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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 36-91).



# About Calliditas

**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. Calliditas' lead product, developed under the name Nefecon, has been granted accelerated approval by the FDA under the brand name TARPEYO® and conditional marketing authorization by the European Commission under the brand name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, setanaxib.

Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market in New York (ticker: CALT).

Visit [www.calliditas.com](http://www.calliditas.com) for further information.



## Business highlights

**In January 2022**, Calliditas announced the commercial availability and initial sales of TARPEYO (budesonide), the first and only FDA approved treatment for IgA nephropathy (IgAN), indicated for reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$ g/g.

- » In February 2022, Calliditas announced that the first patient had been randomized in the company's pivotal phase 2b/3 TRANSFORM study in patients with primary biliary cholangitis (PBC). The TRANSFORM trial is a 52-week, randomized, placebo-controlled, double-blind, adaptive Phase 2b/3 trial that is investigating the effect of NOX 1 and 4 inhibitor setanaxib versus placebo on alkaline phosphatase (ALP) reduction in patients with PBC and with elevated liver stiffness and intolerance or inadequate response to ursodeoxycholic acid (UDCA).
- » In March 2022, Calliditas announced that the company had expanded its licensing agreement with Everest Medicines to extend the territory covered to include South Korea. The extension resulted in an upfront payment of USD 3 million to Calliditas as well as additional payments and royalties related to future potential approvals and commercialization of Nefecon in South Korea. Calliditas and Everest Medicines entered into a license agreement in 2019 to develop and commercialize Nefecon for IgAN in Greater China and Singapore.
- » In May 2022, Calliditas announced that the first patient had been randomized in the Group's proof-of-concept Phase 2 study in patients with squamous cell carcinoma of the head and neck (SCCHN) with the NOX 1 and 4 inhibitor setanaxib.
- » In May 2022, Calliditas announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the granting of a conditional marketing authorization for Kinpeygo for the treatment of primary IgAN in adults at risk of rapid disease progression with a UPCR  $\geq 1.5$  g/gram.
- » In May 2022, the Annual General Meeting (AGM) of Calliditas was held and, among other things, resolved on the election of Henrik Stenqvist and Elisabeth Björk to the Board of Directors and the establishment of a U.S. At-the-Market framework of up to a maximum of 5,908,019 shares, pursuant to which Calliditas may, at its option, sell American Depositary Shares ("ADSs") in the United States at market price, from time to time, in "at the market" transactions on The Nasdaq Global Select Market.

**In July 2022**, Calliditas announced that the European Commission (EC) granted conditional marketing authorization for Kinpeygo for the treatment of IgAN in adults at risk of rapid disease progression with a UPCR  $\geq 1.5$  g/gram. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in Europe. Kinpeygo will be marketed in the European Economic Area (EEA), the UK and Switzerland exclusively by Calliditas' European commercial partner STADA Arzneimittel AG.



- » In September 2022, Calliditas announced that its European commercial partner STADA launched Kinpeygo, the first and only approved treatment in the EU for primary IgAN. STADA initially launched in Germany, with additional European countries to follow.
- » In October 2022, Calliditas announced that Kidney International published the successful results from Part A of the NeflgArd pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter study, on the basis of which the FDA and EMA approved TARPEYO and Kinpeygo in the USA and Europe, respectively.
- » In November 2022, Calliditas announced that its China partner Everest Medicine's New Drug Application for Nefecon was accepted by the Chinese regulatory authority National Medical Products Administration (NMPA).
- » In December 2022, Calliditas announced that it had entered into an exclusive license agreement with Viatrix Pharmaceuticals to register and commercialize Nefecon for the treatment of IgAN in Japan. Under the terms of the agreement, Calliditas received an initial upfront payment of US\$20 million upon signing and is entitled to up to an additional US\$80 million in pre-defined development and commercialization milestones. Viatrix will also pay mid-teens percentage royalties on net sales.
- » In December 2022, Calliditas' partner Everest Medicines announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) recommended Priority Review for the New Drug Application (NDA) of Nefecon.

## Financial summary for the Group

	2022	2021	2020	2019	2018
Net sales (SEK in thousands)	802 879	229,347	874	184,829	-
Loss before income tax (SEK in thousands)	(409,417)	(513,373)	(436,151)	(32,501)	(132,049)
Cash (SEK in thousands)	1,249,094	955,507	996,304	753,540	646,175
Total assets (SEK in thousands)	1,952,973	1,459,910	1,463,908	845,200	648,417
Average number of employees	86	56	23	14	10



## A Transformative Year


**2022 was an extremely exciting and eventful year, marked first and foremost by our transformation into a commercial stage company.**

With the commercial launch of TARPEYO in the US at the end of the January, we became the first company ever to bring an approved medication for IgA nephropathy to market, an achievement that was the culmination of over a decade of work, from clinical development to regulatory interactions to pre-launch commercial preparation. TARPEYO, which from its conception has been designed to specifically and locally target the origin of this rare disease and which holds the promise of disease modification, represents a new era of hope for IgAN patients.

Our transformation from a primarily R&D based company to a commercial stage, fully integrated business has been a journey, which first started four years ago when we brought onboard our first employee in the US. By the end of 2021, the US organization had grown significantly and, with a fully integrated operation and a streamlined supply and distribution chain in place,

was ready and well prepared for a product launch. Our medical affairs team ensured that pre-launch medical education and interactions to raise awareness about the pathophysiology of IgAN had been conducted at conferences, congresses, and on a one to one basis with nephrologists across the country; market research had been undertaken to understand the existing treatment paradigms, the patient journey, and the perceived health economic burden of IgAN; our portal TARPEYO Touchpoints™ was available within hours and prescribers were able to access details regarding the product and could start writing prescriptions for appropriate patients. Upon approval, our specialty sales force engaged with nephrologists, informing them of the new approved treatment option, and our market access team initiated discussions with payors, leading to early and important coverage decisions. As the year progressed and we saw growing interest from prescribers, we decided in early Q3 to expand the sales force from 40 to 60 sales





executives, who became fully operational in late Q4. We also expanded the TARPEYO Touchpoints team, adding additional care navigators to support the increasing numbers of patients taking part in the program. These developments allowed us to continue to build on our initial commercial success and ensure that TARPEYO continues to be readily available for every appropriate IgAN patient. We ultimately ended the year with 642 total unique prescribers and 1,039 enrolments, which translated to \$36.8m (SEK 372.2m) in net sales of TARPEYO for the first 11 months of commercialization. We are immensely proud of this result, and we look forward to continuing to support the IgAN patient community with a drug which we believe can help keep patients out of dialysis due to its unique formulation and mode of action.

We were also thrilled to be able to publish data from our interim readout of our NeflgArd Phase 3 trial. In October, Kidney International published a peer reviewed manuscript containing the details of Part A of the NeflgArd study. There was strong reduction in proteinuria for TARPEYO-treated patients observed at 9 months, and importantly proteinuria continued to decline off-drug for all patients who had reached 12 months at the time of the data cut-off. There was also, notably, immediate protection of kidney function as measured by eGFR in the population at risk of rapid progression. Shortly after this publication, we were able to share and discuss this data with Key Opinion Leaders (KOLs) and nephrologists at the largest kidney conference of the year, the American Society of Nephrology's (ASN's) Kidney Week in Orlando in early November. We were very encouraged by the positive feedback and the many discussions that took place about TARPEYO in various forums; it was clear from these interactions that eGFR data will ultimately drive treatment decisions, as the goal of treating physicians is to protect kidney function rather than to address symptoms. We were therefore particularly excited by the top line data we announced from our full NeflgArd trial readout in March 2023, which seemed to demonstrate that TARPEYO had a durable and clinically relevant impact on kidney function (eGFR) irrespective of proteinuria levels in the full trial population of 364 patients. We look forward to the full data set, which will enable us to file for full approval with regulatory agencies.

2022 was also an important year for our work with our commercial partners. We achieved an approval in Europe, where Nefecon was granted conditional marketing authorization by the European Commission under the brand name Kinpeygo in July. This marked the first time that any drug has received approval for this

rare disease in Europe, where Kinpeygo remains the only approved medication for IgAN. We were delighted to take this important step for IgAN patients alongside our commercial partner, STADA, who launched Kinpeygo in Germany in September. Meanwhile our partners in China, Everest Medicines, received an acceptance of their New Drug Application (NDA) for approval of Nefecon in China in October, followed by a subsequent Priority Review recommendation by the National Medical Products Administration (NMPA) in December. We look forward to continuing to support Everest in their dialogue with the agency and to work together to bring an approved product to patients in China, where IgAN is a significant unmet medical need, with approximately 5 million patients. Finally, in December we entered into another important partnership deal for the Nefecon global franchise, as we signed an out-licensing with Viatris Pharmaceuticals Japan, who will develop Nefecon for patients in the Japanese market. We look forward to beginning our work with Viatris as we strive to bring Nefecon to IgAN patients in Japan as quickly as possible.

