519,189)</b>	<b>(8,466)</b>	<b>(527,655)</b>	
<b>Transactions with owners:</b>									
New share issue		96	323,904	-	-	324,000	-	324,000	
Costs attributable to new share issue		-	(20,909)	-	-	(20,909)	-	(20,909)	
Contribution from non-controlling interest		-	-	-	-	-	2,282	2,282	
Share-based payments	10	-	23,567	-	-	23,567	-	23,567	
Purchase of non-controlling interests		-	-	-	(9,678)	(9,678)	(39,625)	(49,303)	
<b>Total transactions with owners</b>		<b>96</b>	<b>326,562</b>	<b>-</b>	<b>(9,678)</b>	<b>316,979</b>	<b>(37,343)</b>	<b>279,636</b>	
<b>Closing equity December 31, 2021</b>		<b>2,094</b>	<b>2,459,741</b>	<b>(26,979)</b>	<b>(1,426,574)</b>	<b>1,008,281</b>	<b>-</b>	<b>1,008,281</b>	
<b>Opening equity January 1, 2022</b>		<b>2,094</b>	<b>2,459,741</b>	<b>(26,979)</b>	<b>(1,426,574)</b>	<b>1,008,281</b>	<b>-</b>	<b>1,008,281</b>	
Loss for the year		-	-	-	(412,268)	(412,268)	-	(412,268)	
Other comprehensive income/(loss) for the year		-	-	36,286	2,763	39,050	-	39,050	
<b>Total comprehensive loss for the year</b>		<b>-</b>	<b>-</b>	<b>36,286</b>	<b>(409,505)</b>	<b>(373,218)</b>	<b>-</b>	<b>(373,218)</b>	
<b>Transactions with owners:</b>									
Issuance of treasury shares		236	-	-	-	236	-	236	
Repurchase of treasury shares		-	-	-	(236)	(236)	-	(236)	
Exercise of warrants		53	95,070	-	(2)	95,121	-	95,121	
Share-based payments	10	-	36,080	-	-	36,080	-	36,080	
<b>Total transactions with owners</b>		<b>290</b>	<b>131,150</b>	<b>-</b>	<b>(238)</b>	<b>131,201</b>	<b>-</b>	<b>131,201</b>	
<b>Closing equity December 31, 2022</b>	10,25	<b>2,383</b>	<b>2,590,890</b>	<b>9,307</b>	<b>(1,836,317)</b>	<b>766,264</b>	<b>-</b>	<b>766,264</b>	
<b>Opening equity January 1, 2023</b>		<b>2,383</b>	<b>2,590,890</b>	<b>9,307</b>	<b>(1,836,317)</b>	<b>766,264</b>	<b>-</b>	<b>766,264</b>	
Loss for the year		-	-	-	(466,185)	(466,185)	-	(466,185)	
Other comprehensive income/(loss) for the year		-	-	(14,538)	(3,071)	(17,609)	-	(17,609)	
<b>Total comprehensive income/(loss) for the year</b>		<b>-</b>	<b>-</b>	<b>(14,538)</b>	<b>(469,256)</b>	<b>(483,794)</b>	<b>-</b>	<b>(483,794)</b>	
<b>Transactions with owners:</b>									
Share-based payments	10	-	52,337	-	-	52,337	-	52,337	
<b>Total transactions with owners</b>		<b>-</b>	<b>52,337</b>	<b>-</b>	<b>-</b>	<b>52,337</b>	<b>-</b>	<b>52,337</b>	
<b>Closing equity December 31, 2023</b>	10,25	<b>2,383</b>	<b>2,643,226</b>	<b>(5,231)</b>	<b>(2,305,573)</b>	<b>334,807</b>	<b>-</b>	<b>334,806</b>	

## Consolidated Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31,		
		2023	2022	2021
<b>Operating activities</b>				
Operating loss		(373,055)	(421,943)	(524,456)
Adjustments for non-cash items	23	102,478	61,260	66,676
Interest received		32,905	3,553	102
Interest paid		(94,497)	(35,252)	(5,432)
Income taxes paid		(22,747)	(7,392)	(3,949)
<b>Cash flow from operating activities before changes in working capital</b>		<b>(354,915)</b>	<b>(399,774)</b>	<b>(467,058)</b>
<b>Cash flow from changes in working capital</b>				
Changes in inventory		(16,781)	(2,758)	(949)
Changes in operating receivables		(182,589)	(91,878)	(11,712)
Changes in operating liabilities		119,629	183,056	18,131
<b>Cash flow from operating activities</b>		<b>(434,655)</b>	<b>(311,354)</b>	<b>(461,588)</b>
<b>Investing activities</b>				
Purchase of equipment	16	(12,788)	(2,512)	(6,588)
Investments in non-current financial assets	17	(1,560)	(2,633)	(1,686)
Repayment of non-current financial assets		602	-	-
Purchase of intangible assets	15	-	-	(16,066)
<b>Cash flow from investing activities</b>		<b>(13,745)</b>	<b>(5,144)</b>	<b>(24,340)</b>
<b>Financing activities</b>				
New share issue		-	-	324,000
Expenditures attributable to new share issue		-	-	(20,909)
Issuance of treasury shares		-	236	-
Repurchase of treasury shares		-	(236)	-
Exercise of warrants		-	95,121	-
Purchase of non-controlling interests		-	-	(49,303)
Contribution from non-controlling interest		-	-	2,282
New borrowings	20	962,889	491,745	199,524
Expenditures attributable to new loans		(26,625)	(1,260)	(14,858)
Repayment of borrowing		(724,479)	-	-
Repayment of lease liabilities		(12,134)	(9,615)	(5,575)
<b>Cash flow from financing activities</b>		<b>199,650</b>	<b>575,990</b>	<b>435,162</b>
<b>Net increase (decrease) in cash</b>		<b>(248,750)</b>	<b>259,493</b>	<b>(50,766)</b>
<b>Cash at beginning of the year</b>		<b>1,249,094</b>	<b>955,507</b>	<b>996,304</b>
Exchange-rate difference in cash		(26,611)	34,094	9,969
<b>Cash at the end of the year</b>	23	<b>973,733</b>	<b>1,249,094</b>	<b>955,507</b>

# Notes to Consolidated Financial Statements

(SEK in thousands, except per share amounts or as otherwise indicated)

## Description of Business

Calliditas Therapeutics AB (publ) ("Calliditas" or the "Parent Company"), with corporate registration number 556659-9766, and its subsidiaries (collectively, the "Group") conduct development and commercial activities in pharmaceuticals.

These consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the year ended December 31, 2023, 2022 and 2021, respectively. The Group has chosen to, in addition to periods such as required by IFRS, present a consolidated income statement, statement of comprehensive income, consolidated statement of cash flows and consolidated statement of changes in equity with an additional comparison period.

Calliditas is a commercial stage biopharma company focused on identifying, developing and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. The registered address of the corporate headquarters is Kungsbron 1, D5, Stockholm, Sweden.

Calliditas was founded as a public limited liability company under the laws of Sweden on February 20, 2004 under the name Pharmalink AB and registered with the Swedish Companies Registration Office on April 15, 2004. As of December 31, 2023, Calliditas is the Parent Company of four subsidiaries located in Sweden, France and in the United States. The Swedish subsidiary is Nefecon AB which is conducting no operating activities. The subsidiaries in the United States are Calliditas Therapeutics US Inc and Calliditas NA Enterprises Inc, who are conducting commercialization activities in the United States, respectively. The French subsidiary is Calliditas Therapeutics France SAS located in France which is conducting preclinical activities.

The Board of Directors (the "Board") approved, and authorized for issuance, these consolidated financial statements on April 24, 2024, which will be presented for adoption at the Annual General Meeting on June 17, 2024.

## Note 1 Material Accounting Policies

### Basis for Preparation

These consolidated financial statements have been prepared in accordance with the IFRS (R) Accounting Standards published by the International Accounting Standards Board (IASB) as adopted by the European Union (EU). In addition, the consolidated financial statements comply with the recommendation of The Swedish Corporate Reporting Board RFR 1, Supplementary Accounting Regulations for Groups.

### Material accounting policies

The Group provides disclosures of material accounting policies and accounting policy is material if the underlying transaction is material and information in the accounting policy is material to understand the transaction, e.g. if the Group has made a policy choice or if the accounting policy is company specific. When the Group applies an accounting policy as described in the applicable IFRS standard, the Group does not provide any disclosure of the applied accounting policy. In addition to material accounting policies described in this note, the Group has decided to present material accounting policies within the corresponding note that the policy relates to.

### Primary financial statements

The group has elected to present in addition to minimum periods required under IFRS, a consolidated statement of income, consolidated statement of comprehensive income, consolidated statement of cash flows, and consolidated statement of changes in equity, for an additional comparative period. The Group has decided to present the consolidated statement of income based on function of expense.

### Basis for Valuation and Current versus Non-Current Classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification. An asset is current when it is expected to be realized within twelve months after the reporting period. All other assets are classified as non-current. A liability is current when it is due to be settled within twelve months after the reporting period. The Group classifies all other liabilities as non-current.

### Functional Currency and Reporting Currency

The Parent Company's functional currency is Swedish Kronor (SEK), which is also the presentation currency of the Group. This means that the financial statements are presented in Swedish kronor (SEK) and all amounts, unless otherwise stated, are rounded to the nearest thousand (SEK 000s).

Foreign exchange gains and losses as a result of transactions in foreign currency relating to operating receivables and liabilities are recognized net in operating profit as Other operating income or Other operating expenses, while foreign exchange gains and losses on financial receivables and liabilities are recognized net as financial items.

### Cost of Sales

Cost of sales includes the cost of inventory sold, labor costs, manufacturing overhead expenses and reserves for expected scrap, as well as shipping and freight costs. Cost of sales also includes royalty costs related to in-licensing agreements.

### Research and Development

Research and development expenses consist primarily of costs incurred for the Group's development activities, including the development of the Group's product candidates. The Group expenses research and development costs as incurred. The Group recognizes external development costs based on an evaluation of the progress to completion of specific tasks using information provided by Calliditas' service providers. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as a prepaid expense or accrued expense. Research and development tax credits are recognized in Sweden and in France. In Sweden tax credits are recognized on social security costs and in France tax credits are recognized on accredited suppliers. These research and development tax credits are recognized as an offset to research and development expenses in the consolidated statements of income.

### Marketing and Selling Expenses

Marketing and selling expenses consist of salaries and other related costs for personnel in the Group and market access, commercialization and business development.

### Administrative Expenses

Administrative expenses consist of salaries and other related costs for personnel in the Group, finance, corporate and administrative functions. Administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, related travel expenses and facility-related expenses, which include allocated expenses for rent and maintenance of facilities and other operating costs. Acquisition-related costs are included in administrative expenses in the consolidated statements of income and are expensed as the services are performed.

### New and Amended Standards and Interpretations

Updated standards and interpretations from IASB and IFRIC interpretations that came into effect for the year ended December 31, 2023 have had no material impact on the Group. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

### Future Standards and New Interpretations

Other future or altered standards or interpretations that the IASB has published are not expected to have any significant impact on the financial statements for the Group.

### Cash Flow

The consolidated statement of cash flows is prepared in accordance with the indirect method.

## Note 2 Significant Accounting Judgements, Estimates and Assumptions

The preparation of the Group's consolidated financial statements in accordance with IFRS requires management to make judgements, estimates and assumptions that affect the recorded amounts of revenues, expenses, assets and liabilities, and the accompanying disclosures. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

# GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

Judgements, estimates and assumptions are evaluated on an ongoing basis. Changes in judgements, estimates and assumptions are recognized in the period the change has occurred if the change only affects that period, and future period if the change affects both the current period and future periods.

Significant accounting judgements, estimates and assumptions are disclosed in detail in the corresponding note to which the judgement, estimate and assumption relate. Significant accounting judgements, estimates and assumptions relates to:

- Revenue recognition - note 3,
- Loss carryforwards - note 13,
- Intangible assets - note 15, and
- Expected credit losses - note 20.

A summarized description of each significant accounting judgment, estimate and assumption is presented below. For additional details of the significant accounting judgments, estimates and assumptions refer to the notes referenced above.

## Revenue Recognition

### Outlicensing of Product

Revenue for the outlicensing of Nefecon is recognized at the point in time when control of the intellectual property is transferred, while revenue for the provision of certain regulatory services is reported over time as the services are performed. The revenue allocated to the performance obligation for outlicensing is based on the residual approach and the allocation of revenue to the performance obligation for regulatory services is based on the expected costs to provide the service, with the addition of a profit margin based on comparable companies. The identification of and allocation of the transaction price between these performance obligations hence has a significant impact on the Group's revenue recognition, as the revenue recognition patterns differ between the performance obligations.

The revenue contracts also contain variable remuneration in the form of regulatory and commercial milestones. Variable remuneration is initially considered constrained, as there is significant uncertainty as to whether the associated milestones will occur. Compensation attributable to sales-based milestones or royalties is not recognized until the sale that results in the right to the royalties has occurred. Determining whether the criteria for recognition of the variable remuneration has been met hence has significant effects on revenue recognition and requires significant judgment by Management.

### Gross to Net Accounting

There are various sales deductions and rebates relating to product sales in the United States that are deducted from the gross sales as part of the revenue recognition process. As the actual sales deductions are not known at the point of sale, estimates are made in determining the initial deduction of rebates, and are then subject to true-up as actual data is obtained.

## Intangible Assets

### Goodwill and intangible assets, not yet available for use

Goodwill and intangible assets not yet available for use are assessed for impairment at each reporting date based on their recoverable amounts, including key assumptions such as the timing of potential commercialization, market size, market share, probability of reaching the market and the discount rates.

### Capitalization of intangible assets

The Group capitalizes expenditures for the development of pharmaceuticals to the extent that it is expected to meet the criteria in accordance with IAS 38 – Intangible Assets. The assessment is based on significant judgments made by management, including the technical feasibility of completing the intangible asset so that it will be available for use or sale and assumptions used to demonstrate that the asset will generate probable future economic benefits (e.g., projected cash flow projections, discount rate). Capitalization of expenditures is generally made in the late stage of the development, for example after full approval, depending on when the criteria are deemed to have been met. The reason for this is that before then it is uncertain whether the expenditure will generate future economic benefits and that financing the completion of the asset is not yet guaranteed.

### Loss allowance for Expected Credit Losses for Accounts Receivable

Management makes loss allowance for expected credit losses for accounts receivable that correspond to their maturity. The estimate is based on any increased credit risk, on individual or collective basis, considering reason

able and supportable information, including that which is forward-looking. The allowance for expected credit risk is an estimate based on maturity structure accounts receivable and specific customer knowledge. Generally, invoices are due for payment within 30-45 days..

### Loss Carryforwards

The Groups tax losses carried forward have not been recognized as deferred tax assets in the statement of financial position as of December 31, 2022, except for such circumstances where there are future temporary differences that such losses can be used to offset. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

The Group has identified an uncertain tax position in relation to the ability to use tax loss carried forward in France due to transactions performed historically. The related tax losses carried forward has not been recognized as deferred tax assets in the consolidated statements of financial position.

### Key Sources of Estimation Uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year. The Group based its assumptions and estimates on parameters available when the consoli-dated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

## Note 3 Operating segments and revenue from Contracts with Customers

### Material accounting policy - operating segments

An operating segment is a part of the Group that conducts business activities from which it can generate revenue and incur costs, and for which independent financial information is available. Identification of segments is based on internal reporting to the chief operating decision maker ("CODM"). The CODM for the Group is the Chief Executive Officer ("CEO"). The Group does not divide its operations into different segments and the CODM operates and manages the Group's entire operations as one segment, which is consistent with the Group's internal organization and reporting system. The Group's revenue is attributable to the Parent Company in Sweden and to the U.S. subsidiary Calliditas Therapeutics US Inc. The non-current assets are located in Sweden, the U.S., France and Switzerland.

### Material accounting policy - revenue from contracts with customers

The Group is in the business of identifying, developing and commercializing novel treatments in orphan indications. Operating revenue mainly comprises of product sales, outlicensing of Nefecon to our partnerships in Europe, China and Japan and royalty revenue. Revenue is recognized as follows:

### Product Sales

Revenue from product sales is recognized at the transaction price of goods sold excluding sales tax, rebates and returns. At the time of delivery, when the control of the goods passes to the customer, the revenue is recognized in full, as this represents the single performance obligation in the transaction. The customer is defined as the specialty pharmacy who dispenses the good to the end user. As the transaction price is dependent on the rebate paid to the patients' insurance company or government payer, the transaction price is not known upon delivery. This is accounted for by an accrued estimated rebate deduction in the Group based on calculation models considering statistical data, actual amounts incurred and/or historical trends. These liabilities for expected returns and rebates are based on estimates of the amounts received or to be claimed on the related sales. Furthermore, the Group estimates the liability for expected returns of obsolete medicines.

### Outlicensing of Product

Revenue attributable to outlicensing Nefecon consisted of the agreement with STADA for Europe, the expansion of Everest Medicines to South Korea and the agreement with Viatris for Japan. Revenue for outlicensing is recognized at a point in time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreements with the parties were signed. These contracts with customers consist of fixed remuneration as well as variable consideration in the form of regulatory and commercial milestones, and sales-based

royalties. Variable consideration (for example, attributable to future regulatory milestones) is initially considered constrained, as there is significant uncertainty as to whether these will occur. Consideration attributable to sales-based milestones or royalties are not recognized until the sale that results in the right to the milestones or royalties occurs.

#### Royalty Revenue

Calliditas is, in accordance with agreements, entitled to royalties on goods sold. Revenue recognition is based on royalty reports received, which are based on actual net sales statistics of the licensee. Accrued royalty revenue is recognized in the statement of financial position under prepaid expenses and accrued income.

#### Significant accounting judgments, estimates and assumptions - revenue recognition

##### Outlicensing of Product

Revenue for the outlicensing of Nefecon is recognized at the point in time when control of the intellectual property is transferred, while revenue for the provision of certain regulatory services is reported over time as the services are performed. The revenue allocated to the performance obligation for outlicensing is based on the residual approach and consists of the total transaction price for each contract after deducting the stand-alone selling price of all other performance obligations. The allocation of revenue to the performance obligation for regulatory services is based on the expected costs to provide the service, with the addition of a profit margin based on comparable companies. The identification and allocation of the transaction price between these performance obligations hence has a significant impact on the Group's revenue recognition, as the revenue recognition patterns differ between the performance obligations.

Specifically, the significant accounting judgments and estimates within revenue recognition include determining which promises within each contract that are distinct, estimating the expected costs to fulfil the performance obligations that are not based on the residual method, and determining an appropriate profit margin for these. The Group determines the expected costs to complete these performance obligations through an input model based on the expected hours of work required by the Group's personnel, as well as expected costs to be incurred from the Group's suppliers. The Group then determines an appropriate profit margin by identifying comparable peer companies that provide such services separately and bases the margin rate on these. The Group then recognizes revenue for the performance obligation to provide regulatory services as these costs are incurred. These estimates are forward-looking and could be affected by differences between expected and actual costs incurred to fulfil the performance obligations. Management's estimate of the total costs as a measure of progress to completion of the performance obligation hence requires the use of assumptions and estimates.

The revenue contracts also contain variable consideration in the form of regulatory and commercial milestones. Variable consideration is initially considered constrained, as there is significant uncertainty as to whether the associated milestones will occur. Consideration attributable to sales-based milestones or royalties is not recognized until the sale that results in the right to the royalties have occurred. Determining whether the criteria for recognition of the variable remuneration has been met hence has significant effects on revenue recognition and requires significant judgment by Management.

##### Gross to Net Accounting

Revenue from product sales in the United States is recognized when the product is received by the customer and title passes, typically at the time of delivery. There are various sales deductions and rebates that are deducted from the gross sales as part of the revenue recognition process. As the actual sales deductions are not known at the point of sale, estimates are made in determining the initial deduction of rebates, and are then subject to true-up as actual data is obtained. For sales of TARPEYO, returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates or industry averages, if available and those estimates are recorded as a reduction of accounts receivable and as other current liabilities, respectively. Similarly estimates are determined relating to specialty pharma fees, co-pay support redemptions, Medicare/Medicaid and other rebates, and these estimates are reflected as a component in the accrued expenses and deferred revenue and as a reduction of revenue. Once all related variable considerations are resolved and uncertainties as to collectable amounts are eliminated, estimates are adjusted to actual amounts. Accruals for these estimated amounts are reviewed and adjusted on no less than a quarterly basis, see Note 2.