In 2022 we also launched two clinical trials with setanaxib, the lead clinical candidate from our NOX inhibitor platform. The first quarter saw the dosing of the first patient in our pivotal study in PBC, TRANSFORM, and the initiation of our Phase 2 proof-of-concept clinical trial in squamous cell carcinoma of the head and neck. Recruitment in PBC has been challenging, reflecting the overall accessibility of appropriate patients as well as macro factors outside of our control, such as global conflicts and pandemics. We have however seen significant progress in our recruitment rate for the head and neck cancer trial, which will report out biomarker data around mid-year 2023 as previously disclosed. We have also invested significant effort into exploring renal indications in which setanaxib could have a beneficial effect, and as a result of substantial preclinical work in 2022, we are now planning to launch a trial in Alport Syndrome, another rare kidney disease with significant unmet medical need and no medications approved.

While the work we did and the significant milestones we achieved in 2022 occurred against an often difficult and volatile macro backdrop, this was a hugely exciting and transformative year for our company. We are thrilled by the progress we have made, and are more encouraged than ever by what lies ahead for Calliditas.

**Renée Aguiar-Lucander, CEO**



## TARPEYO Commercial Launch

2022 was a historic year for our company as we launched our lead product, TARPEYO, in the United States and transitioned into a commercial stage company. We are proud to have brought the first FDA-approved medication for IgA nephropathy to patients, finally giving them the option of a medication specifically designed to target the origin of their disease.

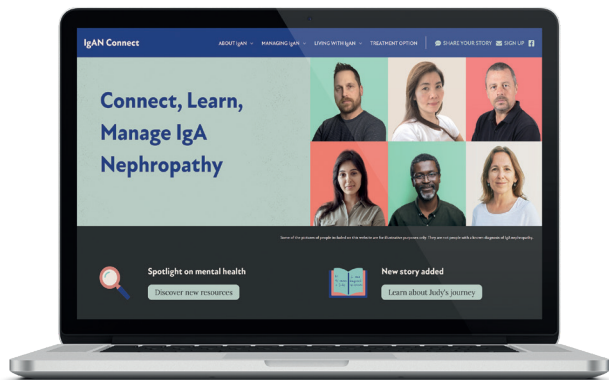
We are extremely encouraged by the strides we have made in our first year on the market, at the end of which we had generated \$36.8m in sales of TARPEYO. This number truly is a reflection of patient demand, since any potential stocking effects are clearly kept at a minimum given that we only have one specialty pharmacy. The excitement from healthcare providers (HCPs) and patients, who at last gained access to an approved product for IgAN, was evident and we ended the year with 1,039 total enrolments written by 642 unique prescribers.

This result is a testament to our entire commercial team, including our specialty sales force, who were onboarded at the very start of the year. Their contingent offers came into effect when TARPEYO received accelerated approval from the FDA on December 15th 2021, and their training began on the first Monday in January. The vast majority of these rare disease account managers joined Calliditas with prior experience in the nephrology market, and a significant number had previously worked in the specialty product space. We initially launched with approximately 40 territories, and in Q3 hired, trained and deployed an additional 20 account managers so as to increase the reach and frequency of our interactions with HCPs, based on market feedback.

By reducing the geographical size of the territories covered, we empowered our sales force to focus even greater attention onto key healthcare centers and physicians, and we look forward to continuing to see the impact of this expansion in the future.

Another key facet of our work to bring TARPEYO to IgAN patients is our patient support service, TARPEYO Touchpoints™, which aims to make the process of prescribing and obtaining our product as seamless as possible. The program, which was fully operational upon approval, is a white glove service that provides access to a dedicated case manager and a designated Rare Pod Team, which includes a fulfilment and distribution team, nurses, and pharmacists, all of whom work to help patients and physicians through the complex process of prescribing and obtaining a specialty product. There have been few novel therapeutic specialty products approved in the nephrology space in the past decade, which made it all the more important for our team to be on hand to help nephrologists navigate the sometimes-challenging typical specialty product approval process. We focus on key metrics in monitoring this program to make sure that even as our patient load increases, each patient and provider continues to receive the highest quality of service, and accordingly in Q3 we expanded our TARPEYO Touchpoints staff.





The drive to help patients is at the core of our mission as a company, as we have continued to place the utmost importance on our work to support the IgAN patient community. We continue to engage with patients and caregivers directly to develop patient educational resources, as well as working with and supporting key advocacy groups in this space. Calliditas partners on an ongoing basis to sponsor programs with advocacy groups that include the IGA Nephrology Foundation, Nephcure, National Kidney Foundation, American Association of Kidney Patients, and American Kidney Fund.

In July, Calliditas was a lead sponsor at the IGA Nephropathy Foundation's SPARK 2022 symposium, continuing our long-standing support of the foundation in its efforts to educate, support and engage the IgAN patient and caregiver community. This year we

also launched a disease awareness patient advocate program and continued to work closely with IgAN patient advocates to raise awareness of this disease and the impact it has on patients and caregivers via multiple digital and social channels. Our patient forum, IgAN Connect, provides resources and support for IgAN patients, offering information about the disease and guides to help navigate conversations with nephrologists.

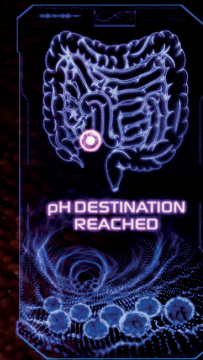
We will continue to do our utmost to help people living with IgA nephropathy throughout their journey and to ensure that they are at the center of all we do as a company.

Having access to this innovative medicine is of pivotal importance to patients but it is a lengthy and complex process, due to insurers/payer formulary review typically taking between 6 to 9 months for a new drug. We are extremely pleased with our progress with payers this year, having hit our high-level goal for the percentage of lives covered by mid-year. Payers have handled TARPEYO as a typical specialty product, understanding the value our product gives to patients and the importance of managing us to our label. We ended the year with well over 90% of US lives covered, which is a phenomenal outcome. The channel mix contains approximately 70% commercially insured patients, with the majority of the remaining 30% being government subsidized insured patients, which include Medicare and Medicaid. Patients enrolled in TARPEYO Touchpoints have a conversion rate of over 80% across commercial, government and patient assistance programs. There are many different players involved

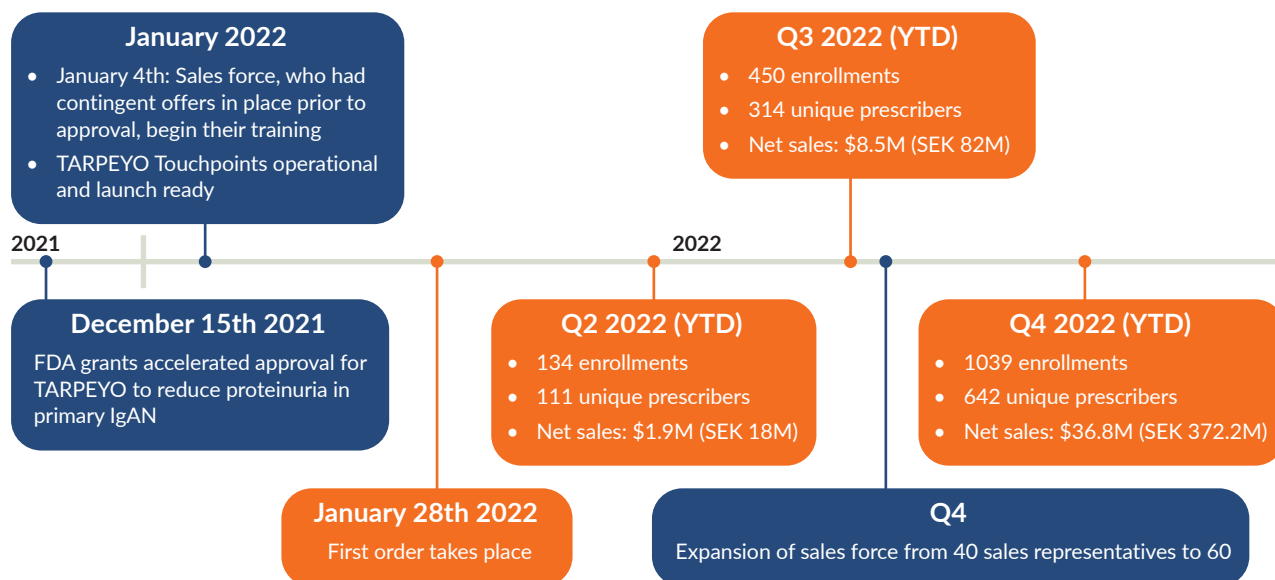
on the fulfilment side, with the pharmacy, payers and HCPs all needing to work together to get patients on drug, and we are proud to have an average of less than 30 days time to fulfilment for successfully concluded prescriptions. We will continue to work to improve these rates as we strive to exceed industry standards.

Education of healthcare professionals continues to progress well. We have engaged in robust educational and promotional efforts across various channels to boost TARPEYO's profile and ensure that awareness of our product is high. Following the required FDA review related to accelerated approved medications, we launched our branded campaign in the middle of the year; this multimedia campaign focused on the unique mechanism of action of TARPEYO and the efficacy and safety results achieved in the clinic. Our peer-to-peer programs continue to emphasize both disease education and the strong clinical benefits of TARPEYO,

For adults at risk of rapid disease progression,  
TARPEYO: First and only  
FDA-approved treatment  
to reduce proteinuria in  
IgA Nephropathy







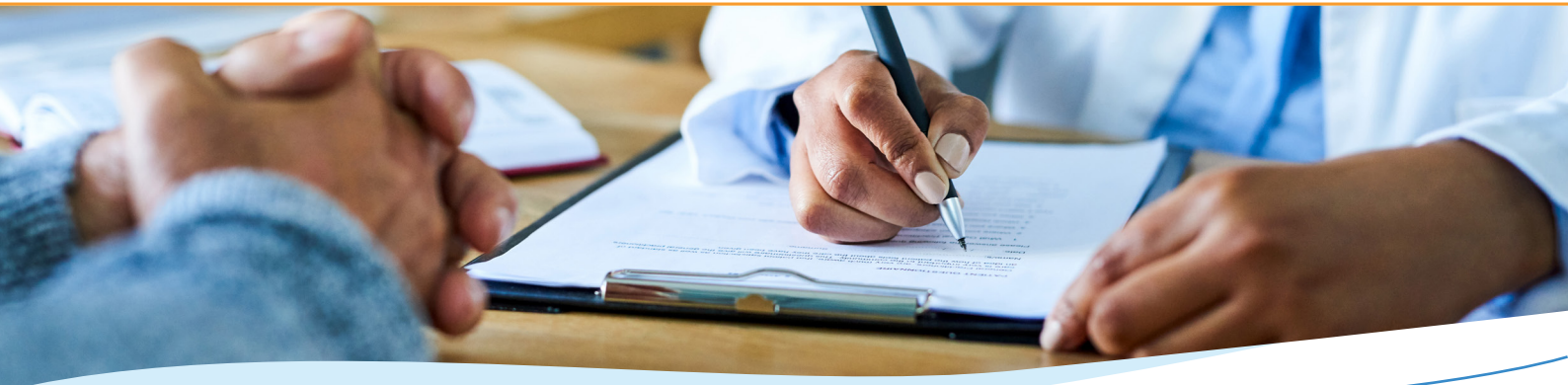
and we continue to engage with Key Opinion Leaders (KOLs) and practicing community nephrologists across the country. Awareness of TARPEYO has continuously increased, with unaided awareness now greater than 80% after one year on the market. In addition, market research conducted with nephrologists continues to demonstrate the effectiveness of our educational and promotional programs.

Our medical affairs team actively worked to prepare thoroughly for the launch in advance of our approval. Our medical science liaisons were out in the field in 2020, educating physicians and raising awareness about IgA nephropathy and the pathophysiology of the disease. In 2022, we continued to build on this work, ensuring our presence at the relevant symposia and congresses and attending conferences such as the National Kidney Foundation's yearly Spring Clinical Meetings educational event and the Annual Rare & Genetic Kidney Disease Drug Development conference. As always, the American Society of Nephrology's yearly Kidney Week was a particular highlight, and we were thrilled to have been able to discuss our recently published data at this event with KOLs and

the broader nephrology community. Data from Part A of the NeflgArd trial was published in *Kidney International* in October, and the strong positive response from our nephrologist interactions spoke to the impact that this publication had on prescribers treating the IgA nephropathy patient population.

### A pioneering start to an exciting journey

Undertaking the role of being the first in the market is both an exciting and challenging task. As the first approved drug for this disease, we are the first company to ever interact with payers about a drug for IgAN, the first to approach nephrologists with a treatment option for their IgAN patients, and the first to engage with patients about an approved product that holds the potential to target the origin of their disease and to be disease modifying. This has required adjustments and the ability to be agile as we established ourselves in this novel market and drove the shift in the treatment paradigm. We are proud to be able to reflect on the year knowing that we have met our own ambitious expectations, and we look forward to building on this success in the years to come.



## A Conversation with Bill, a TARPEYO Patient

*Bill lives in Greenville, South Carolina, where he owns and operates two preschools with his wife. He loves spending time with his children and grandchildren. He has IgA nephropathy and has been living with his diagnosis since 2022. He is currently taking TARPEYO to manage his disease and we were able to chat with him and learn more about his journey.*

» Finding out TARPEYO was an option for me helped ease the burden of my diagnosis.«

### **When were you initially diagnosed with IgAN? How did you feel about your diagnosis?**

I was diagnosed with IgA nephropathy in 2022. At the time, I was experiencing fatigue and headaches, so I went to see my primary care physician. After running a urinalysis, they discovered blood in my urine and I was referred to a nephrologist for a kidney biopsy. My initial biopsy was inconclusive, but my second biopsy led to my diagnosis. When my doctor called me to tell me the news I was at an airport, and I remember sitting down and trying to process the words as quickly as they came out of his mouth. It sounded a bit like a second language to me. I tried to do research on my own, but I struggled to find resources that helped me.

### **What were your treatment options at the time?**

At the time of my diagnosis, I was fortunate that TARPEYO was FDA-approved and available to me. In the same phone call my doctor diagnosed me, he recommended I start on TARPEYO. I felt relieved to be offered a treatment that was created for IgA nephropathy because I know so many people living with this disease have really struggled with their treatment options.

### **What was your reaction to finding out there was an approved treatment for IgAN?**

Finding out TARPEYO was an option for me helped ease the burden of my diagnosis. Knowing that there

was a treatment specifically designed for my disease made me feel a bit more secure. When you start to research this disease, the first thing you learn is that it can lead to dialysis and end-stage renal failure. I am really motivated to live a good life with my wife, children and grandchildren, so it helped to know there was a drug available that might help me.

### **Did your doctor talk to you about why TARPEYO would be a good fit for you?**

My wife and I run a few pre-schools. I interact with the kids and the parents all day, so for me, it was really important that any treatment I took did not alter my physical appearance too much. In discussing my treatment options, my nephrologist explained to me that because TARPEYO was released in my gut specifically, it might mean fewer side effects.

### **What has your experience with TARPEYO been like?**

I have been on TARPEYO for the past 4 months and I am optimistic about continuing with this approach. My doctor is encouraged by my lab results. Overall, what matters most to me is that I feel better. I have had more good days lately. I am less tired and can engage in my life the way I want to.



## Physician Insights on TARPEYO

### Dr Shikha Wadhvani

*Dr. Shikha Wadhvani is the Director of the Glomerular Disease Program at Northwestern University's Feinberg School of Medicine and an Assistant Professor in the Division of Nephrology and Hypertension. She is also the Program Director for the Glomerular Disease Fellowship and co-founder of the Joint Rheum- Renal Lupus Nephritis clinic at Northwestern.*

#### What was your reaction to an FDA-approved product becoming available for your IgAN patients?

I was ecstatic! I have a number of patients who have had high-grade proteinuria and either had side effects to systemic steroids in the past, or the patient and I wanted to avoid systemic steroids. The idea of a targeted therapy that (while not directly compared to systemic steroids), theoretically had a better AE profile was very exciting. Given many of the other IgAN drugs in trials are a SC formulation, the fact that TARPEYO

is orally administered was also appealing. And perhaps most important, other available drugs did not seem to target the underlying immunologic milieu/inflammation but rather downstream processes such as fibrosis. I felt that many patients needed a safe, efficacious drug to target the ongoing "activity" rather than "chronicity" and TARPEYO seemed to be a great option!

#### Were you familiar with TARPEYO before it was approved?

Yes—I was involved in the NEF-301 clinical trial as well as the open label arm. I had 2 patients enrolled in the original trial who continued on (and have now finished) the open label arm. I am also on the speaker's bureau.

#### Based on your experiences with TARPEYO, would you recommend it to other physicians with IgAN patients as an option to explore for their treatment?

Absolutely! In the right patient, it can be extremely effective.

### Dr. Suneel M. Udani

*Suneel Udani is a consulting physician with NANI (Nephrology Associates of Northern Illinois and Indiana) and medical director of the clinical research program. He is a site PI for multiple studies in IgAN and FSGS. His clinical interests are in glomerular disease and cardiorenal syndrome.*

*He completed his undergraduate and medical school at Northwestern University and residency in Internal Medicine at the University of Chicago Medical Center and University of Pittsburgh Medical Center. He completed a Chief Medicine Residency at Cook County Hospital prior to completing his fellowship in Nephrology at the University of Chicago Medical Center including an additional of year training in Glomerular Disease.*

#### When you first began prescribing TARPEYO, was there a specific kind of patient you initiated therapy with?

I was initially targeting patients that demonstrated steroid responsiveness, ie experienced a reduction in proteinuria when on steroids, but were unable to tolerate the associated adverse effects. In addition, I targeted patients who had demonstrated features of "active" inflammatory disease characterized by a sudden spike in proteinuria with associated hematuria

+/- change in kidney function. These types of patients are those who I feel have the potential to most benefit from TARPEYO.