Set out below is the Group's revenue from contracts with customers:

Type of goods or service	Year Ended December 31,		
	2023	2022	2021
Product sales	1,087,418	375,515	-
Outlicensing of product	82,712	421,689	225,252
Royalty income	36,758	2,287	-
Performance of certain regulatory services	-	3,387	4,095
<b>Total</b>	<b>1,206,888</b>	<b>802,879</b>	<b>229,347</b>

Geographical markets	Year Ended December 31,		
	2023	2022	2021
USA	1,075,829	372,247	-
Europe*	39,614	143,955	201,878
Asia	91,445	286,677	27,469
<b>Total</b>	<b>1,206,888</b>	<b>802,879</b>	<b>229,347</b>

\* No net sales were recorded in Sweden in 2023, 2022, and 2021, respectively.

The Group's revenues in 2023 consisted primarily of net sales of TARPEYO in the U.S., and outlicensing of product which consisted of regulatory milestone fees from Everest Medicines.

Revenue from major customers	Year Ended December 31,		
	2023	2022	2021
Customer A	1,045,288	372,247	-
Customer B	91,415	80,643	27,469
Customer C	39,614	143,955	201,878
Customer D	-	206,034	-
Customers below 10% of revenue	30,571	-	-
<b>Total</b>	<b>1,206,888</b>	<b>802,879</b>	<b>229,347</b>

Performance obligations	Year Ended December 31,		
	2023	2022	2021
Expected returns	3,552	15,849	-
Rebates on sales	36,326	8,445	-
<b>Total</b>	<b>39,878</b>	<b>24,294</b>	<b>-</b>

Contract assets	Year Ended December 31,		
	2023	2022	2021
Accrued royalties	7,297	2,287	-
<b>Contract liabilities</b>			
Prepaid income	-	-	3,387

Total non-current assets per geographical market	December 31,	
	2023	2022
Sweden	20,462	43,285
France	3,013	354
Switzerland	497,267	437,508
USA	12,835	17,484
<b>Total</b>	<b>533,577</b>	<b>498,631</b>

Non-current assets included in the above table includes intangible assets, equipment and right-of-use assets.

## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

### Note 4 Other Operating Income

	Year Ended December 31,		
	2023	2022	2021
Exchange rate differences	17,183	-	149
Pass through costs	7,648	439	-
Net gains on disposal of non-current assets	941	-	110
Change in value of the contingent consideration at fair value	18,835	-	-
Other income	1	2,423	-
<b>Total</b>	<b>44,608</b>	<b>2,862</b>	<b>259</b>

Regarding value of the contingent consideration, see Note 27 Contingent consideration.

### Note 5 Other Operating Expenses

	Year Ended December 31,		
	2023	2022	2021
Exchange rate differences	596	7,133	1,807
Net loss on disposal of equipment	-	-	67
Change in value of the contingent consideration at fair value	-	15,941	4,470
Other expenses	539	-	-
<b>Total</b>	<b>1,135</b>	<b>23,074</b>	<b>6,344</b>

### Note 6 Auditors' Fee

	Year Ended December 31,		
	2023	2022	2021
<b>EY</b>			
Audit services	20,951	13,369	6,235
Other audit activities	900	3,370	2,105
Tax advice	-	-	73
<b>Total</b>	<b>21,851</b>	<b>16,739</b>	<b>8,413</b>
<b>KPMG</b>			
Audit services	-	-	472
Other audit activities	-	-	1,178
<b>Total</b>	<b>-</b>	<b>-</b>	<b>1,650</b>
<b>Other auditors</b>			
Audit services	-	-	471
Other audit activities	-	-	79
<b>Total</b>	<b>-</b>	<b>-</b>	<b>550</b>
<b>Total Audit Fee</b>	<b>21,851</b>	<b>16,739</b>	<b>10,613</b>

Audit services relate to the statutory audit of the financial statements and the accounts, as well as the management of the Board of Directors and the CEO. This includes other responsibilities that it is incumbent upon the company's auditor to perform including providing advice or any other assistance that may result from observations in such review or the conduct of such other responsibilities.

Other auditing activities are those services in accordance with a special agreement on financial statements.



## Note 7 Costs according to Type of Cost

	Year Ended December 31,		
	2023	2022	2021
Raw materials, consumables and royalties	60,463	3,179	-
Other external expenses	955,895	939,566	549,079
Personnel costs	558,332	248,952	164,206
Depreciation on equipments and right-of-use assets	48,726	12,913	34,433
Other operating expenses	1,135	23,074	6,344
<b>Total</b>	<b>1,624,551</b>	<b>1,227,684</b>	<b>754,062</b>

## Note 8 Leases

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities for future remaining lease payments and right-of-use assets representing the right to use the underlying assets.

### Right-of-use assets

The Group recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received.

Right-of-use assets are depreciated on a straight-line basis over the estimated lease term, which currently is 1 to 8 years for the Group's leases.

### Lease liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments less any lease incentives receivable and variable lease payments that depend on an index or a rate. In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the commencement date, because the interest rate implicit in the lease is not readily determinable. Following the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, or a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments). The Group's lease liabilities are included in Non-current lease liabilities and other current liabilities in the consolidated statements of financial position (see Note 8 Leases and 19 Financial and non-financial assets and liabilities).

### Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of equipment (i.e., those leases that have a lease term of twelve months or less from the commencement date). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered to be low value. Lease payments on short-term leases and leases of low value assets are recognized as an expense on a straight-line basis over the lease term.

Right-of-use assets	December 31,	
	2023	2022
Opening balance	24,452	33,300
Additional agreements	10,518	-
Remeasurements of agreements	15,887	(427)
Depreciation	(12,360)	(10,807)
Termination of agreement	(113)	-
Exchange differences	(198)	2,386
<b>Net book value</b>	<b>38,186</b>	<b>24,452</b>

Depreciation on right-of-use assets is included in the consolidated statements of income under	Year Ended December 31,		
	2023	2022	2021
Research and development expenses	1,373	1,073	997
Marketing and selling expenses	3,923	3,743	1,522
Administrative expenses	7,064	5,991	3,192
	<b>12,360</b>	<b>10,807</b>	<b>5,711</b>

Lease liabilities	December 31,	
	2023	2022
Non-current lease liabilities	27,088	15,792
Current lease liabilities	12,537	10,374
<b>Total</b>	<b>39,625</b>	<b>26,165</b>

Lease liabilities are included in the consolidated statements of financial position under Non-current lease liabilities and Other current liabilities. Changes in liabilities arising from financing activities, see Note 23 Cash for further information on leasing liabilities.

Maturity analysis on future lease liabilities	December 31,	
	2023	2022
<12 months	25,102	16,467
1-2 years	21,509	12,613
>2 years	18,412	10,053
	<b>65,023</b>	<b>39,133</b>

Future lease payments in accordance with the above are undiscounted.

The leases primarily comprise of leased premises for the Group. The lease agreements for leased premises have terms ending 2024 until 2030 respectively and can be extended unless one of the parties terminates the lease agreements. The Group cannot determine with reasonable certainty whether the extensions will take place based on the Group's development and has therefore not expected utilization after the terms ending. Future lease payments are linked to the development in the CPI index, but with a limitation on negative index change. Index adjustments are included in the lease liability when they come into force and are then adjusted against the right-of-use asset. Lease of low-value assets consists mainly of storage and office equipment.

	Year Ended December 31,		
	2023	2022	2021
Interest expenses attributable to lease liabilities	2,744	1,604	590
Expenses attributable to short-term lease	6	0	633
Expenses attributable to leasing agreements with low value	225	214	146
Expenses attributable to variable lease payments that are not included in lease liabilities	1,726	303	446
Expenses attributable to lease depreciation	12,360	10,807	5,711
<b>Total expensed during the year</b>	<b>17,061</b>	<b>12,928</b>	<b>7,526</b>
This year's lease payments in the Group	16,784	13,231	6,659

## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

### Note 9 Employees and Personnel Costs

#### Average Number of Employees

	Year Ended December 31,					
	2023		2022		2021	
	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.
<b>Parent Company</b>						
Sweden	58	38%	45	33%	29	40%
	<b>58</b>	<b>38%</b>	<b>45</b>	<b>33%</b>	<b>29</b>	<b>40%</b>
<b>Subsidiaries</b>						
France	3	-	2	0%	3	26%
Switzerland	8	38%	6	53%	6	47%
United States	112	46%	33	52%	18	62%
	<b>123</b>	<b>44%</b>	<b>41</b>	<b>51%</b>	<b>27</b>	<b>55%</b>
<b>Total for the Group</b>	<b>181</b>	<b>42%</b>	<b>86</b>	<b>41%</b>	<b>56</b>	<b>47%</b>

#### Wages and Salaries, Pension Costs and Social Security Costs to the Board, Executive Management and Other Employees

Wages and Salaries	Year Ended December 31,		
	2023	2022	2021
<b>Parent Company</b>			
Board and Executive Management <sup>1)</sup>	39,436	33,471	27,792
Other employees	76,055	52,126	33,370
<b>Subsidiaries</b>			
Board and Executive Management	14,783	14,493	4,983
Other employees	315,885	90,055	57,452
<b>Total</b>	<b>446,159</b>	<b>190,145</b>	<b>123,597</b>

<sup>1)</sup> Executive Management includes the Board, CEO and other executive management.

Social Security Costs and Pension Costs	Year Ended December 31,		
	2023	2022	2021
<b>Parent Company</b>			
Pension costs for the Board and Executive Management	3,035	2,167	1,785
Pension costs to other employees	9,343	6,582	4,084
Social security costs	37,634	17,393	17,088
<b>Subsidiaries</b>			
Pension costs for the Board and Executive Management	229	616	167
Pension costs to other employees	7,693	2,647	928
Social security costs	27,346	6,484	8,596
<b>Total</b>	<b>85,280</b>	<b>35,889</b>	<b>32,648</b>

#### Gender Distribution Among the Board and Senior Executives

	Year Ended December 31,		
	2023	2022	2021
Percentage of women on the Board	50%	67%	60%
Percentage of men on the Board	50%	33%	40%
Percentage of women among other executive management	29%	38%	33%
Percentage of men among other executive management	71%	62%	67%

## Disclosures Regarding Total Remuneration of The Board and Executive Management

Year Ended December 31, 2023

	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
<b>Chairman of the Board</b>						
Elmar Schnee	1,020	-	-	-	718	1,738
<b>Board members</b>						
Elisabeth Björk	383	-	-	-	204	586
Frederick Driscoll (from Jun, 23)	303	-	-	-	84	387
Hilde Furberg	458	-	-	-	273	731
Molly Henderson (until May, 23)	295	-	-	-	21	316
Diane Parks	522	-	-	-	273	796
Henrik Stenqvist	558	-	-	-	204	761
<b>Senior executives</b>						
CEO, Renée Aguiar-Lucander	6,725	1,817	3,177	-	6,648	18,367
Other executive management (6 people)	18,737	1,446	5,731	-	8,030	33,945
<i>of which relates to subsidiaries</i>	8,689	229	3,768	-	2,470	15,156
<b>Total</b>	<b>29,000</b>	<b>3,264</b>	<b>8,908</b>	<b>-</b>	<b>16,455</b>	<b>57,626</b>

Year Ended December 31, 2022

	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
<b>Chairman of the Board</b>						
Elmar Schnee	975	-	-	-	647	1,622
<b>Board members</b>						
Elisabeth Björk (from May, 2022)	188	-	-	-	74	261
Hilde Furberg	413	-	-	-	239	651
Lennart Hansson (until May, 2022)	200	-	-	-	33	233
Molly Henderson	590	-	-	-	227	817
Diane Parks	490	-	-	-	239	729
Henrik Stenqvist (from May, 2022)	275	-	-	-	74	349
<b>Senior executives</b>						
CEO, Renée Aguiar-Lucander	5,938	760	2,293	-	4,056	13,048
Other executive management (7 people)	17,784	2,023	5,146	-	8,083	33,037
<i>of which relates to subsidiaries</i>	7,516	616	3,152	-	3,824	15,109
<b>Total</b>	<b>26,853</b>	<b>2,783</b>	<b>7,440</b>	<b>-</b>	<b>13,671</b>	<b>50,747</b>

Year Ended December 31, 2021

	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
<b>Chairman of the Board</b>						
Elmar Schnee	898	-	-	-	465	1,363
<b>Board members</b>						
Hilde Furberg	336	-	-	-	162	498
Lennart Hansson	360	-	-	-	162	522
Molly Henderson	539	-	-	-	124	663
Diane Parks	421	-	-	-	162	583
<b>Senior executives</b>						
CEO, Renée Aguiar-Lucander	4,860	760	1,840	-	3,270	10,730
Other executive management (5 people)	11,279	1,193	2,335	-	5,561	20,368
<i>of which relates to subsidiaries</i>	2,775	167	694	-	1,515	5,151
<b>Total</b>	<b>18,693</b>	<b>1,953</b>	<b>4,175</b>	<b>-</b>	<b>9,906</b>	<b>34,727</b>

# GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

## Remuneration of Executive Management

Remuneration of the CEO and other executive management comprises base salary, pension benefits and variable remuneration. Other executive management comprise the seven (five) individuals who, together with the CEO, comprise Executive Management. Other executive management are: Chief Financial Officer, Chief Medical Officer, Vice President Regulatory Affairs, President, North America, Group General Counsel and Head of Human Resources.

## Pensions

All pension commitments are defined-contribution plans for executive management. The payments made by the Group for defined contribution plans are recognized as expense in the statements of consolidated operations for the period to which they relate. The age of retirement for the CEO is 65 and the pension premium is 20% of base salary. Pension commitments for other Swedish executive management are between 15% and 20% of base salary. The age of retirement is 65 for all other executive management. Defined-benefit pension plans occurs only if required by law or other regulations. In such cases, the defined-benefit level shall be limited to the mandatory level. There are no other pension obligations.

## Variable Remuneration

Variable remuneration refers to a variable bonus based on a fixed percentage of base salary. Outcome is based on a vesting period of one year and depends on fulfillment of a combination of predetermined personal targets and business targets. The maximum outcome for the CEO and for other executive management is 60% according to the guidelines for remuneration to executive management.

## Severance Pay

A notice period of six months applies if employment is terminated by the CEO. A notice period of twelve months applies if employment is terminated by the Group. The CEO is not entitled to separate severance pay but is eligible to receive a salary during the period of notice. A mutual notice period of three to twelve months, with salary paid, applies between the Group and executive management. No severance pay is paid to Board members.

## Guidelines for Executive Remuneration

At the 2023 Annual General Meeting the most recently adopted guidelines for executive remuneration was approved. Remuneration within the Group shall be based on principles of performance, competitiveness and fairness. For additional information of the work of the Board of Directors, please see the Corporate Governance Report on pages 88-93.

Executive management refer to the CEO and other members of the executive management, as well as board members. The guidelines shall apply to employment agreements concluded after the listing on Nasdaq Stockholm, as well as to changes in existing agreements after the listing.

The remuneration to the executive management may consist of fixed remuneration, variable remuneration, share and share price-related incentive programs, pension and other benefits. If local conditions justify variations in the remuneration principles, such variations may occur. The fixed remuneration shall reflect the individual's responsibility and experience level. The fixed remuneration shall be reviewed annually. The executive management may be offered variable remuneration paid in cash. Such remuneration may not exceed 60 percent of the annual fixed remuneration. Variable remuneration shall be connected to predetermined and measurable criteria, designed with the aim of promoting the Groups long-term value creation. Remuneration and other terms of employment for the CEO are prepared by the Remuneration Committee and decided by the Board of Directors. Remuneration and other terms of employment for other members of the executive management are decided by the CEO, in accordance with principles decided by the Board of Directors and the Remuneration Committee.

The Board of Directors is entitled to deviate from the guidelines if the Board of Directors, in a certain case, deems that there are good reasons for the deviation. Decisions as to the current remuneration levels and other conditions for employment of the CEO and the other members of the executive management have been resolved by the Board of Directors. There are no previous payments that have not been due.

## Note 10 Share-Based Payments

### Option Program

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.

Social security costs attributable to equity-related instruments to employees as remuneration for purchased services shall be expensed over the periods during which the services are performed. The cost should then be measured using the same valuation model used when the options were issued. The provision recognized must be revalued at each reporting period on the basis of a calculation of the social security costs that may be paid when the instruments are exercised.

The cost for the remuneration that is recognized in a period is dependent on the original valuation that was made on the date on which the contracts with the participants in the incentive programs were concluded, the number of months of service required for vesting of their options (accruals are made over this period), the number of options that are expected to be vested under the terms of the plans and a continuous reassessment of the value of the tax benefits for the participants under the plans (for determining provisions for social security expenses). Those estimates which affect the cost in a period and the corresponding increase in equity mainly refer to inputs for the valuation of the options. All the options are classified as equity-settled, as vested options are settled in equity. When the options are exercised, the company issues new shares.

Changes and holdings of options for CEO, other executive management and other employees on the opening and closing balance are presented below.

Holder	Options Outstanding as of				
	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Renée Aguiar-Lucander, CEO	296,000	295,000	591,000	250,000	841,000
Other executive management	535,000	520,000	1,055,000	80,000	1,135,000
Other employees and consultants	1,458,000	848,166	2,306,166	1,816,564	4,122,730
<b>Total</b>	<b>2,289,000</b>	<b>1,663,166</b>	<b>3,952,166</b>	<b>2,146,564</b>	<b>6,098,730</b>

#### Calculation of fair value of option program (ESOP)

The fair value on the grant date was calculated using an adapted version of the Black & Scholes valuation model, which takes into consideration the exercise price, the term of the options, share price on the grant date and expected volatility in the share price, and risk-free interest for the term of the options.

	Grant Date	Exercise Date	Fair value Upon Issue of the Options, SEK	Exercise Price, SEK	Volatility	No. of Shares Covered by Options
ESOP 2020:1	July 1, 2020	July 1, 2023	22,14	121,43	39,60%	829,564
ESOP 2020:2	September 17, 2020	September 17, 2023	22,50	116,78	41,60%	104,000
ESOP 2020:3	February 4, 2021	February 4, 2024	30,41	145,07	44,30%	37,000
ESOP 2020:4	March 9, 2021	March 9, 2024	30,41	141,26	45,20%	394,166
ESOP 2021:1	June 14, 2021	June 14, 2024	35,88	140,71	46,00%	487,000
ESOP 2021:2	September 29, 2021	September 29, 2024	25,72	109,38	47,52%	329,500
ESOP 2021:3	March 17, 2022	March 17, 2025	27,64	93,77	43,84%	618,000
ESOP 2022:1	September 27, 2022	September 27, 2025	26,57	94,66	45,14%	1 016,500
ESOP 2022:2	March 9, 2023	March 9, 2026	35,90	116,38	53,84%	455,000
ESOP 2022:3	May 24, 2023	May 24, 2026	39,91	128,54	58,24%	413,000
ESOP 2023:1	July 25, 2023	July 25, 2026	40,76	97,80	57,74%	965,000
ESOP 2023:2	December 19, 2023	December 19, 2026	48,84	118,02	59,17%	450,000
						<b>6,098,730</b>

The total cost of the outstanding option program is presented below. These costs do not affect the Groups consolidated statements of cash flows. The Group has in total 7,000,000 options which are set aside to secure the delivery of shares in connection with the utilization of the option programs. For additional information see Note 25 Equity.

	Year Ended December 31,		
	2023	2022	2021
Share-based payments	50,560	34,549	24,737
Provisions attributable to changes in social security costs (Share-based payments)	20,701	234	9,992
<b>Total</b>	<b>71,261</b>	<b>34,783</b>	<b>34,729</b>

#### Share Awards

Calliditas implements share awards programs which is a performance-based long-term incentive program for members of the Board of Directors in Calliditas. Calliditas currently has three share award programs ongoing at year-end.

For each share award program, the share awards are vested by 1/3 at the end of each period, provided that the participant is still a member of the Board of Calliditas that day.

In addition to these conditions for vesting, for each share award program, the share awards are subject to performance-based vesting based on the development of Calliditas share price. If Calliditas share price has increased by more than 60 percent, 100 percent of the share awards shall be earned, and if the share price has increased by 20 percent, 33 percent of the share awards shall be vested. In the event of an increase in the share price by between 20 and 60 percent, vesting will be linear. If the share price has increased by less than 20 percent, no vesting will take place. Each share award entitles the holder to receive a share in Calliditas free of charge, provided that the holder is still a member of the Board of Calliditas at the relevant vesting date.