#### How often do your patients come in for check-ups?

Patients return approximately 4-6 weeks after initiation to assess tolerance and confirm there has been no significant negative impact. Subsequently, they have labs done every 4-6 weeks and see me every 3 months or sooner if any issues arise.

#### Do you have any patients who have been treated with TARPEYO for over 6 months? What were their results and experience?

Their responses have been consistent with or exceeded the results of the NeflgArd Part A results.

#### For patients whom you've treated with TARPEYO for at least 9 months, how do you envision using/positioning TARPEYO moving forward, if at all?

I have a patient who has been treated for 9 months and has tapered off therapy. We discussed close surveillance for the next year and beyond with the option to retreat if her condition "flares".

# 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

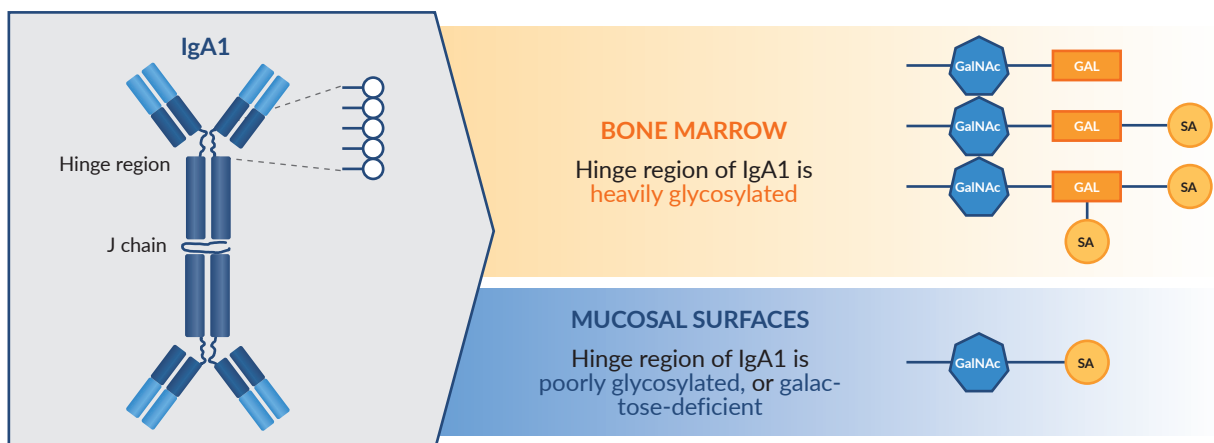
IgAN is a serious progressive autoimmune disease of the kidney, in which up to 50% of patients end up at risk of developing end-stage renal disease (ESRD) within ten to twenty years. The standard of care for ESRD is dialysis or kidney transplant, which represents a significant health economic burden as well as a material impact on patients’ quality of life.

IgAN is an orphan disease that we estimate affects approximately 130,000 – 150,000 people in the US and approximately 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

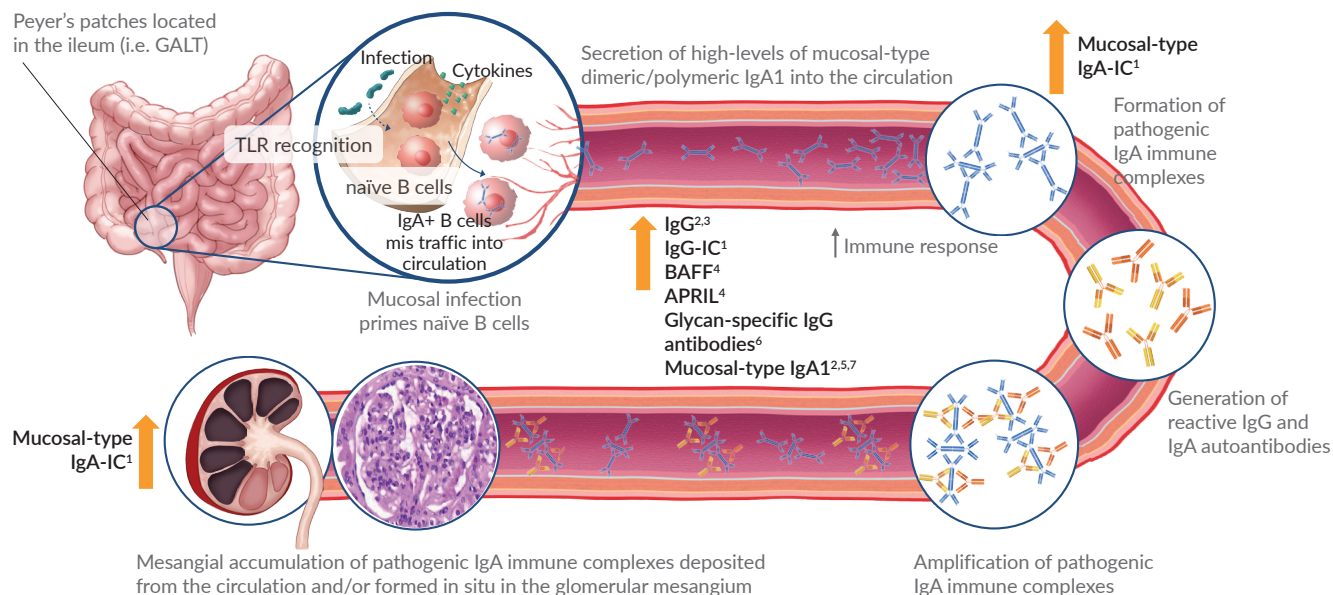
Although IgAN manifests in the kidney, the evidence indicates that it is a disease that starts in the distal part of the intestine, specifically in the ileum. Peyer’s patches, which are concentrated within the gut-associated lymphoid tissue in the ileum, have been identified as a major source of mucosal-type 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,



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





bacterial and dietary factors is presumed to lead to an increased production of these galactose-deficient IgA antibodies. This increased production, potentially in conjunction with increased intestinal permeability, leads to these 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 supportive only, and does not address the underlying cause of IgAN.



## The NeflgArd Trial

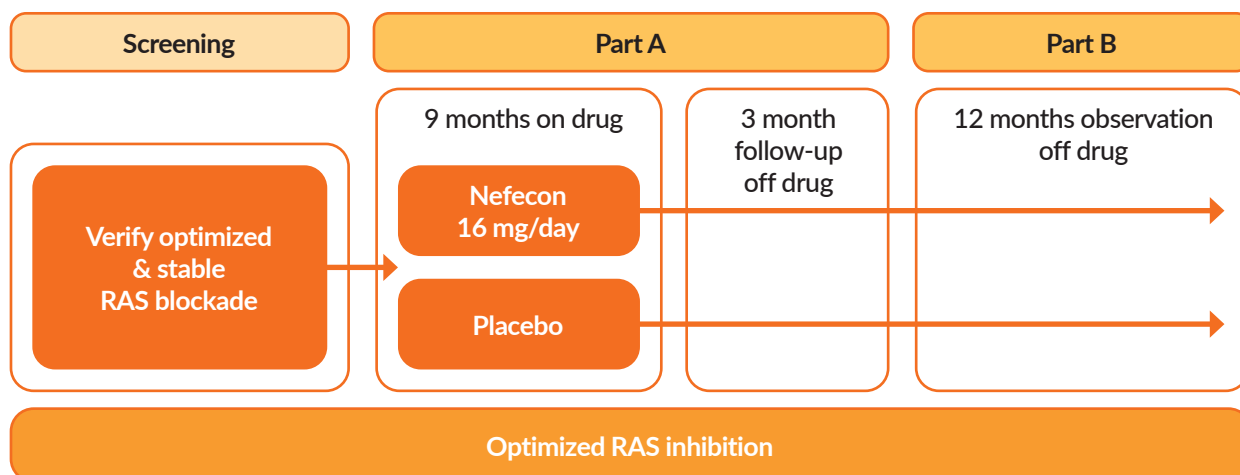
TARPEYO and Kinpeyo, which are the first approved treatments for IgAN in the USA and Europe respectively, were developed under the name Nefecon. Nefecon is an oral, delayed release formulation of budesonide, an immunomodulator with potent glucocorticoid activity and weak mineralocorticoid activity that 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.

Calliditas' regulatory filings with the FDA and European Medicines Agency (EMA) were based on positive data from Part A of the NeflgArd pivotal Phase 3 study, which read out topline data in November 2020. NeflgArd is a pivotal, global Phase 3 trial consisting of two parts. Part A provided data on the efficacy and safety of Nefecon in 200 patients. 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. NeflgArd Part B, meanwhile, was a post-market approval observational trial to confirm long-term renal protection. This part 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. The 364-patient population of the Phase 3 trial included a further 164 patients enrolled in addition to the 200 patients from Part A. The full NeflgArd 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.