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(SEK in thousands, except per share amounts or as otherwise indicated)

Changes and holdings of share awards for the Board on the opening and closing balance are presented below:

Holder	Share Awards Outstanding as of				
	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Elmar Schnee, Chairman of the Board	14,063	-	14,063	-14,063	-
Hilde Furberg, Board member	4,327	-	4,327	-4,327	-
Lennart Hansson, Board member (until May, 2022)	4,327	-1,443	4,327	-4,327	-
Diane Parks, Board member	4,327	-	2,884	-2,884	-
Molly Hendersson, Board member	4,327	-	4,327	-4,327	-
<b>Total</b>	<b>31,371</b>	<b>-</b>	<b>29,928</b>	<b>-29,928</b>	<b>-</b>

Holder	Share Awards Outstanding as of				
	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Elmar Schnee, Chairman of the Board	10,624	-	10,624	-	10,624
Hilde Furberg, Board member	4,086	-	4,086	-	4,086
Lennart Hansson, Board member (until May-22)	4,086	(2,724)	1,362	-	1,362
Diane Parks, Board member	4,086	-	4,086	-	4,086
Molly Hendersson, Board member	4,086	-	4,086	(1,362)	2,724
<b>Total</b>	<b>26,968</b>	<b>(2,724)</b>	<b>24,244</b>	<b>(1,362)</b>	<b>22,882</b>

Holder	Share Awards Outstanding as of				
	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Elmar Schnee, Chairman of the Board	-	13,926	13,926	-	13,926
Hilde Furberg, Board member	-	5,356	5,356	-	5,356
Diane Parks, Board member	-	5,356	5,356	-	5,356
Molly Hendersson, Board member	-	5,356	5,356	(3,570)	1,786
Henrik Stenqvist, Board member	-	5,356	5,356	-	5,356
Elisabeth Björk, Board member	-	5,356	5,356	-	5,356
<b>Total</b>	<b>-</b>	<b>40,706</b>	<b>40,706</b>	<b>(3,570)</b>	<b>37,136</b>

Holder	Share Awards Outstanding as of				
	January 1, 2022	Change	December 31, 2022	Change	December 31, 2023
Elmar Schnee, Chairman of the Board	-	-	-	14,012	14,012
Hilde Furberg, Board member	-	-	-	5,389	5,389
Diane Parks, Board member	-	-	-	5,389	5,389
Fred Driscoll, Board member	-	-	-	5,389	5,389
Henrik Stenqvist, Board member	-	-	-	5,389	5,389
Elisabeth Björk, Board member	-	-	-	5,389	5,389
<b>Total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>40,957</b>	<b>40,957</b>

**For each share award program, calculation of fair value of share-based payments (Board LTIP)**

Fair value at grant day has been measured using a Monte Carlo simulation of future share price developments. The simulated share price trend has been used to both calculate the outcome of the program and the value of each share at the time of acquisition (present value adjusted to the grant date).

	Exercise Date	Fair Value at Grant Date	Number of Share Awards
Board LTIP 2021	July 1, 2024	62,95	22,882
Board LTIP 2022	July 1, 2025	51,54	37,136
Board LTIP 2023	July 1, 2026	57,90	40,957

The total cost of the outstanding share-based payments is presented below. These total costs do not affect the Groups consolidated statement of cash flows. The Group has in total 72,000 warrants, which are set aside to secure the delivery of shares in connection with the exercise of the share award programs. For additional information see Note 25 Equity.

	Year Ended December 31,		
	2023	2023	2022
Share-based payments	1,776	1,531	876
Provisions attributable to changes in social security costs (Share-based payments)	119	(1,614)	297
<b>Total</b>	<b>1,895</b>	<b>(83)</b>	<b>1,173</b>

**Warrants**

Calliditas has implemented warrant programs for employees and key consultants in Calliditas. When warrant is exercised, the holder pays a subscription price and then receives one common share in the Parent

Company. The warrants have been valued according to the Black & Scholes model, which means the value of the warrant depends on factors including the value of the underlying share, which in this case is the common share.

Outstanding Warrants per Year	Warrants Outstanding as of		Inputs used for the Black & Scholes valuation					
	December 31, 2021	December 31, 2022	Exercise Price, SEK	Price per Warrant in SEK	Value per Share in SEK	Risk-Free Rate	Volatility	Expiration Date
Warrant program 2018/2022	856,586	-	74,30	3,29	46,50	(0,28%)	33%	2022-03-31
Warrant program 2019/2022	422,500	-	74,50	6,69*	54,39*	(0,55%*)	36%*	2022-12-31
<b>Total</b>	<b>1,279,086</b>	<b>-</b>						

\* Average value

Changes and holdings of warrants for the Board, CEO, other executive management and other employees and consultants on the opening and closing balance are presented below;

Holder	Warrants Outstanding as of				
	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
CEO Renée Lucander	545,000	-	545,000	(545,000)	-
Other executive management	437,500	-	437,500	(437,500)	-
Other employees, consultants and external parties	296,586	-	296,586	(296,586)	-
<b>Total</b>	<b>1,279,086</b>	<b>-</b>	<b>1,279,086</b>	<b>(1,279,086)</b>	<b>-</b>

**Summary of Granted Warrants, Options and Share Awards**

	Options		Share Awards		Warrants	
	Number of Shares	Weighted Average Exercise Prices	Number of Shares	Weighted Average Exercise Prices	Number of Shares	Weighted Average Exercise Prices
Outstanding as of January 1, 2022	2,289,000	128,18	109,738	-	1,279,086	74,37
Granted	1,751,000	94,33	40,706	-	-	-
Forfeited	(87,834)	133,33	(4,167)	-	-	-
Exercised	-	-	(51,399)	-	(1,279,086)	74,37
<b>Outstanding as of December 31, 2022</b>	<b>3,952,166</b>	<b>113,07</b>	<b>94,878</b>	<b>-</b>	<b>-</b>	<b>-</b>

Outstanding as of January 1, 2023	3,952,166	113,07	94,878	-	-	-
Granted	2,333,000	111,16	40,957	-	-	-
Forfeited	(186,436)	104,54	(34,860)	-	-	-
Exercised	-	-	-	-	-	-
<b>Outstanding as of December 31, 2023</b>	<b>6,098,730</b>	<b>112,51</b>	<b>100,975</b>	<b>-</b>	<b>-</b>	<b>-</b>
Weighted average share price at the date of exercise	-	-	-	-	-	-

# GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

## Note 11 Financial Income

### Material accounting policy - financial income

Financial income consists of interest income and foreign exchange gains. Foreign exchange gains and losses are presented on a net basis.

	Year Ended December 31,		
	2023	2022	2021
Interest income	29,095	3,553	102
Exchange rate differences	1,292	46,642	20,234
<b>Total</b>	<b>30,387</b>	<b>50,195</b>	<b>20,336</b>

## Note 12 Financial Expenses

### Material accounting policy - financial expenses

Financial expenses mainly consist of interest expenses and unrealized foreign exchange losses. Foreign exchange gains and losses are presented on a net basis.

	Year Ended December 31,		
	2023	2022	2021
Interest on lease liabilities	(2,744)	(1,604)	(590)
Other interest expenses	(70,455)	(31,191)	(6,518)
Early repayment of loan	(35,397)	-	-
Other financial expenses	(5,753)	(4,874)	(2,145)
<b>Total</b>	<b>(114,349)</b>	<b>(37,669)</b>	<b>(9,253)</b>

## Note 13 Income Tax Expense

### Material accounting policy - taxes

Deferred tax is recognized on all temporary differences that arise between the tax value of assets and liabilities and their carrying amounts. Temporary differences attributable to participations in Group companies is not recognized, since it is unlikely that such a reversal will take place in the foreseeable future.

The valuation of deferred tax is based on how the underlying assets or liabilities are expected to be realized or settled. Deferred tax is measured with the application of the tax rates and tax rules decided or announced on the closing date, and that are expected to apply when the deferred tax asset in question is realized or the deferred tax liability is settled. Deferred tax liabilities and deferred tax assets are offset as far as possible within the framework of local laws and regulations on taxation.

### Significant accounting judgments, estimates and assumptions - loss carryforwards

The Group's tax losses carried forward have not been recognized as deferred tax assets in the statement of financial position as of December 31, 2022, except for such circumstances where there are future temporary differences that such losses can be used to offset. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

The Group has identified an uncertain tax position in relation to the ability to use tax loss carried forward in France due to transactions performed historically. The related tax losses carried forward has not been recognized as deferred tax assets in the consolidated statements of financial position.

	Year Ended December 31,		
	2023	2022	2021
Current income taxes	(23,484)	(11,539)	(4,581)
Deferred tax	14,316	8,688	8,417
<b>Income tax expense recognized in the consolidated statements of income</b>	<b>(9,168)</b>	<b>(2,851)</b>	<b>3,836</b>

Reconciliation of effective tax rate	Year Ended December 31,		
	2023	2022	2021
Accounting loss before income tax	(457,017)	(409,417)	(513,373)
Tax in accordance with applicable tax rate in Sweden 20.6%	94,145	84,340	105,755
<b>Tax effect of:</b>			
Effect of other tax rates for foreign subsidiaries	(16,159)	(11,857)	11,481
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(68,074)	(64,150)	(101,785)
Non-deductible expenses	(22,406)	(11,184)	(11,615)
Non-taxable income	3,326	-	-
<b>Income tax expense recognized in the consolidated statements of income</b>	<b>(9,168)</b>	<b>(2,851)</b>	<b>3,836</b>
<b>At the effective income tax rate</b>	<b>(2%)</b>	<b>(1%)</b>	<b>1%</b>

In 2021, the Group has costs attributable to new share issue amounted to SEK 20,909, which are recognized directly against equity. These costs are deductible for tax purposes.

The Group has SEK 3,881,336 and SEK 3,562,440 of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position as of December 31, 2023 and 2022, respectively. The tax losses carried forward are allocated between Sweden of SEK 1,772,890, France of SEK 1,209,163 and Switzerland of SEK 899,283, where the tax losses carried forward in Sweden and France may be carried forward indefinitely, but in Switzerland there is a time limit of seven years. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized or to the extent when there are temporary differences against which these will be able to be offset.

## Note 14 Earnings per Share

Loss per share before and after dilution	Year Ended December 31,		
	2023	2022	2021
Net loss for the year attributable to equity holders of the Parent Company	(466,185)	(412,268)	(500,293)
Weighted-average number of common shares outstanding	53,672,069	53,022,550	50,829,255
<b>Loss per share before and after dilution</b>	<b>(8,69)</b>	<b>(7,78)</b>	<b>(9,84)</b>

For calculation of earnings per share after dilution, the weighted-average number of outstanding ordinary shares is adjusted for the dilution effect of all potential ordinary shares, with the exception of treasury shares held by Calliditas. The Parent Company has a category of potential common stock with dilution effect: stock options. These potential common shares are attributable to the options and performance shares granted during the years 2020 - 2023. For additional information see Note 10 Share-Based Payments. If the profit for the year is negative, the options are not considered dilutive. The options also do not impact the numerator in the earnings per share calculation, including the addition of the value of remaining future services to report during the vesting period, exceeding the average market price for the period. There is no dilution effect for issued options with entitlement to subscribe to 6,098,730 shares, since the Group is in



a loss position in 2023, 2022, and 2021 respectively. Further, there is no dilution effect for issued share awards with entitlement to receive 100,975 shares, due to performance-based vesting.

For disclosures regarding the number of outstanding shares, refer to Note 25 Equity.

## Note 15 Intangible Assets and Impairment Testing

### Material accounting policy - intangible assets

#### Research and development expenses

Development expenditures are recognized as an intangible asset when related development projects meet the criteria for capitalization. The most important criteria for capitalization are that the final product of the development process will generate future economic benefits or the ability of cost-savings capacity, including the technical feasibility of completing the intangible asset. Research and development expense are otherwise recognized as operating expenses. Full market approval has not yet been obtained for the Group's products and, accordingly, the Group deems that the conditions for capitalizing development expenditures are not met.

#### Amortization

Until full regulatory market approval has been granted, amortization will not commence in respect of "Licenses and similar rights" that are separately acquired. Following market approval from regulatory authorities, "Licenses and Similar Rights" will be amortized on a straight-line basis over the expected useful life. The Group's expected finite useful lives are:

- Licenses and similar rights - 6-15 years

#### Impairment of intangible assets

The Group bases its impairment measurement on intangible assets on a probability-adjusted cash flow model. The value of licenses is measured by estimating the expected future cash flows and present value adjustments to take into account the development risk. The valuation takes into account cash flow from potential commercialization during the expected useful life and does not include calculation of any residual value thereafter. The most critical assumptions mainly consist of assumptions about the timing of potential commercialization, market size, market share and probability of reaching the market.

When assessing the impairment requirement for goodwill, this is grouped at the lowest levels for which there are separately identifiable cash flows. Calliditas has made the assessment that the Group's operations as a whole comprise a cash-generating unit.

### Significant accounting judgments, estimates and assumptions - intangible assets

The Group's intangible assets are attributable to the Group acquiring the rights to the NOX platform, as well as goodwill in connection with the acquisition of Genkyotex SA. For goodwill and intangible assets not yet available for use the Group assesses for impairment at each reporting date based on their recoverable amounts, including key assumptions such as the timing of potential commercialization, market size, market share, probability of reaching the market and the discount rates.

#### Goodwill and intangible assets, not yet available for use

The Group conducts impairment testing, at least annually, for goodwill and intangible assets not yet available for use. The recoverable amount of the cash-generating unit is determined by calculating the value in use. This calculation requires certain judgments and assumptions to be made. As of December 31, 2023, the Group's goodwill amounted to SEK 48,584 and other intangible assets amounted to SEK 430,754.

#### Capitalization expenditures for the development

The Group capitalizes expenditures for the development of pharmaceuticals to the extent that it is expected to meet the criteria in accordance with IAS 38 – Intangible Assets. The decision to capitalize is based on significant judgments made by management, including the technical feasibility of completing the intangible asset so that it will be available for use or sale and assumptions used to demonstrate that the asset will generate probable future economic benefits (e.g., projected cash flow projections, discount rate). The Group's expenditures for the development of pharmaceuticals were not deemed to meet the capitalization criteria for the year ended

December 31, 2023, and was thus expensed. Capitalization of expenditures are generally made in late stage of the development, for example after full approval, depending on when the criteria are deemed to have been met. The reason for this is that before then it is uncertain whether the expenditure will generate future economic benefits and that financing the completion of the asset is not yet guaranteed.

US Food and Drug Administration (FDA) has granted accelerated approval for TARPEYO® in the U.S. and the European Commission has granted conditional marketing authorization for Kinpeygo® in Europe (EEA). Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial and, accordingly, the conditions for capitalizing development expenditures may change to be reflected in the assumptions when they occur.

	December 31,	
	2023	2022
<b>Licenses and similar rights</b>		
Cost at opening balance	468,711	390,166
Disposal for the year	(62,697)	-
Exchange differences on translation	24,740	78,545
<b>Cost at closing balance</b>	<b>430,754</b>	<b>468,711</b>
<b>Impairment</b>		
Impairment at opening balance	(30,654)	(27,975)
Impairment	(32,132)	-
Disposal for the year	62,697	-
Exchange differences on translation	89	(2,679)
<b>Impairment at closing balance</b>	<b>-</b>	<b>(30,654)</b>
<b>Net book value</b>	<b>430,754</b>	<b>438,057</b>
<b>Goodwill</b>		
Cost at opening balance	45,784	37,227
Exchange differences on translation	2,800	8,557
<b>Cost at closing balance</b>	<b>48,584</b>	<b>45,784</b>

Intangible assets consist of licenses and similar rights of SEK 430,754 and goodwill of SEK 48,584 as of December 31, 2023.

Intangible assets are from the acquisition of the NOX-platform and associated goodwill. The net book value of the NOX-platform amounts to SEK 430,753 as of December 31, 2023. The NOX-platform constitutes a technology, including the lead compound setanaxib, enables the identification of orally available small molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis and inflammation. The estimated fair value of the NOX platform was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence. During the year, an impairment of SEK 32.1 million was recognized, and was related to the in-licensing Budenofalk. The decision to close was attributed to regulatory challenges.

### Impairment Testing

#### Goodwill

The assessment of the value of the Group's goodwill is based on the fair value less cost of disposals for the smallest cash-generating unit, which for Calliditas is deemed to be the full Group. The impairment measurement is based on a probability-adjusted cash flow model, measured at Level 3 of the fair value hierarchy, where the most critical assumptions mainly consist of assumptions about the timing of potential commercialization, market size, market share and probability of reaching the market. The period for the forecast cash flow extends to 2035, where no terminal growth rate has been taken into account. As of December 31, 2023, the Group's goodwill

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amounted to SEK 48,584. There is no impairment for the year ended December 31, 2023.

The following table shows the discount rate used before tax:

Parameter, %	Year Ended December 31,	
	2023	2022
Discount rate Goodwill	12.2	12.0

### Intangible assets, not yet available for use

These assets consist of the NOX platform, which are tested, at least, annually for impairment requirement. The assessment of the value of the technology and the rights is based on the fair value less cost of disposals of the assets. The fair value less cost of disposals is based on cash flows that are expected to be generated over the remaining life of the asset.

The following table shows the discount rate used before tax:

Parameter, %	Year Ended December 31,	
	2023	2022
Discount rate NOX platform	12.2	12.0

When the technology and the rights are tested for impairment requirement, a number of assumptions are made, where the most critical assumptions mainly consist of the timing of potential commercialization, market size, market share, probability of reaching the market and the discount rate. The earlier in the chain of development the project is, the higher the risk. As it passes through the defined phases of development, the likelihood of reaching the market increases. The review of the technology and the rights showed no impairment requirement except for impairment of Budenofalk 3 mg oral capsule amounted to SEK 32,132.

## Note 16 Equipment

	December 31,	
	2023	2022
Cost at opening balance	11,167	7,073
Acquisition for the year	12,788	2,512
Disposal for the year	(65)	-
Exchange differences	260	1,582
<b>Cost at closing balance</b>	<b>24,150</b>	<b>11,167</b>
Depreciation at opening balance	(3,700)	(764)
Depreciation for the year	(4,234)	(2,106)
Exchange differences	(164)	(830)
<b>Depreciation at closing balance</b>	<b>(8,098)</b>	<b>(3,700)</b>
<b>Net book value</b>	<b>16,053</b>	<b>7,468</b>

Depreciation on equipment is included in the statement of income under the sub-items:	December 31,		
	2023	2022	2021
Research and development expenses	1,315	579	59
Marketing and selling expenses	1,057	806	176
Administrative expenses	1,862	721	230
	<b>4,234</b>	<b>2,106</b>	<b>465</b>

Equipment is depreciated on a straight-line basis over the expected useful life.

The Group's expected useful life is:

- Equipment - 5 years
- Computers - 5 years

## Note 17 Non-Current Financial Assets

	December 31,	
	2023	2022
Cost at opening balance	11,210	3,915
Additional acquisition	13,774	7,064
Disposal for the year	(602)	-
Exchange differences	(181)	231
<b>Net book value</b>	<b>24,201</b>	<b>11,210</b>

Non-current financial assets comprise of bank guarantees/deposits amounted to SEK 7,637 and SEK 6,851 as of December 31, 2023 and 2022, respectively. Other non-current receivables amounted to SEK 16,564 and SEK 4,359 as of December 31, 2023 and 2022, respectively. Additional acquisitions are significantly related to future increases in production capacity. In the cash flow, the acquisitions are reported within operating activities.

## Note 18 Deferred Tax Assets and Deferred Tax Liabilities

Deferred tax assets and liabilities as of December 31, 2023	Deferred Tax Assets	Deferred Tax Liabilities	Net
Intangible assets	–	(59,487)	(59,487)
Tangible assets	–	(608)	(608)
Lease assets	–	(2,198)	(2,198)
Lease liabilities	2,465	–	2,465
Other liabilities	3,516	–	3,516
Personnel-related items	20,931	–	20,931
Tax loss carried forward	17,846	–	17,846
Other items	2,209	–	2,209
<b>Total</b>	<b>46,967</b>	<b>(62,293)</b>	<b>(15,326)</b>
Offsetting	(20,652)	20,652	–
<b>Tax assets/liabilities, net</b>	<b>26,315</b>	<b>(41,641)</b>	<b>(15,326)</b>

Tax losses carried forward of SEK 17,846 have been recognized as deferred tax assets in the statement of financial position as of December 31, 2023 due to future temporary differences that such asset can be used to offset.

For information regarding recognition of deferred tax losses, see Note 13 Income Tax Expense.