With the Phase 3 program drawing to a close, we were delighted to be in a position to publish data from Part A of the trial in a peer-reviewed article in *Kidney International*. The full article, which can be accessed [here](#), was published in October 2022, prior to the largest annual meeting for nephrologists, the American Society of Nephrology's (ASN's) Kidney Week in early November. We were very encouraged by the positive feedback we received from the countless interactions with physicians during the conference, and feel confident that having published and peer-reviewed data accessible to health care providers will further bolster our interactions regarding TARPEYO with nephrologists. The strong reduction in proteinuria at 9 months and the continued decline in proteinuria in all patients who had been off drug for 3 months was commented on at ASN as being highly differentiated from all other drug candidates, and the strong protection of kidney function that was seen in the population at highest risk was considered to be very impressive.





### BASELINE CHARACTERISTICS

Age (years) [Median]	44
Sex (n, % male)	135 (67.8%)
Race (n, % White)	171 (85.9%)
Systolic BP/Diastolic BP [Mean]	126 / 79
UPCR (g/gram) [Mean]	1.6
eGFR CKD-EPI (mL/min/1.73 m <sup>2</sup> ) [Mean]	58

### Base inclusion criteria:

- Biopsy proven IgAN; >1 gram of proteinuria; >35 eGFR <90 ml/min, 360 patients, including 200 from Part A
- Patients were required to have well-controlled blood pressure of <140/90 mmHg to enter into the study, to ensure no BP confounding effects on proteinuria reduction
- No immunosuppressive drugs were permitted during the study; changes to anti-hypertensive medications were discouraged

### Part A Data:

As reported by Kidney International, NeflgArd is the first phase 3 IgA nephropathy trial to show clinically important improvements in UPCR and eGFR.

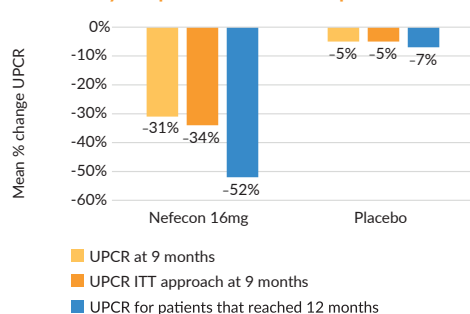
After 9 months, with all patients being maintained on optimized and stable RAS blockade (physicians' choice), those who received Nefecon achieved a 27% reduction in UPCR compared with placebo ( $P = 0.0003$ ). The reductions from baseline values were 31% and 5% in the Nefecon and placebo groups, respectively.

These results were highly consistent among all prespecified groups, including analyses stratified by baseline UPCR, eGFR, and 24-hour proteinuria.

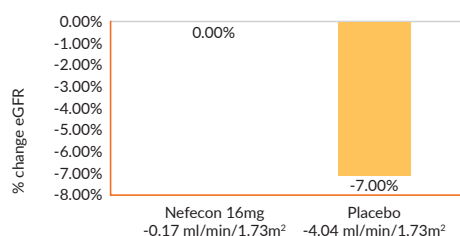
Furthermore, reduction in proteinuria continued off drug for all patients. In Nefecon-treated patients at 12 months, 3 months after treatment discontinuation, there was a 52% reduction compared to baseline with a 48% reduction in UPCR with Nefecon compared with optimized and stable RAS blockade ( $P < 0.0001$ ).

After 9 months of treatment, eGFR in Nefecon-treated patients decreased from baseline by 0.17 ml/min per 1.73 m<sup>2</sup> compared with a decrease of 4.04 ml/min per 1.73 m<sup>2</sup> in the placebo group. This translates to a statistically significant 3.87 ml/min per 1.73 m<sup>2</sup> eGFR treatment benefit ( $P = 0.0014$ ) for Nefecon, which was maintained at 12 months.

### Primary endpoint: Reduction in proteinuria



### Secondary endpoint: Stabilization of eGFR



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



## The NeflgArd Trial: Full Readout

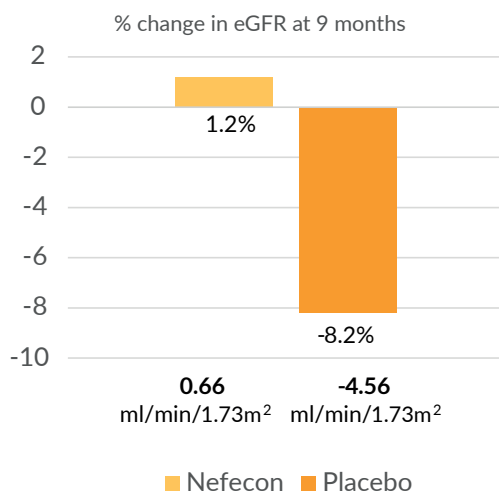
Calliditas reported topline results in March 2023. The analysis included 364 patients diagnosed with primary IgAN and who were on a background of optimized and stable renin-angiotensin system (RAS) inhibitor therapy. The patients were randomized in a 1:1 ratio into one of two treatment groups – Nefecon 16 mg/day orally or placebo – and treated for nine months daily, and then monitored for 15 months off-drug.

### eGFR Data

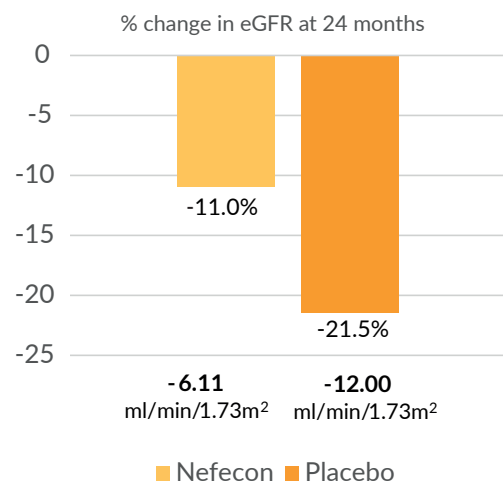
The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in eGFR over the

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.

### Impact on eGFR at 9 months



### Impact on eGFR at 24 months





#### UPCR (Proteinuria) Data:

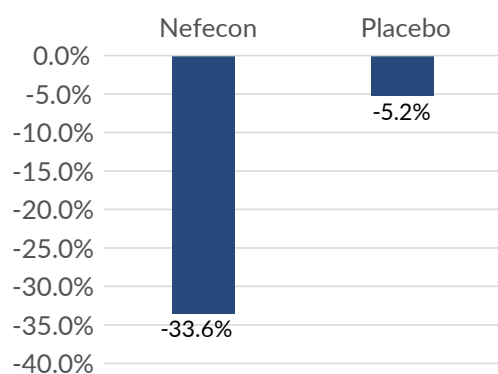
UPCR reductions observed were durable, reflecting a long lasting treatment effect during the 15 month follow-up period off treatment.

#### Safety Profile:

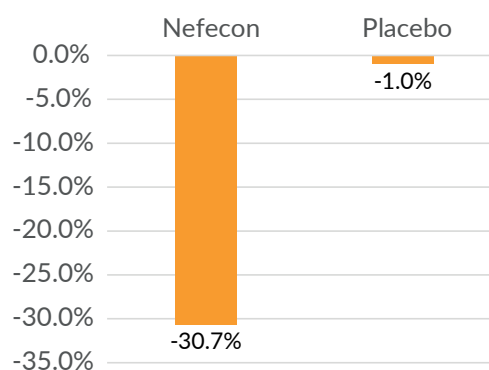
The results indicate that Nefecon was generally well-tolerated and the safety profile was consistent with that observed in Part A of the trial.

The NeflgArd trial is expected to conclude in the third quarter of 2023 when the final 29 patients in China (not required for global submission purposes) have completed nine months of treatment and 15 months of observation.

#### Proteinuria (UPCR) at 9 months



#### Proteinuria (UPCR) at 24 months



# Our Commercial Partnerships

## Europe

Nefecon was granted conditional marketing authorization (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)  $\geq 1.5$  g/gram, becoming the first and only approved treatment for IgAN in Europe.

Kinpeygo will be marketed in the European Economic Area (EEA), Switzerland and the UK exclusively by STADA Arzneimittel AG with whom Calliditas entered into a license agreement in July 2021 to register and commercialize Kinpeygo in Europe. Under the terms of the agreement, Calliditas received an initial upfront payment of EUR 20 million upon signing and has received additional EUR 12.5 million for conditional marketing authorization and commercialization milestones. Calliditas is further entitled to up to an additional EUR 65 million in future payments linked to pre-defined regulatory and commercialization milestones. STADA will also pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

Following the transfer of the conditional marketing authorisation (MA), STADA launched Kinpeygo in Germany in September 2022, with additional European countries to follow. In Germany it is estimated that 3.1 people per 100,000 develop IgAN each year.