Change in deferred tax, 2023	Cost at Opening Balance	Recognized in Profit or Loss	Exchange Differences	Cost at Closing Balance
Intangible assets	(56,789)	765	(3,463)	(59,487)
Tangible assets	(766)	136	22	(608)
Lease assets	(3,060)	788	74	(2,198)
Lease liabilities	3,442	(894)	(83)	2,465
Other liabilities	3,218	444	(146)	3,516
Personnel-related items	10,653	11,289	(1,011)	20,931
Tax loss carried forward	17,037	(229)	1,038	17,846
Other items	311	2,017	(119)	2,209
<b>Total</b>	<b>(25,954)</b>	<b>14,316</b>	<b>(3,688)</b>	<b>(15,326)</b>

Deferred tax assets and liabilities as of December 31, 2022	Deferred Tax Assets	Deferred Tax Liabilities	Net
Intangible assets	–	(56,789)	(56,789)
Tangible assets	–	(766)	(766)
Lease assets	–	(3,060)	(3,060)
Lease liabilities	3,442	–	3,442
Other liabilities	3,218	–	3,218
Personnel-related items	10,653	–	10,653
Tax loss carried forward	17,037	–	17,037
Other items	311	–	311
<b>Total</b>	<b>34,661</b>	<b>(60,615)</b>	<b>(25,954)</b>
Offsetting	(20,863)	20,863	–
<b>Tax assets/liabilities, net</b>	<b>13,798</b>	<b>(39,752)</b>	<b>(25,954)</b>

Tax losses carried forward of SEK 17,037 have been recognized as deferred tax assets in the statement of financial position as of December 31, 2022 due to future temporary differences that such asset can be used to offset.

For information regarding recognition of deferred tax losses, see Note 13 Income Tax Expense.

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Change in deferred tax, 2022	Cost at Opening Balance	Recognized in Profit or Loss	Exchange Differences	Cost at Closing Balance
Intangible assets	(46,175)	-	(10,614)	(56,789)
Tangible assets	(238)	(477)	(51)	(766)
Lease assets	(2,672)	23	(411)	(3,060)
Lease liabilities	2,942	45	455	3,442
Other liabilities	-	3,122	96	3,218
Personnel-related items	4,140	5,699	814	10,653
Tax loss carried forward	15,319	-	1,718	17,037
Other items	23	276	12	311
<b>Total</b>	<b>(26,661)</b>	<b>8,688</b>	<b>(7,981)</b>	<b>(25,954)</b>

### Note 19 Financial and Non-Financial Assets and Liabilities

Financial and non-financial assets and liabilities as of December 31, 2023

December 31, 2023	Financial Assets Measured at Fair Value through Profit or Loss	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
<b>Assets</b>				
Non-current financial assets	-	24,201	-	24,201
Account receivables	-	180,892	-	180,892
Accrued income	-	7,297	-	7,297
Cash	-	973,733	-	973,733
	-	<b>1,186,123</b>	-	<b>1,186,123</b>

	Financial Liabilities Measured at Fair Value through Profit or Loss	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
<b>Liabilities</b>				
Contingent consideration	56,561	-	-	56,561
Non-current interest-bearing liabilities	-	939,508	-	939,508
Non-current lease liabilities	-	27,088	-	27,088
Other non-current liabilities	-	3,783	12,598	16,381
Accounts payable	-	100,564	-	100,564
Other current liabilities	-	12,537	7,249	19,786
Accrued expenses and deferred revenue	-	134,187	146,440	280,627
	<b>56,561</b>	<b>1,217,667</b>	<b>166,287</b>	<b>1,440,515</b>

Financial and non-financial assets and liabilities as of December 31, 2022

December 31, 2023	Financial Assets Measured at Fair Value through Profit or Loss	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
<b>Assets</b>				
Non-current financial assets	-	11,210	-	11,210
Account receivables	-	78,703	-	78,703
Accrued income	-	2,287	-	2,287
Cash	-	1,249,094	-	1,249,094
	-	<b>1,341,295</b>	-	<b>1,341,295</b>

	Financial Liabilities Measured at Fair Value through Profit or Loss	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
<b>Liabilities</b>				
Contingent consideration	75,880	-	-	75,880
Non-current interest-bearing liabilities	-	713,030	-	713,030
Non-current lease liabilities	-	15,792	-	15,792
Other non-current liabilities	-	1,363	2,987	4,350
Accounts payable	-	160,404	-	160,404
Other current liabilities	-	10,374	12,323	22,697
Accrued expenses and deferred revenue	-	75,754	60,692	136,446
	<b>75,880</b>	<b>976,717</b>	<b>76,002</b>	<b>1,128,598</b>

Financial liabilities valued through profit or loss constitutes of contingent consideration of SEK 56,561 and SEK 78,880 as of December 31, 2023 and 2022, respectively. The fair value of contingent consideration is measured at Level 3 of the fair value hierarchy. For additional information regarding the Group's contingent consideration, see Note 27 Contingent Consideration.

The carrying amount for other items above is an approximation of the fair value, which is why these items are not separated into levels according to the fair value hierarchy.

## Note 20 Financial Risks

### Significant accounting judgments, estimates and assumptions - expected credit losses

Management makes allowance for expected credit losses for accounts receivable that correspond to their maturity. The estimate is based on any increased credit risk, on an individual or collective basis, considering reasonable and supportable information, including that which is forward-looking. The allowance for expected credit risk is an estimate based on maturity structure accounts receivable and specific customer knowledge. Generally, invoices are due for payment within 30-45 days.

Through its operations, the Group is exposed to a variety of financial risks: credit risk, market risk (currency risk, interest rate risk and other price risk), refinancing risk, liquidity risk and external risk. The Group's overall risk management focuses on the unpredictability of the financial markets and it endeavors to minimize potentially unfavorable effects on the Group's financial results.

The Group's financial transactions and risks are managed centrally through the Group's CFO and CEO. The overall objective for financial risks is to provide cost-efficient financing and liquidity management and to ensure that all payment commitments are managed in a timely manner.

The Board prepares written policies for both the overall risk management and for specific areas, such as credit risks, currency risks, interest rate risks, refinancing risks, liquidity risks and the use of derivative instruments and investment of surplus liquidity.

### Credit Risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument, leading to a financial loss for the Group. The Group's exposure to credit risk, except for accounts receivable as described below, is limited to deposits with banks with high credit ratings, which means the Group is of the opinion that there is no material credit risk related to deposits with bank.

### Credit risk accounts receivable

The payment terms amount to 30-45 days depending on the counterparty. Of accounts receivables net, SEK 113,115 is to an individual major customer as of December 31, 2023.

### Expected credit losses

	December 31,	
	2023	2022
<b>Accounts receivable</b>		
Gross accounts receivables	181,931	79,873
Provisions, expected credit losses	(1,039)	(1,170)
<b>Net accounts receivables</b>	<b>180,892</b>	<b>78,703</b>
<b>Maturity structure accounts receivable</b>		
Accounts receivables, not yet due	181,931	79,873
Provisions, expected credit losses	(1,039)	(1,170)
<b>Net book value</b>	<b>180,892</b>	<b>78,703</b>
<b>Provisions for expected credit losses</b>		
Opening balance, expected credit loss provisions	(1,170)	-
This year provisions	-	(1,170)
Reversed provisions	87	-
Exchange differences	44	-
<b>Closing balance, expected credit loss provisions</b>	<b>(1,039)</b>	<b>(1,170)</b>

The credit quality of receivables that are not past due or written down is deemed to be good. See Note 3 Revenue from Contracts with Customers for further information.

### Market Risks

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. The type of market risk that impacts the Group is currency risk. The Group does not currently have any loans or holdings that expose the group to interest rate risk or other price risk.

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## Interest Rate Risk

Interest rate risk is the risk that would be adversely impacted by changes in interest rates resulting from increased interest costs. Calliditas exposure to interest rate risk mainly occurs through external loans and cash. Calliditas financing sources primarily consist of equity and borrowings. In the case of interest-bearing liabilities, the Group is exposed to interest rate risk. The Group does not currently have any variable interest rate and as of December 31, 2023 the carrying amount of Non-current interest-bearing liabilities are in all material respect an approximation of the present value.

## Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The primary exposure derives from the Group's purchases in foreign currencies. This exposure is known as transaction exposure. Currency risk is also found in the translation of the assets and liabilities of foreign operations to the Parent Company's functional currency, known as translation exposure.

## Transaction Exposure

Transaction exposure from contracted payment flows in foreign currency is limited in the Group. Refer to the table below for exposure in each currency.

Currency exposure 2023 (%)	Revenue	Operating expenses
USD	72%	16%
EUR	28%	58%
GBP	-	6%
SEK	-	20%
Other currencies	-	0%

Currency exposure 2022 (%)	Revenue	Operating expenses
USD	68%	20%
EUR	32%	48%
GBP	-	4%
SEK	-	27%
Other currencies	-	1%

Currency exposure 2021 (%)	Revenue	Operating expenses
USD	14%	43%
EUR	86%	36%
GBP	-	3%
SEK	-	18%

As presented in the table above, the Group's primary transaction exposure is in Euro and U.S. dollar. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 29,332 (SEK 23,132, SEK 909). A 10% stronger U.S. dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately pos. SEK 49 (SEK 9,624, SEK 22,402).

## Translation Exposure

The Group also has translation exposure that arises on the translation of earnings and net assets of foreign subsidiaries to the Swedish Kronor. Translation against U.S. dollar amounted to SEK 85,240 and SEK 48,771 as of December 31, 2023 and 2022, respectively.

A 10% stronger Swedish Krona against the U.S. dollar would have a positive impact on equity of approximately SEK 8,524 and SEK 4,877 as of December 31, 2023 and 2022, respectively. Translation against Euros amounted to SEK 391,568 and SEK 446,646 as of December 31, 2023 and 2022, respectively. A 10% stronger Swedish Krona against Euros would have a positive impact on equity of approximately SEK 39,157 and SEK 44,665 as of December 31, 2023 and 2022, respectively. Translation against Swiss franc amounted to (SEK 794,449) and (SEK 537,550) as of December 31, 2023 and 2022, respectively. A 10% stronger Swedish

Krona against Swiss franc would have a negative impact on equity of approximately SEK 79,445 and SEK 53,755 as of December 31, 2023 and 2022, respectively.

The Group also has a translation exposure arising from the translation of foreign accounts payable to the Swedish Kronor. This exposure amounted to SEK 24,606 and SEK 19,377 as of December 31, 2023 and 2022, respectively, and in U.S. dollars SEK 68,391 and SEK 80,655 in Euros as of December 31, 2023 and 2022, respectively. A 10% stronger U.S. dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 2,461 and SEK 1,938 as of December 31, 2023 and 2022, respectively. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 6,839 and SEK 8,065 as of December 31, 2023 and 2022, respectively.

## Refinancing Risk

Refinancing risk refers to the risk that cash are not available and the risk that financing cannot be secured at a reasonable cost or at all. The Group is financed with equity, external loan financing and income from operations. The main risks relate to not receiving further contributions from shareholders, external loans or in the event of continued negative cash flow from operations.

## Liquidity Risk

Liquidity risk is the risk that the Group encounters difficulties in meeting its obligations associated with financial liabilities. The Board manages liquidity risks by continuously monitoring cash flow so that it can reduce liquidity risk and ensure its solvency. Given that the Parent Company currently does not have its own earning ability, the Board carries out long-term work with owners and independent investors to ensure that liquidity is available to the Parent Company when a need arises.

The Group's contractual and undiscounted interest payments and repayments of financial liabilities are presented in the table below.

Amounts in foreign currency were translated to SEK at the closing balance rate. Financial instruments with variable interest rates were measured at the rate on the closing balance. Liabilities were included in the earliest period when repayment is required. For future lease payments see Note 8 Leases.

Maturity analysis	December 31, 2023		
	<6 months	6-12 months	2-5 years
Contingent consideration	-	-	56,561
Non-current interest-bearing liabilities	-	-	939,508
Non-current lease liabilities	-	-	27,088
Other non-current liabilities	-	-	16,381
Accounts payable	100,564	-	-
Other current liabilities	11,649	8,138	-
Accrued expenses	255,200	25,427	-

Maturity analysis	December 31, 2022		
	<6 months	6-12 months	2-5 years
Contingent consideration	-	-	75,880
Non-current interest-bearing liabilities	-	-	713,030
Non-current lease liabilities	-	-	15,792
Other non-current liabilities	-	-	4,350
Accounts payable	160,404	-	-
Other current liabilities	13,288	9,409	-
Accrued expenses	121,865	14,581	-

	December 31,	
	2023	2022
<b>Non-current interest-bearing liabilities</b>		
Opening balance	713,030	189,164
New borrowings, net	962,889	491,745
Repayment of borrowings	(724,479)	-
Transaction costs paid	(26,625)	(1,260)
Interest expense	41,148	4,874
Exchange difference on translation	(26,455)	28,507
<b>Closing balance</b>	<b>939,508</b>	<b>713,030</b>

During 2023, Calliditas had signed and fully drawn a term loan of EUR 92 million with funds managed by Athyrium Capital Management, LP. The fair value of the loan at the end of the period amounts to SEK 966,1 million. The net book value of the loan at the end of the period, adjusted for transaction costs and accrued interest expense, is 939,5 million. The interest rate on the loan is 9% per annum with a maturity to December 2027, which is recognized in Financial expenses. The credit agreement contains quarterly financial covenants specifying minimum cash liquidity and minimum product revenue. The credit agreement contains customary affirmative and negative covenants for a senior secured loan. Failure to maintain compliance with the covenants would result in an event of default under the Athyrium Credit Agreement, which could result in enforcement action, including acceleration of amounts due under the Athyrium Credit Agreement.

## Note 21 Inventories

Inventory is recognized as the lower of the acquisition cost and the net realizable value. The acquisition cost for completed goods and goods being manufactured comprises raw materials and other direct costs and applicable indirect manufacturing costs. The net realizable value is the estimated sale price in operating activities after deduction of sales cost.

	December 31,	
	2023	2022
Raw materials	9,058	1,855
Work in progress	4,677	937
Finished goods	6,693	855
<b>Total</b>	<b>20,428</b>	<b>3,647</b>

Inventories recognized as cost of sales amounted to SEK 22,248, SEK 3,179 in 2023 and 2022, respectively. No inventories were recognized as cost of sales in 2021. Write-downs of inventories amounted to SEK 66 in 2023. No write-downs of inventories have occurred in 2022 and 2021, respectively.

## Note 22 Prepaid Expenses and accrued income

	December 31,	
	2023	2022
Accrued income	7,297	2,287
Prepaid insurance premiums	8,755	9,148
Prepaid interest costs	-	3,693
Prepaid expenses for research and development	43,085	45,454
Prepaid expenses for marketing and selling	16,722	8,194
Other prepaid administration expenses	8,465	1,964
<b>Total</b>	<b>84,324</b>	<b>70,741</b>

## Note 23 Cash

	December 31,	
	2023	2022
Cash at Banks	973,733	1,249,094
<b>Total</b>	<b>973,733</b>	<b>1,249,094</b>

Cash and Banks balances are primarily in SEK, EUR and USD.

### Adjustments for non-cash items in the consolidated statements of cash flows:

	Year Ended December 31,		
	2023	2022	2021
Depreciations and impairments	48,726	12,913	34,433
Change in Provisions	20,888	(3,346)	5,856
Share-based payments	52,591	35,791	21,960
Change of Contingent consideration	(18,835)	15,941	4,470
Other items	(892)	(39)	(43)
<b>Total</b>	<b>102,478</b>	<b>61,260</b>	<b>66,676</b>

### Reconciliation of liabilities from financing activities

	January 1, 2023	Cash-Flow	Non-Cash-Items	December 31, 2023
Non-current interest-bearing liabilities	713,030	211,785	14,693	939,508
Lease liabilities	26,165	(12,134)	25,594	39,625
	<b>739,195</b>	<b>199,651</b>	<b>40,287</b>	<b>979,133</b>

	January 1, 2022	Cash-Flow	Non-Cash-Items	December 31, 2022
Non-current interest-bearing liabilities	189,164	490,485	33,381	713,030
Lease liabilities	33,642	(9,615)	2,138	26,165
	<b>222,806</b>	<b>480,870</b>	<b>35,519</b>	<b>739,195</b>

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## Note 24 Group Companies

Company	Principal Activities	Country of Incorporation	% Equity Interest		
			2023	2022	2021
<b>Parent Company</b>					
Calliditas Therapeutics AB	Research and development of pharmaceuticals	Sweden	-	-	-
<b>Subsidiaries</b>					
Nefecon AB	Administration of incentive programs issued by the Parent Company	Sweden	100%	100%	100%
Calliditas NA Enterprises Inc	Market access activities in the United States	United States	100%	100%	100%
Calliditas Therapeutics US Inc	Commercial activities in the United States	United States	100%	100%	100%
Calliditas Therapeutics France SAS	Research and development of pharmaceuticals	France	100%	100%	100%
Calliditas Therapeutics Suisse SA	Research and development of pharmaceuticals	Switzerland	100%	100%	100%

## Note 25 Equity

### Treasury shares

When Callidita's shares classified as equity are repurchased the amount for the purchase price paid is recognized as a reduction in equity. Repurchased shares are classified as Treasury shares and reported as one deduction item under equity. When Treasury shares are subsequently sold or reissued the amount received is reported as an increase in equity and the surplus or deficit resulting from the transaction is transferred to or from other contributed capital.

	Year Ended December 31,		
	2023	2022	2021
Total registered shares at the beginning of the year	59,580,087	52,341,584	49,941,584
New share issue*	-	-	2,400,000
Exercise of warrants	-	1,322,985	-
Issuance of treasury shares	-	5,908,018	-
Shares subscribed but not registered during the year	-	7,500	-
<b>Total registered and subscribed but not registered shares at the end of the year</b>	<b>59,580,087</b>	<b>59,580,087</b>	<b>52,341,584</b>
<b>Shares</b>			
Ordinary shares	59,580,087	59,580,087	52,341,584
<b>Total</b>	<b>59,580,087</b>	<b>59,580,087</b>	<b>52,341,584</b>
- of which shares are held by Calliditas	5,908,018	5,908,018	-
<b>Total registered and subscribed but not registered shares at the end of the year, net of shares held by Calliditas</b>	<b>53,672,069</b>	<b>53,672,069</b>	<b>52,341,584</b>
<b>December 31,</b>			
<b>Share Capital</b>	<b>2023</b>	<b>2022</b>	<b>2021</b>
Opening balance	2,383	2,094	1,998
New share issue*	-	-	96
Exercise of warrants	-	53	-
Issuance of treasury shares	-	236	-
<b>Closing balance</b>	<b>2,383</b>	<b>2,383</b>	<b>2,094</b>

\* New share issue in August 2021

\*\* As of December 31, 2022, there was an on-going issue of 7,500 shares under registration related to the exercise under the Warrant Program 2019/2022. These shares have been included in the weighted-average number of shares outstanding for the period.



### Share Capital

All shares have been fully paid and no shares are reserved for sale. All shares are common shares, confer the same entitlement to capital, and carry one vote. The quotient value is SEK 0.04 per share.

### Transactions in Treasury Shares

As of December 31, 2023, Calliditas had 5,908,018 ordinary shares held as treasury shares by the Parent Company. At the Annual General Meeting 2023, authorization was given that Calliditas can transfer (sale) these ordinary shares with the purpose to finance an acquisition of operations, to procure capital to finance the development of projects, repayment of loans or to commercialize Calliditas' products. No transfer (sale) of treasury shares have occurred as of December 31, 2023. The total number of issued shares as of December 31, 2023, is presented in the tables above.

### Translation Reserve

The reserves pertain in their entirety to translation reserves. The translation reserve includes all exchange rate differences arising on the translation of the financial statements from foreign operations.

Translation Reserve	December 31,		
	2023	2022	2021
Opening balance	9,307	(26,979)	(6,090)
Change of the year	(14,538)	36,286	(20,889)
<b>Closing balance</b>	<b>(5,231)</b>	<b>9,307</b>	<b>(26,979)</b>

## Note 26 Provisions

### Material accounting policy - provisions

A provision differs from other liabilities as there is uncertainty in the time of payment or the size of the amount to settle the provision. A provision is reported in the group's statement of financial position when there is an existing legal or informal obligation as a result of an event that has occurred, and it is likely that an outflow of financial resources will be required to settle the obligation and a reliable estimate of the amount may be done. Provisions are made with the amount that is the best estimate of what is required to settle the existing obligation at the balance sheet date. Where the effect of when in time payment takes place is significant, provisions are calculated by discounting the expected future cash flow.

Provisions as of December 31, 2023	Social Security Costs on Share-Based Payment	Other provisions	Provisions, net
Opening balance	11,792	-	11,792
Provisions for the year	21,109	-	21,109
Exchange differences	(306)	-	(306)
<b>Total</b>	<b>32,595</b>	<b>-</b>	<b>32,595</b>

Provisions as of December 31, 2022	Social Security Costs on Share-Based Payment	Other provisions	Provisions, net
Opening balance	13,084	1,446	14,530
Provisions for the year	1,027	-	1,027
Amounts claimed for the year	(204)	-	(204)
Reversal of unused amounts	(2,666)	(1,573)	(4,239)
Exchange differences	551	127	678
<b>Total</b>	<b>11,792</b>	<b>-</b>	<b>11,792</b>

### Social Security Costs on Share-Based Payment

There is uncertainty as to when social security costs for share-based payments will be paid in the future, and what amount they will ultimately be adjusted to as it is dependent on market values at the time when performance shares are used.

# GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

## Note 27 Contingent Consideration

### Material accounting policy - contingent consideration

The Group's contingent consideration is classified as financial liabilities that are recognized at fair value through profit or loss. Measurement is both initially and in subsequent periods made at fair value in the Group's consolidated statements of financial position, where changes in fair value are recognized in the Group's consolidated statements of income. The components of the change in fair value relating to exchange rate effects are recognized in net financial items and other changes in fair value are recognized in operating profit or loss.

	December 31,	
	2023	2022
Opening balance	75,880	54,399
Change for the year	(18,835)	15,942
Exchange differences	(484)	5,539
<b>Net book value</b>	<b>56,561</b>	<b>75,880</b>

### Contingent Consideration

In connection with the business combination of Genkyotex SA, the Group has undertaken to make potential future milestone payments relating to contingent consideration, provided that future regulatory approvals or marketing authorizations regarding setanaxib are obtained. The transaction stipulates the following contingent consideration:

Milestone 1: EUR 30.0 million if Genkyotex is granted the right to commercially manufacture, market and sell setanaxib in the United States by the FDA.

Milestone 2: EUR 15.0 million if Genkyotex is granted the right to commercially manufacture, market and sell setanaxib in the European Union by the European Commission.

Milestone 3: EUR 10.0 million if Genkyotex is, by the FDA or European Commission, granted the right to commercially manufacture, market and sell setanaxib in the United States or European Union for the treatment of IPF or Type 1 Diabetes.

The fair value of contingent consideration is measured at Level 3 of the fair value hierarchy. Contingent consideration is recognized as a financial liability in the consolidated statements of financial position, which is revalued at fair value each reporting period. Any revaluation gains and losses are recognized in the consolidated statements of income. The contingent consideration has been computed in accordance with the present value method and the probability has been taken into account if and when the various milestones will occur. The calculations are based on a discount rate of 12.2 percent. The most significant input affecting the valuation of the contingent consideration is the company's estimate of the probability of the milestones being reached and the change of the year was primarily derived from the assumptions regarding the probability of success in the clinical trials.

The Group has assessed the weighted average probability of outcome at 19.7% and 20.8% as of December 31, 2023 and 2022, respectively. A 10% higher probability of success in the clinical trials would have a negative impact on profit after tax of approximately SEK 5,656 and SEK 7,588 as of December 31, 2023 and 2022, respectively. A higher probability of success in the clinical trials will increase the fair value of the liability and a lower probability will decrease the fair value. There are no interrelationships between unobservable inputs used in the fair value measurement.

## Note 28 Pension Liabilities

### Assumption in valuations of the pension obligations

The valuation of pension obligations and pension costs is based on actuarial assumptions.

### Defined-Benefit Pension Plan

The defined-benefit pension obligations are based on actuarial principles. Calliditas has defined-benefit pension plans for the subsidiaries in France and Switzerland for retirement, death and disability. The present value of the obligation includes special payroll tax, in accordance with IAS 19, for the Swiss pension plans. Pension expenses are recognized under research and development expenses and administrative expenses in the consolidated statements of income.

Net obligation per country	December 31,	
	2023	2022
Switzerland	(3,394)	(789)
France	(127)	(94)
<b>Total</b>	<b>(3,521)</b>	<b>(884)</b>

## Changes in the defined-benefit pension obligations

	Defined Benefit Plan Obligation (Switzerland)	Defined Benefit Plan Obligation (France)	Fair Value of Plan Assets (Switzerland)	Employee Benefit Obligations
<b>January 1, 2023</b>	<b>(6,027)</b>	<b>(94)</b>	<b>5,238</b>	<b>(884)</b>
Service costs	(1,599)	(18)	-	(1,617)
Interest expense	(117)	(4)	119	(1)
Employee contribution	-	-	920	920
<b>Subtotal included in the operating loss in the consolidated statements of income</b>	<b>(1,716)</b>	<b>(21)</b>	<b>1,039</b>	<b>(698)</b>
Amounts paid/received	2,441	-	(2,441)	-
Return on assets (excluding interest expenses)	-	-	(67)	(67)
Actuarial gains/(losses) related to changes in demographic assumptions	-	(13)	-	(13)
Actuarial gains/(losses) related to changes in financial assumptions	(2,316)	-	-	(2,316)
Other actuarial gains/(losses)	52	-	-	52
Plan amendment	(433)	-	-	(433)
<b>Subtotal included in other comprehensive income</b>	<b>(2,697)</b>	<b>(13)</b>	<b>(67)</b>	<b>(2,777)</b>
Employer contributions	-	-	920	920
Currency translation effect	(397)	2	313	(82)
<b>December 31, 2023</b>	<b>(8,395)</b>	<b>(127)</b>	<b>5,001</b>	<b>(3,521)</b>

	Defined Benefit Plan Obligation (Switzerland)	Defined Benefit Plan Obligation (France)	Fair Value of Plan Assets (Switzerland)	Employee Benefit Obligations
<b>January 1, 2022</b>	<b>(7,942)</b>	<b>(111)</b>	<b>4,871</b>	<b>(3,182)</b>
Service costs	(1,530)	(26)	-	(1,556)
Interest expense	(27)	(1)	18	(10)
Employee contribution	-	-	887	887
<b>Subtotal included in the operating loss in the consolidated statements of income</b>	<b>(1,558)</b>	<b>(27)</b>	<b>906</b>	<b>(679)</b>
Amounts paid/received	2,140	-	(2,140)	-
Return on assets (excluding interest expenses)	-	-	34	34
Actuarial gains/(losses) related to changes in demographic assumptions	-	54	-	54
Actuarial gains/(losses) related to changes in financial assumptions	2,846	-	-	2,846
Other actuarial gains/(losses)	(454)	-	-	(454)
<b>Subtotal included in other comprehensive income</b>	<b>2,392</b>	<b>54</b>	<b>34</b>	<b>2,480</b>
Employer contributions	-	-	887	887
Currency translation effect	(1,059)	(9)	679	(390)
<b>December 31, 2022</b>	<b>(6,027)</b>	<b>(94)</b>	<b>5,238</b>	<b>(884)</b>

# GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

Distribution by Plan Assets (Switzerland)	December 31,	
	2023	2022
Cash	430	137
Bonds	515	3,048
Mortgage loans	75	655
Shares	1,450	126
Real estate	1,581	901
Other investments	950	372
<b>Total</b>	<b>5,001</b>	<b>5,238</b>

Of the plan assets above, SEK 515 and SEK 3,048 as of December 31, 2023 and 2022, respectively, has a quoted price in an active market.

For pension obligations in France, there are no plan assets.

#### Risks connected to defined-benefit pension plans

Through its defined-benefit pension plans for post-employment benefits, the Group is exposed to a number of risks. The most significant risks are:

**Life expectancy assumption:** Most of the pension commitments entail that the employees covered by the plan will receive life-long benefits and, accordingly, the longer life expectancy assumptions will result in higher pension liabilities. This is particularly significant in the Swiss plan, in which inflation increases result in higher sensitivity to changes in life expectancy assumptions.

**Inflation risk:** Some of the plan's pension commitments are linked to inflation. Higher inflation leads to higher liabilities (although, in most cases, a ceiling has been set for the level of inflation to protect the plan against exceptional increases in inflation). Most of the plan assets are either unaffected by (fixed-rate bonds), or weakly correlated with (shares) inflation, which means that an increase in inflation will also increase the deficit.

**Discount rate:** A decrease in the interest rate on corporate bonds will increase the liabilities of the plan, although this will partially be offset by an increase in the value of the bond holdings. The Swiss pension plan is covered by The Swiss Federal Act on Occupational Retirement, Survivor's and Disability Pension Plans (BVG).

The French pension plan is covered by the labor law and the collective bargaining agreement of the pharmaceutical industry. The Swiss and French plans are based on final salary.

Actuarial Assumptions on the Closing Balance	December 31,	
	2023	2022
<b>Swiss pension plan</b>		
Discount rate	1.45%	2.30%
Mortality table	LPP 2020 generation	LPP 2020 generation
Salary revaluation rate	2.00%	1.00%
Retirement pension inflation rate	1.00%	0.50%
Deposit rate on savings accounts	1.50%	1.00%
Turnover rate	10.00%	10.00%
Remaining life expectancy after retirement	23.1 years	18.6 years
Retirement age	65 years	65 years

Sensitivity Analysis	December 31,	
	2023	2022
Pension commitments under current assumptions for Swiss pension plans	8,395	6,027
Discount rate, -0.5%	9,426	6,615
Discount rate, +0.5%	7,511	5,518
Retirement pension inflation rate, -0.5%	7,940	5,797
Retirement pension inflation rate, +0.5%	8,902	6,281
Salary revaluation rate, -0.5%	8,231	5,927
Salary revaluation rate, +0.5%	8,567	6,131

The amounts above show what the value of the pension obligation would have been assuming the change in the individual assumption. The sensitivity analyses are based on a change in one assumption, with all other assumptions remaining constant. In practice, this is highly unlikely to occur and some of the changes in the assumptions may be correlated. When calculating the sensitivity of the defined-benefit obligations to significant actuarial assumptions, the same method (present value of the defined-benefit obligation applying the projected unit credit method at the end of the reporting period) has been applied as when calculating the pension liability recognized in the consolidated statements of financial position.

As the defined benefit pension plans in France are deemed to be insignificant for the Group, no further information has been provided.

Contributions to plans for post-employment benefits are expected to be SEK 941 and SEK 813 in 2023 and 2022, respectively. The weighted average maturity of the obligation is an estimated 23.1 and 18.6 years in 2023 and 2022, respectively.

## Note 29 Other Non-Current Liabilities

	December 31,	
	2023	2022
Opening balance	4,350	-
Additional liabilities	12,031	4,350
<b>Net book value</b>	<b>16,381</b>	<b>4,350</b>

## Note 30 Accrued Expenses and Deferred Revenue

	December 31,	
	2023	2022
Vacation pay liabilities	11,257	8,310
Accrued salaries and Board fees	52,502	28,186
Social security costs	8,935	7,065
Accrued rebates on sales	36,326	15,849
Accrued expenses for royalty	37,419	12,023
Accrued expenses for research and development	107,302	34,637
Accrued expenses for marketing and selling	10,773	21,543
Accrued expenses for administration	16,113	8,833
<b>Total</b>	<b>280,627</b>	<b>136,446</b>

## Note 31 Related-Party Transactions

For information regarding remuneration of executive management, refer to Note 9 Employees and Personnel Costs and Note 10 Share-Based Payments.

There are no additional agreements or transactions with related parties, other than those described in Notes 9 Employees and Personnel Costs and 10 Share-Based Payments.

## Note 32 Pledged Assets, Contingent Liabilities and Other Obligations

The Group is required to pay Kyowa Kirin Services Ltd., f/k/a Archimedes Development Ltd ("Archimedes") a fixed royalty of 3% of net sales of Nefecon/Tarpeyo covered by the license in according to the Group's agreement with Archimedes pursuant to which Calliditas were granted (i) an exclusive license to joint intellectual property developed with Archimedes and (ii) a non-exclusive license to certain of Archimedes' know-how as necessary or useful to develop and commercialize Nefecon or other product candidates.

The Group has exclusive rights to use, develop and market the formulation under the license agreement with Archimedes, and Archimedes only has rights to royalties when the product is sold. The Group will then have an obligation to pay a low single digit percentage of royalties based on net sales until the exclusive license for the patent covering the formulation of Nefecon expires in 2029.

Pledged assets in the group amounted to SEK 943,364 and SEK 6,859 as of December 31, 2023 and 2022, respectively. The year's pledges refer to restricted bank accounts and lease deposits SEK 7,637 and SEK 6,859 as December 31 and 2022, respectively. Other pledge assets for the benefit of lenders, refers to participations in Group companies and financial assets SEK 935,727 as December 31. Financial covenants for interest-bearing liabilities, see note 20.

## Note 33 Events After the Reporting Period

FEBRUARY 13, 2024

Calliditas Therapeutics AB announced that the United States Patent and Trademark Office (USPTO) issued patent no. 11896719, entitled "New Pharmaceutical Compositions, on January 24, 2024 with validity as of today, February 13, 2024. This is Calliditas' second patent for TARPEYO in the United States, and provides product protection until 2043.

The patent covers a method of treating IgA nephropathy with a composition that encompasses TARPEYO® (budesonide) delayed release capsules, developed under the name "NEFECON®". Filing for listing in the Orange Book has thus been made. Calliditas intends to file corresponding patent applications in additional territories around the world, including Europe and China. Book has thus been made. Calliditas intends to file corresponding patent applications in additional territories around the world, including Europe and China.

MARCH 6, 2024

Calliditas Therapeutics AB announced that the FDA has granted an orphan drug exclusivity period of seven years for TARPEYO®, expiring in December 2030 based on when the company obtained full approval with a new indication for this drug product. Following full approval in December 2023, TARPEYO® (budesonide) indicated "to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression". The exclusivity period reflects the new indication covering all adult patients with primary IgAN at risk of disease progression based on a confirmed reduction of kidney loss reflecting a clinical benefit on kidney function for adult patients with primary IgAN.

## Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31,	
		2023	2022
Net sales	2	805,551	548,977
Cost of goods sold		(60,399)	(15,141)
<b>Gross profit</b>		<b>745,151</b>	<b>533,836</b>
Research and development expenses	7	(456,970)	(384,453)
Marketing and selling expenses	7	(402,436)	(310,372)
Administrative expenses	5,6,7	(273,359)	(212,971)
Other operating income	3	220,293	165,697
Other operating expenses	4	(475)	(7,101)
<b>Operating loss</b>		<b>(167,796)</b>	<b>(215,364)</b>
<i>Profit/(loss) from financial items</i>			
Other interest received and similar items	8	42,626	43,259
Interest expense and similar items	9	(148,348)	(36,443)
<b>Loss before income tax</b>		<b>(273,518)</b>	<b>(208,548)</b>
Income tax expense	10	-	-
<b>Loss for the year</b>		<b>(273,518)</b>	<b>(208,548)</b>

## Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31,	
		2023	2022
<b>Loss for the year</b>		<b>(273,518)</b>	<b>(208,548)</b>
Other comprehensive income/(loss)		-	-
<b>Total comprehensive loss</b>		<b>(273,518)</b>	<b>(208,548)</b>

## Balance Sheet

(SEK in thousands)	Note	December 31,	
		2023	2022
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible Assets</i>			
Licenses and similar rights	11	-	32,132
		-	<b>32,132</b>
<i>Tangible Assets</i>			
Equipment	12	342	567
		<b>342</b>	<b>567</b>
<i>Non-Current Financial Assets</i>			
Participations in Group companies	13	450,904	425,589
Receivables to Group companies	14	653,815	453,537
Other non-current financial assets	15	20,467	8,329
		<b>1,125,186</b>	<b>887,456</b>
<b>Total non-current assets</b>		<b>1,125,528</b>	<b>920,154</b>
<b>Current assets</b>			
Inventory	16	20,428	3,647
Accounts receivables		49,777	6,877
Receivables to Group companies		164,441	115,676
Other current assets		9,481	6,537
Prepaid expenses	17	67,603	61,092
		<b>311,730</b>	<b>193,830</b>
<i>Cash</i>	18	817,871	1,059,655
<b>Total current assets</b>		<b>1,129,602</b>	<b>1,253,485</b>
<b>TOTAL ASSETS</b>		<b>2,255,130</b>	<b>2,173,639</b>

## Balance Sheet

(SEK in thousands)	Note	December 31,	
		2023	2022
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>	19		
<i>Restricted shareholders' equity</i>			
Share capital		2,383	2,383
Statutory reserve		3,092	3,092
		<b>5,475</b>	<b>5,475</b>
<i>Non-restricted shareholders' equity</i>			
Share premium reserve		2,521,419	2,521,419
Retained earnings		(1,343,602)	(1,187,391)
Net loss for the year		(273,518)	(208,548)
		<b>904,299</b>	<b>1,125,481</b>
<b>Total shareholders' equity</b>		<b>909,774</b>	<b>1,130,956</b>
<b>Non-current liabilities</b>			
Provisions	20	25,924	9,512
Non-current interest-bearing liabilities	21	939,508	713,030
Liabilities to Group companies	24	105	105
Other non-current liabilities		16,381	4,350
<b>Total non-current liabilities</b>		<b>981,918</b>	<b>726,997</b>
<b>Current liabilities</b>			
Accounts payable		62,562	100,469
Liabilities to Group companies	24	110,175	138,173
Other current liabilities		3,510	3,577
Accrued expenses and deferred revenue	22	187,191	73,468
<b>Total current liabilities</b>		<b>363,438</b>	<b>315,686</b>
<b>TOTAL SHAREHOLDERS EQUITY AND LIABILITIES</b>		<b>2,255,130</b>	<b>2,173,639</b>



## Statements of Changes in Shareholders' Equity

(SEK in thousands, except per share amounts)	Restricted Shareholders' Equity		Non-Restricted Shareholders' Equity			Total
	Share Capital	Statutory Reserve	Share Premium Reserve	Retained Earnings	Net Loss For the Year	
<b>Opening equity January 1, 2022</b>	<b>2,094</b>	<b>3,092</b>	<b>2,420,698</b>	<b>(863,175)</b>	<b>(354,405)</b>	<b>1,208,303</b>
Transfer of previous year's loss	-	-	-	(354,405)	354,405	-
Loss for the year	-	-	-	-	(208,548)	(208,548)
Other comprehensive income/(loss)	-	-	-	-	-	-
<b>Total comprehensive income/(loss)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(208,548)</b>	<b>(208,548)</b>
<b>Transactions with owners:</b>						
Issuance of treasury shares	236	-	-	-	-	236
Repurchase of treasury shares	-	-	-	-236	-	-236
Exercise of warrants	53	-	100 721	-5 654	-	95 121
Share-based payments	-	-	-	36 080	-	36 080
<b>Total transactions with owners</b>	<b>290</b>	<b>-</b>	<b>100,721</b>	<b>30,190</b>	<b>-</b>	<b>131,201</b>
<b>Closing equity December 31, 2022</b>	<b>2,383</b>	<b>3,092</b>	<b>2,521,419</b>	<b>(1,187,391)</b>	<b>(208,548)</b>	<b>1,130,956</b>
<b>Opening equity January 1, 2023</b>	<b>2,383</b>	<b>3,092</b>	<b>2,521,419</b>	<b>(1,187,391)</b>	<b>(208,548)</b>	<b>1,130,956</b>
Transfer of previous year's loss	-	-	-	(208,548)	208,548	-
Loss for the year	-	-	-	-	(273,518)	(273,518)
Other comprehensive income/(loss)	-	-	-	-	-	-
<b>Total comprehensive income/(loss)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(273,518)</b>	<b>(273,518)</b>
<b>Transactions with owners:</b>						
Share-based payments	-	-	-	52,337	-	52,337
<b>Total transactions with owners</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>52,337</b>	<b>-</b>	<b>52,337</b>
<b>Closing equity December 31, 2023</b>	<b>2,383</b>	<b>3,092</b>	<b>2,521,419</b>	<b>(1,343,602)</b>	<b>(273,518)</b>	<b>909,774</b>

## Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31,	
		2023	2022
<b>Operating activities</b>			
Operating loss		(167,796)	(215,364)
Adjustments for non-cash items	18	75,789	17,584
Interest received		29,561	3,551
Interest paid		(91,740)	(33,648)
<b>Cash flow from operating activities before changes in working capital</b>		<b>(154,186)</b>	<b>(227,877)</b>
<b>Cash flow from changes in working capital</b>			
Changes in inventory		(16,781)	(2,758)
Changes in operating receivables		(40,501)	(144,845)
Changes in operating liabilities		53,716	212,279
<b>Cash flow from operating activities</b>		<b>(157,751)</b>	<b>(163,201)</b>
<b>Investing activities</b>			
Purchase of equipment	12	-	(269)
Investments in non-current financial assets	14	(274,220)	(282,391)
Repayment of non-current financial assets	14	-	1,948
<b>Cash flow from investing activities</b>		<b>(274,220)</b>	<b>(280,712)</b>
<b>Financing activities</b>			
Issuance of treasury shares		-	236
Repurchase of treasury shares		-	(236)
Exercise of warrants		-	95,121
New borrowings	21	962,889	491,744
Costs attributable to new loans		(26,625)	(1,260)
Repayment of borrowing		(724,479)	-
<b>Cash flow from operating activities</b>		<b>211,784</b>	<b>585,605</b>
<b>Net increase (decrease) in cash</b>		<b>(220,187)</b>	<b>141,691</b>
<b>Cash at beginning of the year</b>		<b>1,059,655</b>	<b>894,455</b>
Exchange-rate difference in cash		(21,597)	23,509
<b>Cash at the end of the year</b>	18	<b>817,871</b>	<b>1,059,655</b>

# Notes to Financial Statements

(SEK in thousands, except per share amounts or as otherwise indicated)

## Note 1 Accounting Policies

### Basis for Preparation

The Parent Company prepared its annual report in accordance with the Annual Accounts Act and the recommendations from the Swedish Corporate Reporting Board, RFR 2 "Accounting for legal entities".