A world map with a light blue background. The landmasses are shown in a light gray color. China and Japan are highlighted in a bright orange color. A thin orange line starts from the top right of the page, curves down and left, passing through the text box for Greater China, then curves down and right, passing through the text box for Japan, and finally curves down and left towards the bottom of the page.

## Greater China

Calliditas entered into a license agreement to develop and commercialize Nefecon for IgAN in China and Singapore with Everest Medicines (HKEX 1952.HK) in 2019. Calliditas received an initial upfront payment of USD 15 million upon signing, and has received USD 13 million in additional milestones, and may receive future payments linked to regulatory and commercialization milestones up to an additional USD 95 million, plus royalties. In March 2022, this agreement was expanded to include South Korea, resulting in an upfront payment of USD 3 million to Calliditas as well as additional future payments and royalties related to future potential approvals and commercialization of Nefecon in South Korea.

Everest Medicine's New Drug Application (NDA) for Nefecon was accepted by the Chinese regulatory authority National Medical Products Administration (NMPA) in November 2022, and in December the Center for Drug Evaluation (CDE) of the NMPA recommended Priority Review. A regulatory decision is expected in 2H 2023.

## Japan

At the end of 2022, Calliditas entered into a partnership to commercialize Nefecon in Japan with Viatriis Pharmaceuticals Japan, a subsidiary of Viatriis Inc. (Nasdaq: VTRS). Viatriis is a global healthcare company which, while headquartered in the United States, has a presence in over 165 countries and territories, and also operates approximately 40 manufacturing facilities. Calliditas received an initial upfront payment of USD 20 million upon signing and is eligible to receive up to an additional USD 80 million in pre-defined development and commercialization milestones. Viatriis will also pay mid-teens percentage royalties on net sales.



# A NOX Inhibitor Platform

Calliditas' pipeline contains development programs based on a first in class, novel NOX inhibitor platform that includes lead compound setanaxib, the first NOX inhibitor to reach the clinical trial stage.

Calliditas is presently conducting trials with setanaxib in Primary Biliary Cholangitis (PBC) and in Squamous Cell Carcinoma of the Head & Neck (SCCHN).

## NOX Enzymes

NOX enzyme inhibitors are a set of promising novel experimental drugs in a new therapeutic class, recognised 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 and sole function. They are transmembrane enzymes that transfer electrons from NADPH in the cytoplasm across the cell membrane, which results in the formation of ROS. There are seven NOX members, each differing in composition, modes of activation and the ROS type they produce. NOX1, NOX2, NOX3, and NOX5 transfer electrons from NADPH to molecular oxygen, producing superoxide anion ( $O_2^-$ ). NOX4, DUOX1 and DUOX2, meanwhile, mainly produce hydrogen peroxide ( $H_2O_2$ ).



At appropriate concentrations, ROS have essential functions in cellular signaling processes, helping to regulate cell proliferation, differentiation and migration, as well as modulating the innate immune response, inflammation and fibrosis. However, disruption of the redox homeostasis has been implicated in multiple disease pathways. Oxidative stress, caused by an excess of ROS, is a likely common underlying mechanism for many disorders, including cardiovascular diseases, neurodegenerative disorders, and cancer disease pathways. Setanaxib inhibits NOX1 and NOX4, enzymes which are implicated in inflammation and fibrosis pathways.

## Clinical Development of Setanaxib

### Setanaxib in Primary Biliary Cholangitis (PBC)

#### PBC Disease Background

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. The origin of this autoimmune response is believed to be the production of cytotoxic T-cells and B-cell derived autoantibodies directed towards the epithelial cells of the small bile ducts in the liver, resulting in inflammation and damage to the duct cells and eventually in the destruction of the bile ducts. This destruction results in the accumulation of increased bile acid in the liver, a condition known as cholestasis, to levels that are toxic to the liver cells, which in turn results in the destruction of liver cells and formation of fibrous tissue.

Early symptoms of PBC include fatigue, itchy skin, and dry eyes and mouth. As the disease progresses, symptoms range from pain in the upper right abdomen and musculoskeletal pain to oedema, jaundice, osteoporosis, elevated cholesterol and hypothyroidism. If untreated, active liver tissue is destroyed and replaced by fibrous tissue, leading to liver failure and the need for a liver transplant. Individuals with PBC are also at a greater risk than the general population of developing hepatocellular carcinoma.

#### Current Approved Treatments for PBC

Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, known as Ocaliva, are the only FDA- and EMA-approved treatments for PBC. These drugs are primarily anti-cholestatic. UDCA is a bile acid analogue which is incorporated into the bile acid pool, replacing other more toxic bile acids and reducing inflammation and cholestasis. However, while it remains the first-line

therapy for patients with PBC, only 40% to 60% of patients respond adequately to UDCA. Ocaliva, a modified bile acid, is a farnesoid X receptor (FXR) agonist which modulates bile acid homeostasis, decreasing bile acid synthesis and increasing its clearance. 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 Trial

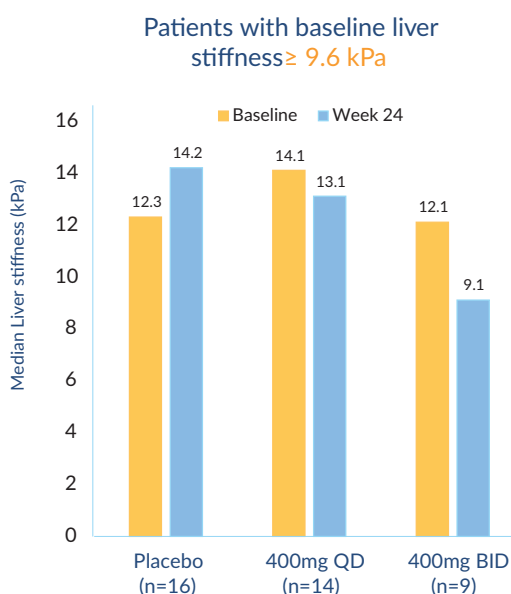
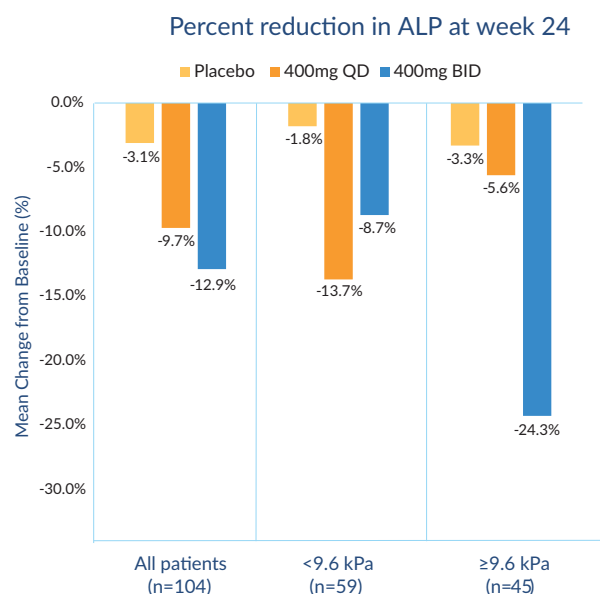
Setanaxib previously has been investigated in a 24 week Phase 2 trial with 111 patients and has received orphan drug designation for the treatment of PBC in the United States and Europe. Although the study did not meet its primary endpoint, it met key secondary endpoints related to change in alkaline phosphatase (ALP), liver stiffness and important quality of life metrics.

Setanaxib 400mg BID achieved significant reduction in ALP of 12% vs placebo over the 24-week treatment period ( $p < 0.001$ ).

Furthermore, in a pre-defined patient population with an estimated liver fibrosis stage of F3 or higher (defined as liver stiffness of  $\geq 9.6$  kPa), setanaxib had a more pronounced effect on ALP reduction and fibrosis.

Patients with elevated liver stiffness are at greater risk of disease progression. In patients with a liver stiffness score of  $\geq 9.6$  kPa, setanaxib 400mg BID achieved a 24% reduction in ALP over the 24-week treatment period, and a 22% reduction in liver stiffness as compared to a 4% increase for placebo ( $p = 0.038$ ).

Furthermore, there was a statistically significant impact on fatigue, a very common and frequently disabling symptom of PBC which is not currently addressed by existing therapies, as well as demonstrated positive effects on emotional and social aspects of the disease. Setanaxib has also demonstrated a favorable safety profile in a Phase 1 clinical study in healthy subjects, which evaluated the safety and pharmacokinetics of the drug at doses up to 800 mg twice daily.



## PIPELINE

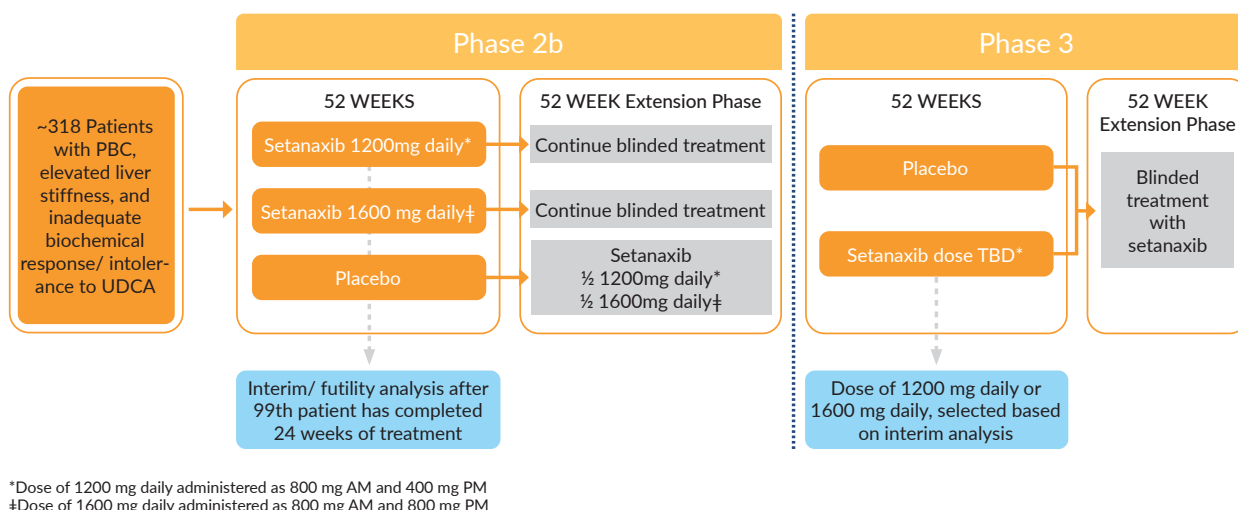
### Phase 2b/3 TRANSFORM Trial

Calliditas has initiated a pivotal 52-week, randomized, placebo-controlled, double-blind, trial with an adaptive Phase 2b/3 design.

Setanaxib will be administered to approximately 318 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to UDCA in a global trial conducted at up to 150 investigational centres.

The primary endpoint is ALP reduction, with key secondary endpoints including change in liver stiffness, and effect on pruritus (itching) and fatigue. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in H1 2024, subject to recruitment rate.

In August 2021, Calliditas received FDA Fast Track Designation for setanaxib in PBC.



### Setanaxib in Head and Neck Cancer

Calliditas is also initiating a Phase 2 clinical trial to evaluate setanaxib in head and neck cancer. The response to immuno-oncology therapies can be affected by the tumour microenvironment, in particular by the numbers of tumour-infiltrating lymphocytes (TILs) and cancer-associated fibroblasts (CAFs) in the tumour. A relationship between CAFs and prognosis in Squamous Cell Carcinoma of the Head & Neck (SCCHN) has been established.

NOX4 is highly over-expressed in CAFs and drives myofibroblastic activation within tumours, shielding them from CD8+ TILs. Targeting CAFs with setanaxib could improve patients' responses to immunotherapies, and function as an adjunct therapy. There is increasing

use of pembrolizumab as 1st line monotherapy in patients with relapsed or metastatic SCCHN, although response rates are low (ORR approx. 20%).

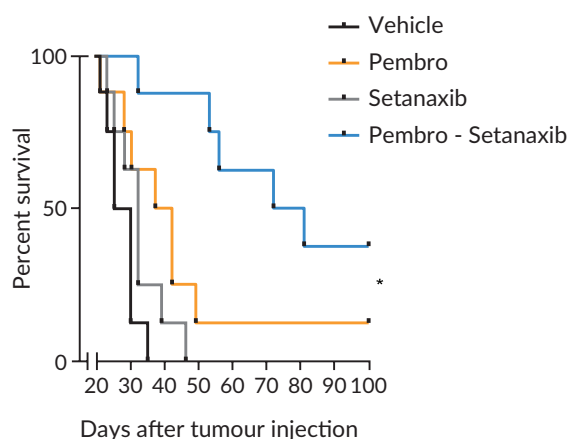
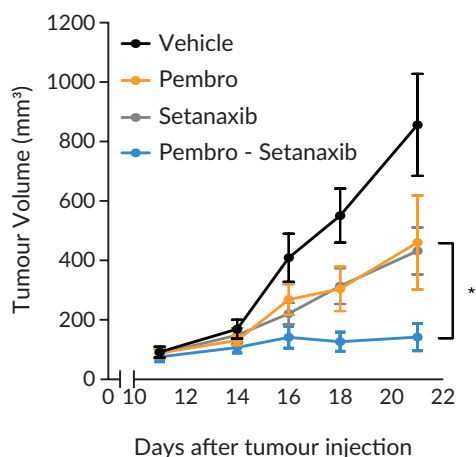
Setanaxib has shown promising preclinical data in mice, reversing CAF differentiation and overcoming CD8-cell exclusion in vivo.

This research paper, '[NOX4 Inhibition Potentiates Immunotherapy by Overcoming Cancer-Associated Fibroblast-Mediated CD8 T-cell Exclusion from Tumors](#)', was one of the most highly cited Cancer Research articles in 2020 and 2021 and was featured at the American Association for Cancer Research (AACR) Annual Meeting 2022.



Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:

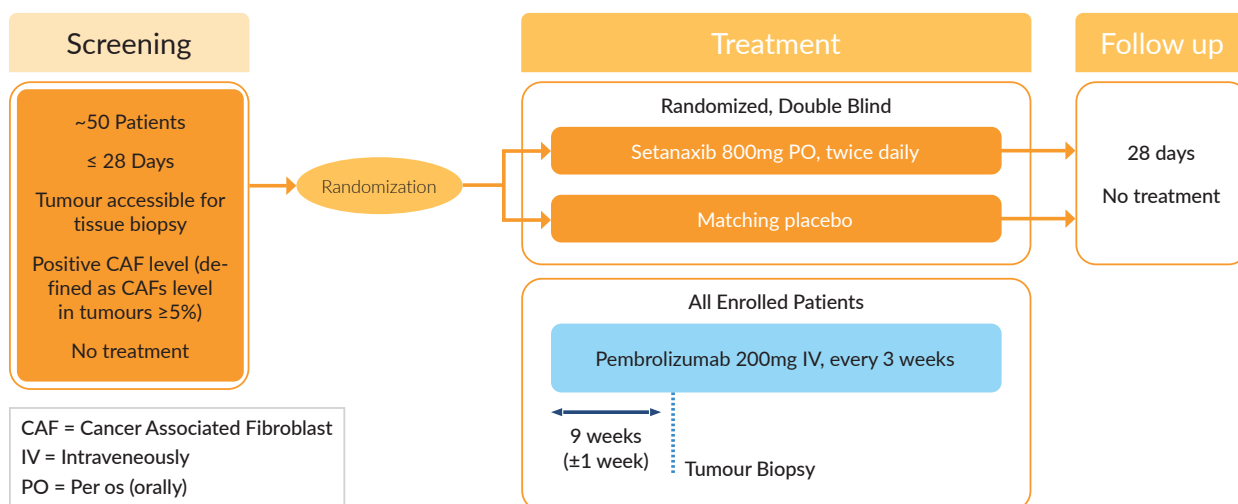
- Improved penetration of TILs into the centre of the tumour
- Slowing of tumour growth
- Improved survival



Calliditas is conducting a double-blind, randomized, placebo-controlled, proof-of-concept Phase 2 study, which will investigate the effect of setanaxib 800mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks, in approximately 50 patients with relapsed or metastatic SCCHN and tumors with moderate or high levels of CAFs. A tumor biopsy will be taken prior to randomization and again after

approximately 9 weeks of treatment. Treatment will continue until unacceptable toxicity or disease progression, in keeping with standard practice for oncology trials.

An interim analysis is targeted for mid 2023, subject to recruitment rate, and final data read out is expected in 2024.





## Interview with Professor Gareth Thomas

Gareth Thomas is Professor of Experimental Pathology at the University of Southampton, UK. As a clinical pathologist and tumor biologist, Professor Thomas's research is focused on how fibroblasts affect cancer progression, characterizing the phenotypes and functions of different fibroblast subpopulations and investigating how fibroblasts interact with immune cells to suppress anti-tumor immunity. The research has a strong translational component aiming to develop new therapies that target fibroblasts to overcome immunotherapy resistance.

### **What are cancer-associated fibroblasts (CAFs)?**

Cancer-associated fibroblasts (CAFs) are a type of normal cell that becomes hijacked by cancers. Fibroblasts are healthy cells that normally maintain the structure of tissues, but they are corrupted by cancer cells to enable tumors to develop and progress.


### **How do CAFs affect outcomes in patients with solid tumours?**

The presence of high levels of CAFs usually means that the cancer will behave aggressively, whatever the cancer type, and we have shown this in several large patient survival studies. Most types of solid tumors

contain a CAF-rich subgroup - in head & neck cancer around 50% of patients have tumors with high or moderate levels of CAFs, and it is even higher in some tumor types, including oesophageal, colorectal and pancreatic cancers, so a significant number of cancer patients have this feature.