The differences between the Group's and the Parent Company's accounting policies are presented below. The accounting policies for the Parent Company stated below have, unless otherwise stated, been applied consistently over all periods presented in the financial statements. The financial statements provide comparative information in respect of the previous period.

### Subsidiaries

Participations in subsidiaries have been recognized on a historical cost basis in the Parent Company, which implies that transaction costs are included in the carrying amount of participations in subsidiaries.

### Financial Assets and Liabilities

Due to the relationship between accounting and taxation, the regulations for financial instruments in accordance with IFRS 9 are not applied in the Parent Company as a legal entity. The Parent Company applies a historical cost basis in accordance with the Annual Accounts Act. For this reason, financial assets are measured in the Parent Company at cost less any impairment and financial current assets are measured at the lower of cost and net realisable value.

### Leases

The Parent Company applies the exemption contained in RFR 2 for legal entities and recognizes all lease agreements as an expense through the statement of income on a straight-line basis over the lease term.

### Group and Shareholder Contributions

Both received and provided Group contributions are recognized as appropriations in accordance with the alternative rule. Shareholders' contributions are recognized in the shareholders' equity of the recipient and capitalized in "Participations in Group companies" by the contributor, where impairment is not required.

## Note 2 Revenues

Type of goods or service	Year Ended December 31,	
	2023	2022
Product sales	686,081	121,613
Outlicensing of product	82,712	421,689
Royalty income	36,758	2,287
Performance of certain regulatory services	-	3,387
<b>Total</b>	<b>805,551</b>	<b>548,977</b>
<b>Geographical markets</b>		
USA	674,492	118,345
Europe	39,614	143,955
Asia	91,445	286,677
<b>Total</b>	<b>805,551</b>	<b>548,977</b>

For more information, see Note 3 Revenue from Contracts with Customers for the Group.

## Note 3 Other Operating Income

	Year Ended December 31,	
	2023	2022
Pass through costs	209,929	163,318
Exchange rate differences	10,364	-
Other income	-	2,379
<b>Total</b>	<b>220,293</b>	<b>165,697</b>

## Note 4 Other Operating Expense

	Year Ended December 31,	
	2023	2022
Exchange rate differences	475	7,101
<b>Total</b>	<b>475</b>	<b>7,101</b>

## Note 5 Auditors' Fee

EY	Year Ended December 31,	
	2023	2022
Audit services	20,951	12,215
Other audit activities	900	3,370
<b>Total</b>	<b>21,851</b>	<b>15,585</b>

Audit services relate to the statutory audit of the financial statements and the accounts, as well as the management of the Board of Directors and the CEO. This includes other responsibilities that it is incumbent upon the company's auditor to perform including providing advice or any other assistance that may result from observations in such review or the conduct of such other responsibilities.

Other audit activities are those services in accordance with a special agreement on financial statements.

## Note 6 Leases

Leasing expenses for the year in respect to operating leases amounted to SEK 7,811 and SEK 6,310 for the year ended December 31, 2023 and 2022, respectively. Future payment commitments for operating leases are specified as follows:

Future minimum lease payments	Year Ended December 31,	
	2023	2022
Within 1 year	17,556	9,445
Between 1-2 years	13,971	5,070
More than 2 years	10,478	-
<b>Total</b>	<b>42,005</b>	<b>14,515</b>

## Note 7 Employees and Personnel Costs

For salaries and benefits to employees and executive management and information about the number of employees, refer to Note 9 Employees and Personnel Costs for the Group. For information about options and share-based payments, see Note 10 Share-Based Payments for the Group.

# PARENT COMPANY - NOTES TO FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

## Note 8 Other Interest Received and Similar Items

	Year Ended December 31,	
	2023	2022
Interest income from Group companies	17,263	9,296
Other interest income	25,363	3,551
Exchange rate differences	-	30,412
<b>Total</b>	<b>42,626</b>	<b>43,259</b>

## Note 9 Interest Expense and Similar Items

	Year Ended December 31,	
	2023	2022
Interest expense	70,386	31,569
Early repayment of loan	35,397	-
Other financial expenses	5,753	4,874
Exchange rate differences	36,812	-
<b>Total</b>	<b>148,348</b>	<b>36,443</b>

## Note 10 Income Tax Expense

	Year Ended December 31,	
	2023	2022
Current income taxes	-	-
<b>Income tax expense recognized in the statements of income</b>	<b>-</b>	<b>-</b>
<b>Reconciliation of effective tax rate</b>		
Accounting loss before tax	(273,518)	(208,548)
Tax in accordance with applicable tax rate for the Parent Company 20.6%	56,345	42,961
<i>Tax effect on:</i>		
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(36,030)	(34,371)
Non-deductible expenses	(20,315)	(8,590)
<b>Income tax expense recognized in the statements of income</b>	<b>-</b>	<b>-</b>
At the effective income tax rate	-	-

The Parent Company has SEK 1,769,195 and SEK 1,594,293 of tax losses carried forward for which deferred tax assets have not been recognized in the statements of financial position as of December 31, 2023 and 2022, respectively. The tax losses carried forward are not restricted in time. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

## Note 11 Intangible Assets

	December 31,	
	2023	2022
<b>Licenses and similar rights</b>		
<b>Cost at opening balance</b>	<b>32,132</b>	<b>32,132</b>
Disposal for the year	(32,132)	-
<b>Cost at closing balance</b>	<b>-</b>	<b>32,132</b>
<b>Impairment</b>		
Impairment at opening balance	-	-
Impairment	(32,132)	-
Disposal for the year	32,132	-
Impairment at closing balance	-	-
<b>Net book value</b>	<b>-</b>	<b>32,132</b>

For additional information on intangible assets in the Parent Company, see Note 15 Intangible Assets and Impairment Testing in the Group.

## Note 12 Equipment

	December 31,	
	2023	2022
<b>Cost at opening balance</b>	<b>795</b>	<b>526</b>
Acquisition for the year	-	269
<b>Cost at closing balance</b>	<b>795</b>	<b>795</b>
<b>Depreciation at opening balance</b>	<b>(228)</b>	<b>(12)</b>
Depreciation for the year	(225)	(216)
<b>Depreciation at closing balance</b>	<b>(453)</b>	<b>(228)</b>
<b>Net book value</b>	<b>342</b>	<b>567</b>

## Note 13 Participations in Group Companies

	December 31,	
	2023	2022
Cost at opening balance	429,328	410,177
Acquisition for the year	-	-
Shareholders' contributions	25,315	19,151
<b>Cost at closing balance</b>	<b>454,643</b>	<b>429,328</b>
Impairment at opening balance	(3,739)	(3,739)
<b>Impairment at closing balance</b>	<b>(3,739)</b>	<b>(3,739)</b>
<b>Net book value</b>	<b>450,904</b>	<b>425,589</b>

Shareholders' contributions correspond to share-based remuneration recognized in the subsidiaries.

Company / Corporate Registration Number / Registered office	December 31,	
	2023	2022
<i>Nefecon AB, 556604-9069, Stockholm</i>	2023	2022
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	1,000	1,000
<b>Net book value</b>	<b>100</b>	<b>100</b>
<i>Calliditas Therapeutics NA Enterprise Inc., 83-4094951, USA</i>		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	1,000	1,000
<b>Net book value</b>	<b>44,264</b>	<b>27,107</b>
<i>Calliditas Therapeutics US Inc., 86-3169403 USA</i>		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	1,000	1,000
<b>Net book value</b>	<b>10,507</b>	<b>3,313</b>
<i>Calliditas Therapeutics France SAS, 439 489 022, France</i>		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	14,074,165	14,074,165
<b>Net book value</b>	<b>396,033</b>	<b>395,069</b>

## Note 14 Receivables from Group Companies

	December 31,	
	2023	2022
Opening balance	453,537	142,724
Additional receivables	289,582	296,928
Repayment of receivables	-	(1,948)
Reclassification to current receivables	(83,478)	(5,526)
Exchange differences	(5,826)	21,360
<b>Net book value</b>	<b>653,815</b>	<b>453,537</b>

## Note 15 Other Non-Current Financial Assets

	December 31,	
	2023	2022
Opening balance	8,329	3,762
Additional acquisition	12,215	4,349
Exchange differences	(77)	218
<b>Net book value</b>	<b>20,467</b>	<b>8,329</b>

Additional acquisitions are significantly related to future increases in production capacity. In the cash flow, the acquisitions are reported within operating activities.

## Note 16 Inventories

	December 31,	
	2023	2022
Raw materials	9,058	1,855
Work in progress	4,677	937
Finished goods	6,693	855
<b>Total</b>	<b>20,428</b>	<b>3,647</b>

## Note 17 Prepaid Expenses and Accrued Income

	December 31,	
	2023	2022
Accrued income	7,297	2,287
Prepaid rental charges	3,862	1,876
Prepaid insurance premiums	8,048	8,827
Prepaid interest costs	-	3,693
Prepaid expenses for research and development	43,085	43,472
Other prepaid administration expenses	5,311	937
<b>Total</b>	<b>67,603</b>	<b>61,092</b>

# PARENT COMPANY - NOTES TO FINANCIAL STATEMENTS

(SEK in thousands, except per share amounts or as otherwise indicated)

## Note 18 Cash

	December 31,	
	2023	2022
Cash at Banks	817,871	1,059,655
<b>Total</b>	<b>817,871</b>	<b>1,059,655</b>

### Adjustments for non-cash items:

	Year Ended December 31,	
	2023	2022
Depreciation	32,356	217
Change in Provisions	16,411	438
Share-based payments	27,022	16,929
<b>Total</b>	<b>75,789</b>	<b>17,584</b>

### Reconciliation of liabilities from financing activities:

	January 1, 2023	Cash Flow	Non-Cash-Items	December 31, 2023
Non-current interest-bearing liabilities	713,030	211,785	14,693	939,508
<b>Total</b>	<b>713,030</b>	<b>211,785</b>	<b>14,693</b>	<b>939,508</b>

	January 1, 2022	Cash Flow	Non-Cash-Items	December 31, 2022
Non-current interest-bearing liabilities	189,164	490,485	33,381	713,030
<b>Total</b>	<b>189,164</b>	<b>490,485</b>	<b>33,381</b>	<b>713,030</b>

## Note 19 Shareholders' Equity

As of December 31, 2023, share capital consists of 59,580,087 shares, of which 5,908,018 shares are held by Calliditas. As of December 31, 2023 share capital consists 59,580,087. The quotient value of SEK 0.04 and SEK 0.04 as of December 31, 2023 and 2022, respectively. All shares have the same entitlement to the company's profits, with the exception of treasury shares held by Calliditas which have no right to the company's dividend. For additional information see the Group's Note 25 Equity.

The share premium reserve refers to capital from new share issues that were issued at a price that exceeds the quotient value less cost attributable to new share issues.

### Proposed appropriation of earnings

The following earnings are at the disposal of the Annual General Meeting:

	December 31,	
	2023	2022
Share premium reserve	2,521,419	2,521,419
Retained earnings	(1,343,602)	(1,187,391)
Net loss for the year	(273,518)	(208,548)
	<b>904,299</b>	<b>1,125,481</b>
To be distributed as follows:		
<b>To be carried forward</b>	<b>904,299</b>	<b>1,125,481</b>

## Note 20 Provisions

	December 31,	
	2023	2022
Opening balance	9,512	9,075
Provisions for the year	16,411	641
Amounts claimed for the year	-	(204)
<b>Total</b>	<b>25,924</b>	<b>9,512</b>

For additional information on Provisions in the Parent Company, see Note 26 Provisions in the Group.

## Note 21 Non-Current Interest-Bearing Liabilities

	December 31,	
	2023	2022
Due for payment between 1 and 5 years		
Non-current interest-bearing liabilities	939,508	713,030
<b>Total</b>	<b>939,508</b>	<b>713,030</b>

For additional information, see Note 20 Financial Risks in the Group.

## Note 22 Accrued Expenses and Deferred Revenue

	December 31,	
	2023	2022
Accrued salaries and Board fees	13,201	10,094
Vacation pay liability	6,123	5,475
Social security costs	8,688	6,875
Accrued expenses for royalty	37,419	12,023
Accrued expenses for research and development	106,964	33,642
Accrued expenses for marketing and selling	-	418
Accrued expenses for administration	14,796	4,941
<b>Total</b>	<b>187,191</b>	<b>73,468</b>

## Note 23 Assets Pledged and Contingent Liabilities

Information concerning assets pledged and any contingent liabilities in the Parent Company can be found in the Group's Note 32 Assets Pledged, Contingent Liabilities and Other Obligations. In the Parent Company restricted bank accounts and lease deposits amounts to SEK 3,902 and SEK 3,987 as of December 31, 2023 and 2022, respectively and other pledge assets for the benefit of lenders amounts to SEK 1,342,414, as of December 2023. Other pledge assets refers to participations in Group companies and financial assets.

## Note 24 Related-Party Transactions

Subsidiaries	Sales of Goods/ Services	Purchase of Goods/ Services	Other	Receivables on Closing Balance	Liabilities on Closing Balance
Year Ended December 31, 2023	879,645	437,786	-	818,256	110,280
Year Ended December 31, 2022	282,288	332,971	-	569,213	138,278

For information regarding remuneration of executive management, refer to the Group's Note 9 Employees and Personnel Costs.

The undersigned declare that the annual report has been prepared in accordance with generally accepted accounting principles in Sweden and these consolidated financial statements have been prepared in accordance with the IFRS(R) Accounting Standards, as adopted by the European Union (EU). The annual report and consolidated financial statements respectively provide fair and accurate impression of the financial position and earnings of the Group and the Parent Company.

The Report of the Board of Directors' for the Parent Company and Group gives a true and fair view of the performance of the Parent Company's and the Group's operations, position and results and describes the significant risks and uncertainties facing the Parent Company and the companies included in the Group.

Stockholm, April 24, 2024

Elmar Schnee  
*Board Chairman*

Renée Aguiar-Lucander  
*CEO*

Elisabeth Björk  
*Board member*

Frederic Driscoll  
*Board member*

Hilde Furberg  
*Board member*

Diane Parks  
*Board member*

Henrik Stenqvist  
*Board member*

Our audit report was submitted April 24, 2024

Ernst & Young AB

Jakob Grunditz  
Authorized Public Accountant

# Auditor's report

To the general meeting of the shareholders of Calliditas Therapeutics AB, corporate identity number 556659-9766

## Report on the annual accounts and consolidated accounts

### Opinions

We have audited the annual accounts and consolidated accounts of Calliditas Therapeutics AB (publ) for the year 2023. The annual accounts and consolidated accounts of the company are included on pages 32-79 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company as of 31 December 2023 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2023 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the statement of income and balance sheet for the parent company and the statement of income and statement of financial position for the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

### Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.



## Estimate of variable consideration for revenue recognition

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### *Description*

As is stated in Note 3 of the consolidated financial statements, for the year ended December 31, 2023, the Group's revenues from product sales were SEK 1,087,418 thousands. As more fully described in Notes 2 and 3, revenue from the sale of goods is calculated net of actual and estimated rebates to government payers, among other deductions. The Group's determination of variable consideration at December 31, 2023, requires management to make assumptions about amounts of rebates that will be payable by the Group as a result of the sale of products for which control has transferred.

We determined the estimate of variable consideration for revenue recognition to be a key audit matter, as auditing management's estimate of variable consideration was complex because the calculation involves significant management judgement to determine rebates owed to government payers.

### *How our audit addressed this key audit matter*

To test the estimate of variable consideration, our audit procedures included, among others, performing analytical procedures to assess the historical accuracy of management's estimates by comparing previous estimates of payor rebates to the amount of actual payments in subsequent periods. Where available, we tested management's estimate as of December 31, 2023, by comparison to actual invoices received subsequently. We also tested the completeness and accuracy of dispensing data used by the Group in its determination of the estimated payor mix, by agreeing it to third-party data.

We involved professionals with government pricing subject matter experience to assist in evaluating management's methodology and calculations used to measure rebates owed to government payors.

We reviewed the disclosures provided in the annual report.

### Impairment assessment of intangible assets

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#### **Description**

Intangible assets for the Group amount to SEK 430,754 thousands as of December 31, 2023. As explained in Note 2 and Note 15 of the consolidated financial statements, the Group performs an impairment assessment of intangible assets not yet available for use, on an annual basis or when there is an indication that an asset may be impaired. The Group's impairment assessment of intangible assets involves the comparison of the recoverable amount of each asset or cash generating unit to their carrying values.

The recoverable amount of intangible assets is estimated based on a probability-adjusted cash flow model, where the amount is determined by estimating the expected future cash flows and present value adjustments, including the probability of reaching the market. Changes in assumptions used by management could have a significant impact on the recoverable amount.

We determined the impairment assessment of intangible assets to be a key audit matter, as auditing the impairment assessment of intangible assets was complex, due to the significant judgments made by management to estimate the recoverable amount, including assumptions related to the timing of potential commercialization, the market size, the probability of reaching the market and the discount rate used.

#### **How our audit addressed this key audit matter**

We performed audit procedures related to the impairment assessment of intangible assets, which included, among others, evaluating management's methodology, testing the completeness and accuracy of inputs utilized by management in the assumptions, including the timing of potential commercialization, expected market size and the probability of the products reaching the market. In doing so, we compared these inputs to third-party statistical data for the clinical indications targeted and for other development projects within the industry.

With the assistance of our valuation specialists, we evaluated the discounted cash flow methodology and assessed the discounts rates used in the value in use estimates, by comparing to underlying source information, testing the mathematical accuracy of the calculations and preparing an independent range based on market and peer company observable data and comparing to that used by management.

We reviewed the disclosures provided in the annual report.

### **Other Information than the annual accounts and consolidated accounts**

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-31 and 88-103. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

### **Responsibilities of the Board of Directors and the Managing Director**

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is

however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

### **Auditor's responsibility**

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.

## AUDITOR'S REPORT

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or related safeguards applied.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

## Report on other legal and regulatory requirements

### Report on the audit of the administration and the proposed appropriations of the company's profit or loss

#### Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Calliditas Therapeutics AB (publ) for the year 2023 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

#### Basis for opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization

is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

#### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the

company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions

taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

### The auditor's examination of the ESEF report

#### **Opinion**

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Calliditas Therapeutics AB for the financial year 2023.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

#### **Basis for opinion**

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the ESEF report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Calliditas Therapeutics AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### **Responsibilities of the Board of Directors and the Managing Director**

The Board of Directors and the Managing Director are responsible for the preparation of the Esef report in accordance with Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

#### **Auditor's responsibility**

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies ISQM 1 Quality Management for Firms that Perform Audits or Reviews of Financial Statements, or other Assurance or Related Services Engagements which requires the firm to design, implement and operate a system of quality management, including policies and procedures regarding compliance with professional ethical requirements, professional standards and applicable legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design audit procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a validation that the Esef report has been prepared in a valid XHTML format and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the Esef report have been marked with iXBRL in accordance with what follows from the Esef regulation.

Ernst & Young AB, Hamngatan 26, 111 47 Stockholm, was appointed auditor of Calliditas Therapeutics AB by the general meeting of the shareholders on May 30, 2023 and has been the company's auditor since April 15, 2004.

Stockholm April 24, 2024  
Ernst & Young AB

Jakob Grunditz  
Authorized Public Accountant

# Corporate Governance Report

## Introduction

Calliditas Therapeutics AB (publ), "Calliditas" is a Swedish public limited liability company with its registered office in Stockholm. The company's share was listed on June 29, 2018 on Nasdaq Stockholm and on June 5, 2020 on Nasdaq Global Select US and is traded under the ticker CALTX and CALT, respectively. This report pertains to the financial year of 2023 and has been examined by the company's auditors.

## Background

Corporate governance refers to the systems through which shareholders, directly or indirectly, control the company. Good corporate governance is an essential part of efforts to generate value for Calliditas' shareholders. Corporate governance in Calliditas is based on Swedish law, Nasdaq Stockholm's Rule Book for Issuers and internal rules and regulations. The company also applies the Swedish Code of Corporate Governance (the "Code"). The Code applies to all Swedish companies whose shares are listed on a regulated market in Sweden. The company need not comply with all of the rules of the Code as the Code itself offers an opportunity to deviate from the rules, on the condition that any such deviation, and the chosen alternative solution, is described and the reasons explained in the Corporate Governance Report (according to the comply or explain principle). However, the company has not deviated from any of the rules established in the Code during the year. The company is classified as a Foreign Private Issuer (FPI) in accordance with the regulations established by the US Securities and Exchange Commission (SEC) and therefore follows market practice in the domestic market, ie Swedish corporate governance.

## Examples of Important Rules and Regulations

### Important internal rules and regulations

- Articles of Association
- Rules of procedure of the Board of Directors and Committees
- Directives for the CEO
- Policy documents

### Important external rules and regulations

- Swedish Companies Act
- Swedish and international accounting legislation
- Nasdaq Stockholm's Rule Book for Issuers
- Nasdaq U.S Rule Book for Issuers
- Swedish Code of Corporate Governance
- Sarbanes-Oxley Act

## Shareholders

Calliditas' shares were admitted to trading on Nasdaq Stockholm, Mid Cap, in June 2018 and on Nasdaq Global Select, in June 5, 2020. At the end of 2023, Calliditas had 18,807 (18,585) shareholders and the ten largest shareholders owned 47.0 (48.3) % of all outstanding shares, excluding shares held by Calliditas. As of December 31, 2023, BVF Partners LP, Linc AB and Stiftelsen Industrifonden were the single largest shareholders in the company corresponding to 10.5%, 10.0% and 5.3%, respectively, of the capital.

## Dividend Policy

The company has so far not paid out any dividend. Any future dividend and the size thereof, will be determined based on long-term growth, earnings trends and capital requirements of Calliditas. It is the view of the Board of Directors that Calliditas should prioritize progression of the development program and commercialization of TARPEYO in the US, and therefore financial resources should mainly be used to finance Calliditas' development programs and commercialization activities. In view of company's financial position and negative earnings, the Board of Directors does not intend to propose any dividend before the company generates long-term sustainable profits and positive cash flow. Dividends shall, as far as a dividend is proposed, be balanced with regard to the business risk.

## Annual General Meeting

### Right to participate in the Annual General Meeting

Shareholders who wish to participate in the Annual General Meeting (AGM) must be included in the shareholders' register maintained by Euroclear Sweden on the day falling six banking days prior to the meeting, and notify the company of their participation no later than on the date stipulated in the notice convening the meeting. Shareholders may attend the shareholders' meetings in person or by proxy and may be accompanied by a maximum of two assistants. Typically, it is possible for a shareholder to register for the AGM in several different ways as indicated in the notice of the meeting. A shareholder may vote for all company shares owned or represented by the shareholder. Notice of the AGM shall be published in the Swedish Official Gazette and on the company's website, within such time as set forth in the Swedish Companies Act (2005:551). It shall be announced in Svenska Dagbladet that a notice has been issued.



### Annual General Meeting 2024

Calliditas' 2024 AGM will be held on Monday, June 17, 2024, kl 14:00, at Klara Konferens, Klarabergsviadukten 90, Stockholm.

The minutes from the AGM will be made available at [www.calliditas.se](http://www.calliditas.se).

### Participation at the Annual General Meeting

Information on participation at the Annual General Meeting will be provided in the notice of the Annual General Meeting. The notice will be distributed no later than four weeks in advance of the Annual General Meeting and will be available at [www.calliditas.se](http://www.calliditas.se).

Shareholders who wish to have a matter brought before the AGM must submit a written request to the Board of Directors. Such request must normally be received by the Board of Directors no later than seven weeks prior to the Meeting.

### Nomination Committee

Companies applying the Code shall have a Nomination Committee. According to the Code, the AGM shall appoint the members of the Nomination Committee or resolve on procedures for appointing the members. The Nomination Committee shall, pursuant to the Code, consist of at least three members of which a majority shall be independent in relation to Calliditas and the Group Management. In addition, at least one member of the Nomination Committee shall be independent in relation to the largest shareholder in terms of voting rights or group of shareholders who cooperate in terms of the company's management.

At the Extraordinary General Meeting held on September 14, 2017, it was resolved that the Nomination Committee shall be composed of the Chairman of the Board of Directors together with one representative of each of the three largest shareholders, based on ownership in Calliditas as of the end of the third quarter of the fiscal year.

The Nomination Committee for 2024 consists of:

- Patrik Sobocki, appointed by Stiftelsen Industrifonden
- Spike Loy, appointed by BVF
- Karl Tobieson, appointed by Linc AB
- Elmar Schnee, Chairman of the Board

Should any of the three largest shareholders renounce its right to appoint one representative to the Nomination Committee, such right shall transfer to the share-

holder who then in turn, after these three, is the largest shareholder in Calliditas. The Board of Directors shall convene the Nomination Committee. The member representing the largest shareholder shall be appointed Chairman of the Nomination Committee, unless the Nomination Committee unanimously appoints someone else. Should a shareholder having appointed a representative to the Nomination Committee no longer be among the three largest shareholders at a point in time falling three months before the AGM at the latest, the representative appointed by such shareholder shall resign and the shareholder who is then among the three largest shareholders shall have the right to appoint one representative to the Nomination Committee. Unless there are specific reasons otherwise, the already established composition of the Nomination Committee shall, however, remain unchanged in case such change in the ownership is only marginal or occurs during the three-month period prior to the AGM. Where a shareholder has become one of the three largest shareholders due to a material change in the ownership at a point in time falling later than three months before the AGM, such a shareholder shall however in any event have the right to take part of the work of the Nomination Committee and participate at its meetings. Should a member resign from the Nomination Committee before his or her work is completed, the shareholder who has appointed such member shall appoint a new member, unless that shareholder is no longer one of the three largest shareholders, in which case the largest shareholder in turn shall appoint the substitute member. A shareholder who has appointed a representative to the Nomination Committee shall have the right to discharge such representative and appoint a new representative.

Changes to the composition of the Nomination Committee shall be announced immediately. The term of the office for the Nomination Committee ends when the next Nomination Committee has been appointed. The Nomination Committee shall carry out its duties as set out in the Code.

The Nomination Committee will be constituted and will meet in advance of the 2024 AGM and its proposals will be presented in the convening notice of the AGM and on Calliditas' website. Shareholders may submit proposals to the Nomination Committee in accordance with what has been published on the company's website, [www.calliditas.se](http://www.calliditas.se), prior to the AGM.

### Auditor

In accordance with the Articles of Association, Calliditas must appoint a registered firm of accountants as external auditor. The 2023 AGM elected the registered

## CORPORATE GOVERNANCE REPORT

firm of accountants Ernst & Young AB as auditor, up to the 2024 AGM. The Auditor-in-Charge is Jakob Grunditz. The auditor examines the Parent Company's and the Group's accounts and administration on behalf of the AGM. The external audit of the Parent Company's and the Group's accounts and the Board's and CEO's administration is conducted using generally accepted auditing standards in Sweden. The company entrusted the auditor to review one interim reports in 2023, which satisfies the requirements of the Code. For information about remuneration of the auditor, refer to Note 6 Auditors' Fee.

### Board of Directors

The Board of Directors is the second highest decision-making body of the company after the AGM. According to the Swedish Companies Act, the Board of Directors is responsible for the organization of Calliditas and the management of the company's affairs, which means that the Board of Directors is responsible for, among other things, setting targets and strategies, securing routines and systems for evaluation of set targets, continuously assessing the financial condition and profits as well as evaluating the operating management. The Board of Directors is also responsible for ensuring that annual reports and interim reports are prepared in a timely manner. Moreover, the Board of Directors appoints the CEO.

Members of the Board of Directors are normally appointed by the AGM for the period until the end of the next AGM. According to Calliditas' Articles of Association, the members of the Board of Directors elected by the AGM shall be not less than three and not more than ten members with no deputy members of the Board of Directors.

According to the Code, the Chairman of the Board of Directors is to be elected by the AGM and have a special responsibility for leading the work of the Board of Directors and for ensuring that the work of the Board of Directors is efficiently organized.

The Board of Directors applies written rules of procedure, which are revised annually and adopted by the inaugural board meeting every year. Among other things, the rules of procedure govern the practice of the Board of Directors, functions and the division of work between Board members and the CEO. At the inaugural board meeting, the Board of Directors also adopts instructions for the CEO, including instructions for financial reporting.

The Board of Directors meets according to an annual predetermined schedule. In addition to these meetings, additional Board meetings can be convened to handle issues which cannot be postponed until the next ordinary board meeting. In addition to the Board meetings, the Chairman of the Board of Directors and the CEO continuously discuss the management of the company.

Currently, the company's Board of Directors consists of six ordinary members elected by the AGM.

### Board Independence

The company satisfies the requirements of the Code as most of the Board members elected by the AGM are independent of the company and management, and that at least two of these are independent in relation to major shareholders. The table below presents the independence of members at the date on which this report was published.

### Board members' independence, attendance and remuneration in 2023

Name	Position	Board member since	Independent in relation to		Attendance			Total remuneration, SEK in thousand
			The company and management	Major shareholders	Board meetings	Audit Committee meetings	Remuneration Committee meetings	
Elmar Schnee	Board Chairman	2019	Yes	Yes	13/13	-	5/5	1,738
Hilde Furberg	Board Member	2014	Yes	Yes	13/13	11/11	-	731
Diane Parks	Board Member	2019	Yes	Yes	13/13	-	5/5	796
Molly Henderson (until May 2023)	Board Member	2020	Yes	Yes	5/5	5/6	-	316
Henrik Stenqvist	Board Member	2022	Yes	Yes	13/13	11/11	-	761
Elisabeth Björk	Board Member	2022	Yes	Yes	13/13	-	5/5	586
Fred Driscoll (from May 2023)	Board Member	2023	Yes	Yes	8/8	5/5	-	387

## Work of the Board in 2023

During 2023, the Board of Directors held a total of 13 meetings, of which 10 were ordinary and 3 were extraordinary meetings. Calliditas' CEO participates in Board meetings, as does the company's CFO and General Counsel, who is secretary at the meetings. Other employees from Calliditas have reported on particular issues at the meetings.

## Board Remuneration

The directors' fees shall be paid with SEK 940,000 to the chairman of the Board of Directors and SEK 365,000 to each one of the other members who are not employed in the Group, SEK 200,000 to the chairman of the audit committee and SEK 100,000 to the other members of the audit committee who are not employed in the Group as well as SEK 50,000 to the chairman of the remuneration committee and SEK 25,000 to the other members of the remuneration committee who are not employed in the Group. In addition to the above-proposed remuneration for ordinary board work, it is proposed that board members residing in the United States shall receive an additional amount of SEK 140,000 and that board members residing in Europe, but outside the Nordics, shall receive an additional amount of SEK 50,000. For more information regarding remuneration of Board members, refer to Note 9 Employees and Personnel Costs.

## Board Committees

### Audit Committee

Calliditas has an Audit Committee consisting of three members: Henrik Stenqvist (Chairman), Fred Driscoll and Hilde Furberg. The Audit Committee shall, without it affecting the responsibilities and tasks of the Board of Directors, monitor the company's financial reporting, monitor the efficiency of the company's internal controls, internal auditing and risk management, keep informed of the auditing of the annual report and the consolidated accounts, review and monitor the impartiality and independence of the auditors and pay close attention to whether the auditors are providing other services besides audit services for the company, and assist in the preparation of proposals for the AGM's decision on election of auditors.

The Committee held eleven meetings in 2023. The company's auditors took part in five of the meetings, where discussions included the auditors' planning of the audit, their observations and examination of the company and the company's financial statements and internal control over financial reporting.

### Remuneration Committee

Calliditas has a Remuneration Committee consisting of three members: Elmar Schnee (Chairman), Elisabeth

Björk and Diane Parks. The Remuneration Committee shall prepare matters concerning remuneration principles, remuneration and other employment terms for the CEO and the executive management.

The Committee held five meetings in 2023. At these meetings, the Committee discussed the current compensation system in the company, including a proposal for remuneration of the CEO and senior executives and the direction and terms of the incentive program that was approved for implementation by the Annual General Meeting on May 30, 2023.

## Remuneration of the CEO and Executive Management

The following principles regarding remuneration for the CEO and Executive Management are proposed for AGM 2024. Calliditas shall offer remuneration in accordance with market practice to enable the recruitment and retention of qualified executive management. Remunerations within Calliditas shall be based on principles of performance, competitiveness and fairness. The executive management refer to the CEO and other members of the executive management, as well as board members. The remuneration to the executive management may consist of fixed remuneration, variable remuneration, share and share-price related incentive programs, pension and other benefits. If local conditions justify variations in the remuneration principles, such variations may occur. The fixed remuneration shall reflect the individual's responsibility and experience level. The fixed remuneration shall be reviewed annually. The executive management may be offered cash bonuses. Variable remuneration paid in cash may not exceed 80% of the annual fixed remuneration. Variable remunerations shall be connected to predetermined and measurable criteria, designed with the aim of promoting the company's long-term value creation.

Share and share-price related incentive programs shall, if resolved on, be decided by the AGM. Pension shall, where possible, be premium based. For the CEO and other members of executive management, the premium may, in situations where premium-based pension is applicable, amount to a maximum of 30% of the fixed salary. Notwithstanding the above, the Board of Directors is entitled to offer other solutions which, in terms of cost, are equivalent to the above.

## Evaluation of the Board and CEO

Every year, the Board Chairman initiates an evaluation of the Board's work. The evaluation aims to gain an opinion of the views of Board members on how the work of the Board is progressing and what measures can be implemented to enhance the efficiency of the Board. The aim is also to gain an opinion of the type of issues the Board

believes should be offered more space and areas where further expertise may be needed on the Board. The Board of Directors continuously assesses the work of the CEO by monitoring the performance of the operations compared with established targets and makes a formal assessment each year.

### CEO and Management Team

The role of the CEO is subordinate to the Board of Directors, and his or her primary task is to attend to the company's daily management and operations in the company. The Rules of Procedure for Decision-making for the Board and instructions for the CEO present which issues that the company's Board of Directors are to consider and decide and which are the responsibility of the CEO. The CEO is also responsible for preparing reports and required documentation for decision-making prior to board meetings and is the reporting person on the material at board meetings.

Calliditas' management consisted of seven individuals and included, in addition to the CEO, the Chief Financial Officer, Chief Medical Officer, Vice President Regulatory Affairs, President North America, Head of Human Resources and Group General Counsel. For information about current senior executives at Calliditas, when these assumed their positions, and date of birth, education, experience, shareholding in the company and current and previous assignments, refer to pages 96-99 and the company's website, [www.calliditas.se](http://www.calliditas.se).

### Internal Control and Risk Management

The Board of Director's responsibility for the internal control is governed by the Swedish Companies Act, the Swedish Annual Reports Act – which requires that information about the main features of Calliditas' system for internal control and risk management related to financial reporting each year must be included in the corporate governance report – and the Code. The Board of Directors shall, among other tasks, ensure that Calliditas has sufficient internal control and formalized routines to ensure that established principles for financial reporting and internal control are adhered to and that there are effective systems to monitor and control the company's operations and the risks associated with the company and its operations.

The overall purpose of the internal control is to ensure that the company's operating strategies and targets are monitored and that the owners' investments are protected, to a reasonable degree. Furthermore, the internal control shall ensure that the external financial reporting, with reasonable certainty, is reliable and prepared in accordance with generally accepted accounting practice, that applicable laws and regulations are followed, and that the requirements imposed on

listed companies are complied with. The internal control primarily consists of the following five components.

#### Control environment

The Board of Directors has the overall responsibility for the internal control in relation to financial reporting. In order to create and maintain a functioning control environment, the Board of Directors has adopted a number of policies and guidelines governing financial reporting. These documents primarily comprise the rules of procedure for the Board of Directors, instructions for the CEO, rules of procedure for the Audit Committee and instructions for financial reporting. The Board of Directors has also adopted a delegation of signatory authority and a treasury policy. The company also has a financial manual which contains principles, guidelines and process descriptions for accounting and financial reporting. Furthermore, the Board of Directors has established an Audit Committee whose main task is to monitor the company's financial position, to monitor the effectiveness of the company's internal control, internal audit and risk management, to be informed about the audit of the annual report and consolidated financial statements, and to review and monitor the auditor's impartiality and independence. The responsibility for the ongoing work of the internal control over financial reporting has been delegated to the company's CEO. The CEO regularly reports to the Board of Directors in accordance with the established instructions for the CEO and the instructions for financial reporting. The Board of Directors also receives reports from the company's auditor.

The responsibility for the internal, business-specific control in the daily operations lies with the CEO.

#### Risk assessment

Risk assessment includes identifying risks that may arise if the basic requirements for the financial reporting of the company are not met. Calliditas' management team has, in a specific risk register, identified and evaluated the risks that arise in the company's operations, and has assessed how these risks can be managed. Calliditas' management shall annually perform a risk assessment of strategic, operational and financial risks and present the assessment to the Audit Committee and the Board of Directors. The CEO is responsible for the presentation. The management's risk assessment shall be reviewed on an annual basis by the CFO.

#### Control activities

Control activities limit the identified risks and ensure accurate and reliable financial reporting. The Board of Directors is responsible for the internal control and monitoring of the company's management. This is done

through both internal and external control activities, and through examination and monitoring of the company's guidelines related to risk management. The effectiveness of the control activities are assessed annually and the results from these assessments are reported to the Board of Directors and the Audit Committee. In agreements with essential subcontractors, the company has secured the right to audit each respective subcontractors' fulfillment of relevant services, including quality aspects.

### Monitoring

Compliance with, and effectiveness of, the internal controls are constantly monitored. The CEO ensures that the Board of Directors continuously receives reports on the development of the company's activities, including the development of the company's results and financial position, as well as information on important events, such as research results and important contracts. The CEO also reports on these matters at each ordinary Board meeting. The company's compliance with relevant policy's and guidelines are assessed annually. The results from these assessments are compiled by the CFO in the company and then reported to the Board of Directors and the Audit Committee annually.

### Information and communication

The company has information and communication channels to promote the accuracy of the financial

reporting and to facilitate reporting and feedback from operations to the Board of Directors and senior management, for example by making corporate governance documents such as internal policies, guidelines and instructions regarding the financial reporting available and known to the employees concerned. The Board of Directors has also adopted an information policy governing the company's disclosure of information. The company did also in 2021 initiate an implementation of an internal control structure according to the Sarbanes-Oxely Act to meet the requirements for companies listed in the USA. In addition to the abovementioned internal control, there is also internal, business-specific control of data as regards research and development, as well as quality control including systematic surveillance and evaluation of the company's development and manufacturing operations.

### Internal Audit

The Board of Directors has assessed the need for an internal audit function and decided that such a function is not justified in Calliditas, taking into account the scope of operations and that the Board's monitoring of internal control is considered sufficient to ensure that internal control is effective. The Board of Directors reassess the requirement when changes take place that may give rise to a reassessment and at least once per year.

## Auditor's report on the corporate governance statement

*To the general meeting of the shareholders of Calliditas Therapeutics AB (Publ), corporate identity number 556659-9766*

### Engagement and responsibility

It is the Board of Directors who is responsible for the corporate governance statement for the year 2023 on pages 88-93 and that it has been prepared in accordance with the Annual Accounts Act.

### The scope of the audit

Our examination has been conducted in accordance with FAR's standard RevR 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards

on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

### Opinions

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Stockholm, April 24, 2024  
Ernst & Young AB

Jakob Grunditz  
Authorized Public Accountant

# Board of Directors



## Elmar Schnee

### Chairman

Born 1959. Board member since 2019.

#### Education:

Master's degree in marketing and management from SIB.

#### Board Committees:

Chairman of the Remuneration Committee.

#### Experience:

Elmar Schnee was previously CEO of Merck Serono and was instrumental in the acquisition of Serono by Merck KGaA. He has also served as General Partner and member of the Executive Board of Merck KGaA and has held previously several senior global management positions with UCB and Sanofi.

#### Other current assignments:

Chairman of the board of directors of ProCom Rx SA, Moleac Pte Lts and Noorik Biopharmaceuticals AG, Executive Chairman EnteroBiotix as well as a member of the board of directors of Kuste Biopharma, Mindmaze SA and Damian Pharma AG.

#### Holdings in the Company:

Elmar Schnee holds 33,236 shares in the company, 10,624 share awards in LTIP 2021, 13,926 share awards in LTIP 2022 and 14,012 share awards in LTIP 2023.

Independent in relation to the Company and its management and in relation to major shareholders.



## Hilde Furberg

### Non-executive Director

Born 1958. Board member since 2014.

#### Education:

Master of Science from Oslo University, Norway.

#### Board Committees:

Member of the Audit Committee.

#### Experience:

Hilde Furberg is an independent consultant and professional Board member. She has extensive experience of leadership from her 35 years in sales, marketing, strategy and management in Pharma/Biotech. Her experience is in various therapeutic areas which she gained working in small companies and large global corporations. Hilde has worked in companies such as Genzyme and Baxter, she was most recently SVP and General Manger / European Head of Rare Diseases at Sanofi Genzyme. In addition to working for Genzyme/Sanofi Genzyme, Hilde has since 2005 worked as non-executive director and Board member of Probi, Pronova, Clavis, Bergenbio and Algeta.

#### Other current assignments:

She is currently an industrial advisor to Investinor and Board member of PCI Biotech, Herantis Pharma, Sedana Medical, Bio-Me, Pluvia Biotech, and Borkenholm AS.

#### Holdings in the company:

Hilde Furberg holds 53,199 shares in the company, 4,086 share awards in LTIP 2021, 5,356 share awards in LTIP 2022 and 5,389 share awards in LTIP 2023.

Independent in relation to the Company and its management and in relation to major shareholders.



## Henrik Stenqvist

### Non-executive Director

Born 1967. Board member since 2022.

#### Education:

Master of Science in Business Administration and Economics, University of Linköping.

#### Board Committees:

Chairman of the Audit Committee.

#### Experience:

Henrik Stenqvist has served as CFO of several listed life science companies and currently, he is the CFO of SOBI. Previous positions include CFO at Recipharm, CFO at Meda, Regional Finance Director at AstraZeneca, Finance Director at Astra Export & Trading and Board member of MedCap AB.

#### Other current assignments:

Board member in Midsona AB and Orion Corporation (from March 20, 2024).

#### Holdings in the company:

Henrik Stenqvist holds 10,000 shares in Calliditas, 5,356 share awards in LTIP 2022 and 5,389 share awards in LTIP 2023.

Independent in relation to the Company and its management and in relation to major shareholders.



## Diane Parks

### Non-executive Director

Born 1952. Board member since 2019.

#### Education:

Master's degree from Kansas State University and an MBA from Georgia State University.

#### Board Committees:

Member of the Remuneration Committee.

#### Experience:

Diane Parks is a senior executive with deep sales and marketing experience from the US, where she has held positions such as Head of US Commercial for Kite Pharma, VP of Sales for Amgen and Head of Global Marketing at Pharmacyclics.

#### Other current assignments:

Board member in Kura Oncology, Soligenix and Celularity.

#### Holdings in the Company:

Diane Parks holds 8,499 shares in the company, 4,086 share awards in LTIP 2021, 5,356 share awards in LTIP 2022 and 5,389 share awards in LTIP 2023.

Independent in relation to the Company and its management and in relation to major shareholders.



## Fred Driscoll

### Non-executive Director

Born 1950. Board member since 2023.

#### Education:

B.S. Accounting, Bentley University.

#### Board Committees:

Member of the Audit Committee.

#### Experience:

Mr. Driscoll has served as Interim Chief Financial Officer at Invivyd, Inc. from Oct. 2022 to May 2023. Since May 2021 until Nov. 2021, Mr. Driscoll served as Chief Financial Officer at Flexion Therapeutics which was acquired by Pacira Biosciences, a role he previously served from 2013 to 2017, spearheading the initial public offering in 2014. Prior to joining Flexion Therapeutics, he was Chief Financial Officer at Novavax, Inc., a publicly traded biopharmaceutical company, from 2009 to 2013. From 2008 to 2009, Mr. Driscoll served as Chief Executive Officer of Genelabs Technologies, Inc., a publicly traded biopharmaceutical and diagnostics company later acquired by GlaxoSmithKline. He previously served as Genelabs' Chief Financial Officer from 2007 to 2008. From 2003 to 2006, Mr. Driscoll served as Chief Executive Officer at OXiGENE, Inc., a biopharmaceutical company and from 2000 to 2003 as Chief Financial Officer. Mr. Driscoll has also served as Chairman of the Board and Audit Committee Chair at OXiGENE and as a member of the Audit Committee for Cynapsus, which was sold to Sunovion Pharmaceuticals in 2016.

#### Other current assignments:

Mr. Driscoll currently serves as a board member for Collectar BioSciences, Cue BioPharma and MEI Pharma.

#### Holdings in the Company:

5,389 share awards in LTIP 2023.

Independent in relation to the Company and its management and in relation to major shareholders.



## Elisabeth Björk

### Non-executive Director

Born 1961. Board member since 2022.

#### Education:

MD degree, Karolinska Institute, Stockholm and Associate Professor, Medicine, Uppsala University

#### Board Committees:

Member of the Remuneration Committee.

#### Experience:

Elisabeth Björk is an endocrinologist by training and an associate professor of medicine at Uppsala University, Sweden. Elisabeth Björk has been the Senior Vice President, Head of Late-stage Development, Cardiovascular, Renal and Metabolism (CVRM), BioPharmaceuticals R&D at AstraZeneca leading the global development of medicines within this area since 2012. Throughout her career at AstraZeneca, she has gained broad drug development experience covering clinical development phase I-IV, large outcomes programs, major global filings and health authority interactions (FDA, EMA, Japan) and commercial strategy/implementation.

#### Other current assignments:

Board member in Rocket Pharmaceuticals, Pharvaris NV, Vicore Pharma AB, Chalmers University of Technology, Betula Consulting AB.

#### Holdings in the Company:

Elisabeth Björk holds 4,086 share awards in LTIP 2021, 5,356 share awards in LTIP 2022 and 5,389 share awards in LTIP 2023.

Independent in relation to the Company and its management and in relation to major shareholders.

# Management team



## Renee Aguiar-Lucander

### *Chief Executive Officer*

Born 1962.  
CEO since 2017.

#### **Education:**

BA in Finance from Stockholm School of Economics. MBA from INSEAD.

#### **Experience:**

Before joining Calliditas, Renée Aguiar-Lucander was a Partner and COO of Omega Fund Management, an international venture capital company focused on investments within the life science sector. Before that, she served as a Partner in the venture capital group 3i Group plc in London, where she managed the publicly quoted assets and was co-head of the global healthcare and technology portfolio. Prior to this, Renée Aguiar-Lucander was the European Group Head and Managing Director at a global investment bank and has more than 12 years' experience in corporate finance. Prior to her career in investment banking, she was the Head of European Sales and Marketing in a company focused on the sale of software for financial services.

#### **Other current assignments:** –

#### **Holdings in the Company:**

Renée Aguiar-Lucander holds 643,000 shares in the Company and 841,000 options.



## Fredrik Johansson

### *Chief Financial Officer*

Born 1977.  
CFO since 2017.

#### **Education:**

Studies in Business Law at Jönköping International Business School. Studies in Business and American law, Economics and Finance at Georgia State University, University of South Carolina and Lund University.

#### **Experience:**

Fredrik Johansson has extensive experience in executive positions, primarily within telecom and software. Previously, he was CFO and COO at Birdstep Technology/ Techstep ASA, listed on the Oslo Stock Exchange, where he, among other things, was in charge of the acquisition and reversed listing of Teki Solutions. Previous CFO positions also include Phone Family, Teligent Telecom and Wayfinder Systems.

#### **Holdings in the Company:**

Fredrik Johansson holds 42,750 shares in the Company and 305,000 options.





## Frank Bringstrup

### *Vice President Regulatory Affairs*

Born 1959.  
VP Regulatory Affairs since 2019.

#### **Education:**

Medical education from the University of Copenhagen. He has a diploma in Managing Medical Product Innovation (MMPI) from the Copenhagen School of Economics, a diploma in business administration from Warwick University, and a post graduate specialist course in public health science from the National Board of Health, Denmark.

#### **Experience:**

Frank Bringstrup has over 17 years of experience in the pharmaceutical industry within regulatory affairs and health authority interactions. Prior to joining Calliditas, he worked in various positions at Novo Nordisk A / S. He started his professional career first as a clinic doctor and then Frederiksborg County Medical Advisor.

#### **Holding in the Company:**

Frank Bringstrup holds 8,000 shares in the Company and 135,000 options.



## Sandra Frithiof

### *Head of Human Resources*

Born 1975.  
Head of HR since 2020.

#### **Education:**

Bachelor's Degree in Human Resource Management from Örebro University, Sweden.

#### **Experience:**

Sandra Frithiof has more than 23 years of HR experience in different industries. Before joining Calliditas Sandra worked as Head of HR and COO at Ramberg Advokater. Previous HR positions also include Karolinska University Hospital, UTC, CGI and Manpower Group.

#### **Holdings in the Company:**

Sandra Frithiof holds 105,000 options.

# Management team



## Richard Philipson

### Chief Medical Officer

Born 1964.  
Chief Medical Officer since 2020.

#### Education:

BSc in Biomedical Sciences at London University and MB MS, Middlesex Hospital Medical School. Fellow of the Royal College of Physicians and Fellow of the Faculty of Pharmaceutical Medicine.

#### Experience:

Dr. Richard Philipson is a physician with 24 years of experience in the pharmaceutical industry from both large pharmaceutical companies and smaller biotechs. He has extensive experience in rare diseases, having brought several products from early development to the market. Prior to joining Calliditas, Richard worked as CMO with the UK-based biotech company Trizell where he led the Adstiladrin® phase 3 clinical program and Biologics License Application in non-muscle invasive bladder cancer, submitted to the FDA in September 2019. Before Trizell, he worked for Takeda as an Executive Medical Director and spent 16 years at GlaxoSmithKline, where he held a number of senior positions, including Disease Area Head and Acting Chief Medical Officer for the Rare Diseases Unit.

Before joining the industry, Richard worked as a physician in several clinical positions with various patient populations, including patients with IgA nephropathy.

#### Holdings in the Company:

Richard Philipson holds 270,000 options.



## Maria Törnsén

### President North America

Born 1978. President,  
North America since 2024.

#### Education:

MSc in International Business Administration from Lund University, Sweden.

#### Experience:

Maria Törnsén has more than 20 years of experience in the pharmaceutical industry. Maria is currently a Board Director for Immunic Therapeutics and before joining Calliditas, she worked as Chief Commercial Officer at Passage Bio. Prior to Passage Bio, Maria held various commercial leadership roles at Sarepta, Sanofi and Shire. Maria began her career at Eli Lilly in sales and also worked at Merck KGaA in sales and marketing.

#### Holdings in the Company:

Maria Törnsén holds 125,000 options.



## Brian Gorman

### *Group General Counsel*

Born 1976.  
Group General Counsel since 2023.

#### **Education:**

Bachelor's Degree from Gettysburg College, J.D from Villanova University School of Law.

#### **Experience:**

Brian is an accomplished legal and business executive with more than 20 years of experience advising corporate boards and executive management teams of life science companies. He joins Calliditas after having served most recently as Executive Vice President, Corporate Development & General Counsel at Opiant Pharmaceuticals, which was acquired by Indivior PLC. Prior to Opiant, Brian held senior legal leadership roles at Endo Pharmaceuticals, AstraZeneca and Wyeth Pharmaceuticals (now Pfizer). He began his career at the international law firm, Cleary Gottlieb Steen & Hamilton.

#### **Holdings in the Company:**

Brian Gorman holds 75,000 options.



## Lars Stubberud

### *Head of Technical Operations*

Born 1964. Head of Technical Operations since 2023.

#### **Education:**

Master of Science (candidatus pharmaciae) and PhD in Pharmaceutical Science from the University of Oslo, Norway.

#### **Experience:**

Lars Stubberud has more than 30 years experience in the pharmaceutical industry, within the broader CMC area, including Formulation Sciences, Product Development, Technology Transfer/Technical Stewardship as well as Regulatory Affairs- CMC and Quality Assurance. Prior to joining Calliditas Lars has held various positions, including leadership roles, at Nyomed AS, Norway, AstraZeneca Sweden, as well as Cubist Pharmaceuticals GmbH, Biogen International GmbH and Alexion Pharma GmbH in Switzerland.

#### **Holdings in the company:**

Lars Stubberud holds 100 000 options.

# Scientific Steering Committee

Some of the most prominent IgA nephropathy specialists in the world serve as external advisors and members of the Company's advisory board.

## Brad H. Rovin

*Professor, Director of the Division of Nephrology and Vice Chairman of Medicine for Research at the Ohio State University Wexner Medical Center, Columbus, Ohio, US*

## Heather N. Reich

*Department Division Director of Nephrology, University of Toronto; Senior Scientist, Toronto General Hospital Research Institute; Nephrologist, University Health Network, Toronto, Ontario, Canada*

## Héran Trimarchi

*Professor of Medicine, Universidad Católica Argentina; Head, Nephrology Service, Hospital Británico; Head, Kidney transplant unit, Hospital Británico, Buenos Aires, Argentina*

## Hong Zhang

*Professor of Medicine and Doctoral supervisor, Nephrology Division, Peking University First Hospital, Peking University Institute of Nephrology, Beijing, China*

## Jonathan Barratt

*Professor, Department of Infection, Immunity and Inflammation, University of Leicester; Honorary Consultant Nephrologist in the John Walls Renal Unit, Leicester General Hospital, Leicester, UK*

## Jürgen Floege

*Professor, head of the Department of Renal and Hypertensive Diseases, Rheumatological and Immunological Diseases (Medicine II) at the Aachen University Hospital; Director of the Department of Nephrology and Clinical Immunology at the University of Aachen, Aachen, Germany*

## Richard Lafayette

*Professor of Medicine (Nephrology), the Stanford University Medical Center; Director, the Stanford Glomerular Disease Center, Stanford, California, US*

## Vladimir Tesar

*Professor, Head of the Department of Nephrology, 1st Faculty of Medicine, Charles University, Prague, Czech Republic*

## Financial Calendar

Interim Report for the period January 1–March 31, 2024	May 23, 2024
Annual General Meeting 2024	June 17, 2024
Interim Report for the period January 1–June 30, 2024	August 13, 2024
Interim Report for the period January 1–September 30, 2024	November 11, 2024
Year-End Report for the period January 1–December 31, 2024	February 20, 2025

# Glossary

**ACE inhibitors (ACEIs):** Angiotensin Converting Enzyme inhibitors (ACEIs) are a type of blood pressure medication that work by limiting the effects of the hormone angiotensin II, which has a constricting effect on blood vessels and stimulates salt and water retention in the body and thus increases blood pressure. Angiotensin II is activated by a molecule called Angiotensin Converting Enzyme (ACE,) which is blocked by ACE inhibitors

**Adaptive Design:** An adaptive design trial is one in which the design allows for modifications to the trial and/or statistical procedures of the trial after its initiation without undermining its validity and integrity

**ALP:** Alkaline phosphatase (ALP) is an enzyme which is used as a marker in PBC. A rise in ALP levels indicates impaired bile flow in the liver

**Angiotensin Receptor Blockers (ARBs):** ARBs work by blocking the AT1 receptors that the hormone angiotensin II acts on, thereby limiting its action and lowering blood pressure

**Autoimmune disease:** Disease that is manifested because of the immune system's harmful attack with autoantibodies on the body's own tissue. All people have some degree of autoimmunity, but when it gets too high it becomes harmful

**Budesonide:** a potent glucocorticoid with rapid elimination that fits very well with local treatment where you want to minimize systemic side effects

**CAF:** A cancer-associated fibroblast (CAF) is a key cell type within the tumor microenvironment. CAFs promote tumor growth via a variety of mechanisms, including initiating the remodelling of the extracellular matrix or secreting cytokines

**Corticosteroids:** a class of steroid hormones and synthetic analogues. Corticosteroids are used systemically for the treatment of inflammatory and immunological diseases, including IgA nephropathy, autoimmune hepatitis and primary biliary cholangitis

**Creatinine:** a chemical substance made by muscles. Measured in the blood circulation and produced in a relatively even amount. Eliminated through the kidneys. Too high a concentration in the blood is a measure of impaired kidney function. It is used to calculate eGFR. High creatinine corresponds to low eGFR

**Dimeric:** Also known as 'polymeric', a dimeric molecule is composed of two identical simpler molecules (monomers)

**DKD:** Diabetic kidney disease (DKD,) also called diabetic nephropathy, is kidney disease that is due to Type 1 or Type 2 diabetes

**Double blind:** A double-blind study is one in which neither the participants nor the experimenters know who is receiving a particular treatment

**eGFR:** estimated glomerular filtration rate. A measure of the kidney's ability to filter and purify the blood. When a kidney disease worsens, eGFR decreases

**EMA:** European Medicines Agency

**ESRD:** end-stage renal disease

**Enteric:** relating to or occurring in the small intestine. The enteric coating on Nefecon refers to the fact that it is designed to dissolve in the ileum, which is in the distal part of the small intestine

**FDA:** US Food and Drug Administration

**Galactose:** a type of sugar that is similar to glucose. Antibodies such as IgA have sugar chains attached to them. These sugar chains contain, among other things, galactose

**Glomerulus:** An anatomical structure of the kidney. Blood vessel bundles where the blood is filtered to urine

**Glomerulonephritis:** an inflammation of the glomeruli, the kidney's filtration function

**HbA1c:** HbA1c is a term commonly used in relation to diabetes and is a measure of average blood sugar levels. The term refers to glycated haemoglobin, which develops when haemoglobin joins with glucose in the blood, becoming 'glycated'

**IgA:** Immunoglobulin A (an antibody.) Also referred to as IgA1

**IgA Nephropathy (IgAN):** a rare autoimmune kidney inflammatory disease, within the glomerulonephritis class

**Ileum:** the distal end of the small intestine, also called the bowel arm, is 2–4 meters long and connects to the colon

**Immunoglobulin:** antibodies (proteins) used by the body's immune system to detect and identify foreign substances that can cause damage

**Incidence:** number of new patients per year in a disease

**Immunosuppressive agents:** a class of drugs that suppress, or reduce, the strength of the body's immune system

**Immunotherapy:** Immunotherapy is the treatment of disease by activating or suppressing the immune system

**Investigator-Led Study:** Investigator led studies are clinical studies initiated and managed by a non-pharmaceutical company researchers, like individual investigators, institutions, collaborative study groups or cooperative groups

**IPF:** Idiopathic pulmonary fibrosis (IPF) is a condition in which the lungs become scarred and breathing becomes increasingly difficult, the causes of which are unclear

**KDIGO:** Kidney Disease: Improving Global Outcomes, a non-profit organization that develops global guidelines for treatment in kidney disease

**Monomeric:** a monomeric molecule is one that is a single unit and can be bonded to other identical molecules to form a polymer

**NADPH Oxidase:** NADPH oxidase (nicotinamide adenine dinucleotide phosphate oxidase,) also known as NOX enzymes, are membrane-bound enzyme complexes, which catalyse the production of reactive oxygen species

**Nephrologist:** a physician specialized in kidney disease

**Off-label prescription:** prescription of an approved drug outside the approved indication

**On-label:** prescription of an approved drug within the approved indication

**Open-label:** An open-label trial is one in which information about which treatment is being administered is not withheld from trial participants and researchers

**Orphan disease:** a rare disease that falls within the criteria of orphan drug law

**Oxidative Stress:** Oxidative stress is when there is an imbalance between the production and the accumulation of reactive oxygen species (ROS) in cells and tissues and the body's ability to detoxify these reactive products

**PBC:** Primary biliary cholangitis, a rare autoimmune fatty liver disease

**Peyer's patches:** lymph tissue of the ileum, the distal part of the small intestine, part of the body's immune system

**Prevalence:** number of people in a population having a disease

**Proteinuria:** a condition characterized by the presence of greater than normal amounts of protein in the urine; a measure of leakage in the kidney's filtration function

**Proof of Concept Trial:** Proof of Concept Principle studies are an early stage of clinical drug development when a compound has shown potential in animal models and early safety testing, and often is the step between a Phase 1 and a dose ranging Phase 2 study

**RAS:** Renin-angiotensin system, which regulates blood pressure and fluid in the body; a RAS blocker lowers blood pressure; RAS blockade is when a patient is on drugs that block RAS, which can be ACEIs and/or ARBs

**Randomised:** A randomised trial is one in which participants are randomly assigned to 2 or more groups

**Reactive Oxygen Species:** Reactive oxygen species are highly reactive chemical molecules formed through the electron acceptability of O<sub>2</sub>

**Redox Homeostasis:** Redox homeostasis is attained by the regulation of the formation and removal of reactive oxygen species (ROS) from the body system

**RRT:** renal replacement therapy; a treatment for terminal kidney failure where the function of the diseased kidney is replaced by dialysis or kidney transplantation

**Transient Elastography:** Transient elastography (FibroScan) is an ultrasound exam that uses pulse-echo ultrasound acquisitions to measure liver stiffness in kilopascals (kPa,) which allows for a noninvasive assessment of liver stiffness

**UPCR:** Urine protein creatinine ratio, a measure of leakage in the kidney's filtration function

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