### **Why are CAFs important to patient responses to treatments like checkpoint inhibitors?**

CAFs have many tumor-promoting functions, but one of their major features is that they protect tumors from immune attack, and this is important in the context of immunotherapy. Immunotherapy treatment harnesses



» Inhibiting NOX4 using setanaxib prevents CAF formation and improves immunotherapy response in mouse cancer models. This was a very exciting finding for us - setanaxib had been developed to treat organ fibrosis; its potential use for cancer therapy had not been considered, but could be considerable. «

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the power of the body's own immune system to fight cancer. Its success depends on our own 'killer' T-cells penetrating into a tumor to combat malignant cells. However, most patients fail to respond, often because the T-cells are blocked at the edge of the tumor. We found that CAFs play a major role in this process by forming a protective shield around the tumor and preventing T-cells from accessing tumors, and this produces resistance to checkpoint inhibitors.

#### **What effects does setanaxib have on CAFs?**

We found that CAF activation is regulated and maintained by the enzyme NOX4. Inhibiting NOX4 using setanaxib prevents CAF formation and improves immunotherapy response in mouse cancer models. This was a very exciting finding for us - setanaxib had been developed to treat organ fibrosis; its potential use for cancer therapy had not been considered, but could be considerable.

#### **What does this mean for patients?**

Immunotherapy for cancer has been a very exciting development, but still doesn't work in most patients. Our results suggest that in many cases, treatment resistance is caused by CAFs, and we think this could potentially be overcome by targeting NOX4 with setanaxib, and that this has the potential to hugely improve immunotherapy response rates in patients with cancers that contain a lot of CAFs.

#### **Why head & neck cancer?**

Clinically I work as a head & neck pathologist, and my lab has always studied the biology of head & neck cancer. It was the analysis of tumors from patients with head & neck cancer that revealed the association between high CAF levels and poor patient survival, and suggesting that CAFs may be a potential therapeutic target.

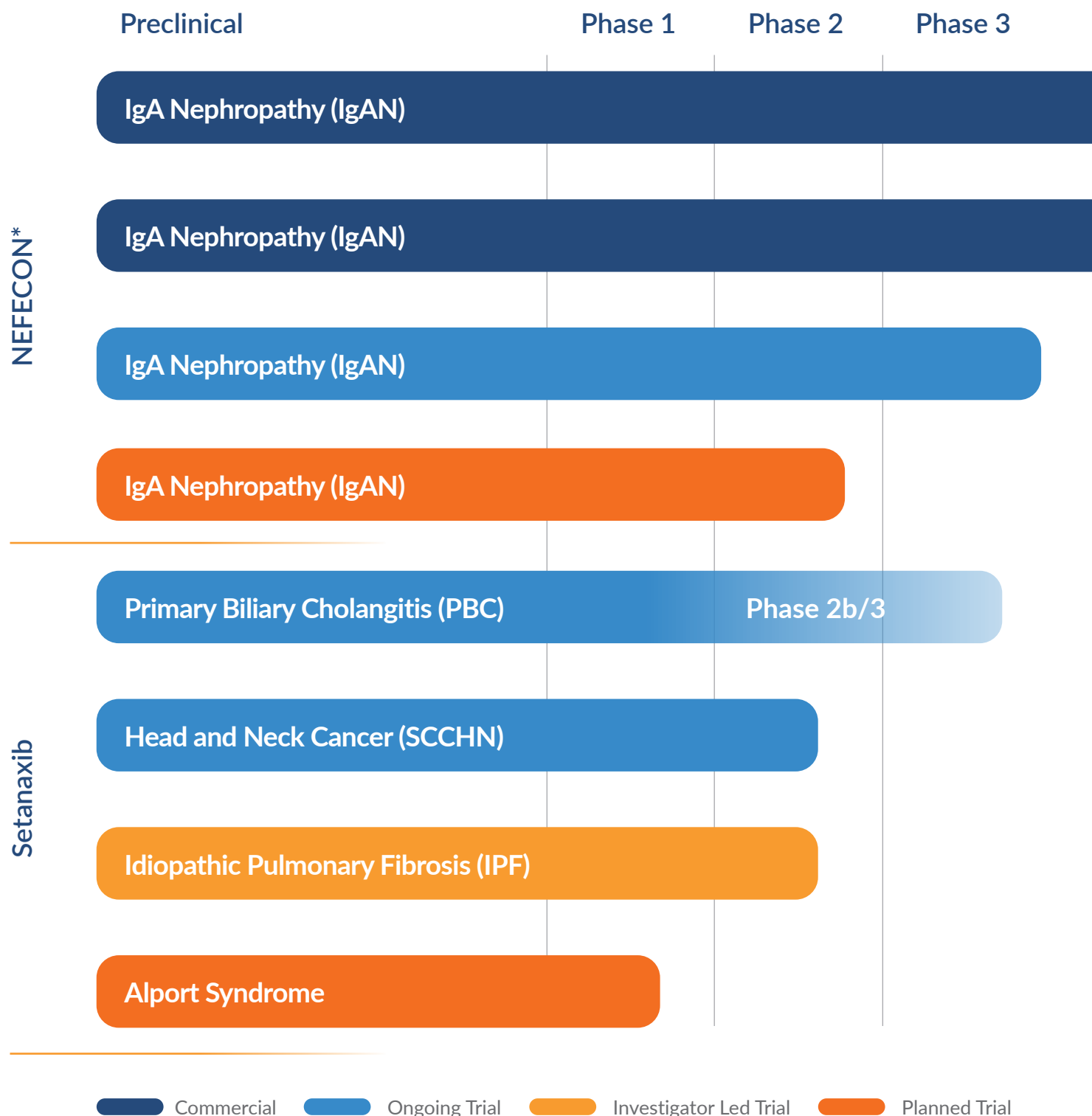
Head & neck cancer is actually pretty common (it is the sixth most common cancer worldwide with nearly a million cases a year). Treatment of SCCHN is difficult and expensive and over half of patients' tumors recur or spread. New treatments are needed, but checkpoint immunotherapy works relatively poorly in head & neck cancer compared with other tumor types (around 15% of patients respond). Our hope is that that combining immunotherapy with setanaxib will significantly improve this response rate.

#### **Which other cancers could be addressed by setanaxib – which other solid tumours have an association with CAFs?**

Most solid cancers have a CAF-rich subgroup, including very common cancers such as lung, colon and breast cancers, so there is great potential for CAF-targeting to improve immunotherapy response rates.



# Our Pipeline



\* Approved in the United States under accelerated approval, under the brand name TARPEYO® (budesonide) delayed release capsules to reduce the levels of protein in the urine (proteinuria) in adults with primary IgA nephropathy who are at high risk of rapid disease progression, generally urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/g and granted conditional marketing authorization by the European Commission, under the brand name Kinpeygo® for the treatment of primary IgA nephropathy in adults at risk of rapid disease progression with a (UPCR)  $\geq 1.5$  g/g.

Marketed	Rights	Commercial region	Upcoming milestones
 <b>TARPEYO™</b> (budesonide) delayed release capsules • 4 mg	 <b>calliditas</b> THERAPEUTICS	United States	File for regulatory approval in the US – around July 2023
 <b>KINPEYGO 4 mg</b> Modified-release hard capsules budesonide	 <b>STADA</b>	European Economic Area, UK, Switzerland	Support STADA EMA filing in 2023
	 <b>EVEREST MEDICINES</b>	China, HK, Macau, Taiwan, Singapore, South Korea	NDA accepted and FTD received in China. Decision expected in 2H 2023
	 <b>VIATRIS™</b>	Japan	
	 <b>calliditas</b> THERAPEUTICS	Global	Interim Analysis: 1H 2024 (subject to recruitment)
	 <b>calliditas</b> THERAPEUTICS	Global	Interim Data Readout: Mid 2023 (subject to recruitment)
	 <b>calliditas</b> THERAPEUTICS	Global	
	 <b>calliditas</b> THERAPEUTICS	Global	Trial launch planned for Q2 2023



## Environmental, Social, and Corporate Governance

Our ultimate goal and our most significant contribution towards a more sustainable society at Calliditas is our work to provide medication to patients with high unmet medical needs. As we work to achieve this, we are committed to acting ethically and responsibly in every area of our business, ensuring we maintain the highest standards of business ethics and uphold the safety and quality of our products and workplace.

Calliditas works within a highly regulated industry in which responsible business practice is paramount, and we are fully committed to always being in strict compliance with all relevant regulations and to making sure that ethical practices underpin all of our business operations. Through a clear sustainability agenda that permeates the entire company, we will contribute to a more sustainable world.

### **Sustainability has always been important to Calliditas.**

This year, we appointed a Sustainability Manager and instituted an Environmental, Social and Corporate Governance (ESG) Committee, which includes a cross-section of employees from across the company's three office bases (Stockholm, New York City, and Geneva). This group has presented both to management and to the broader company at our annual Strategy Day, and has provided input on the company's policies and strategy.

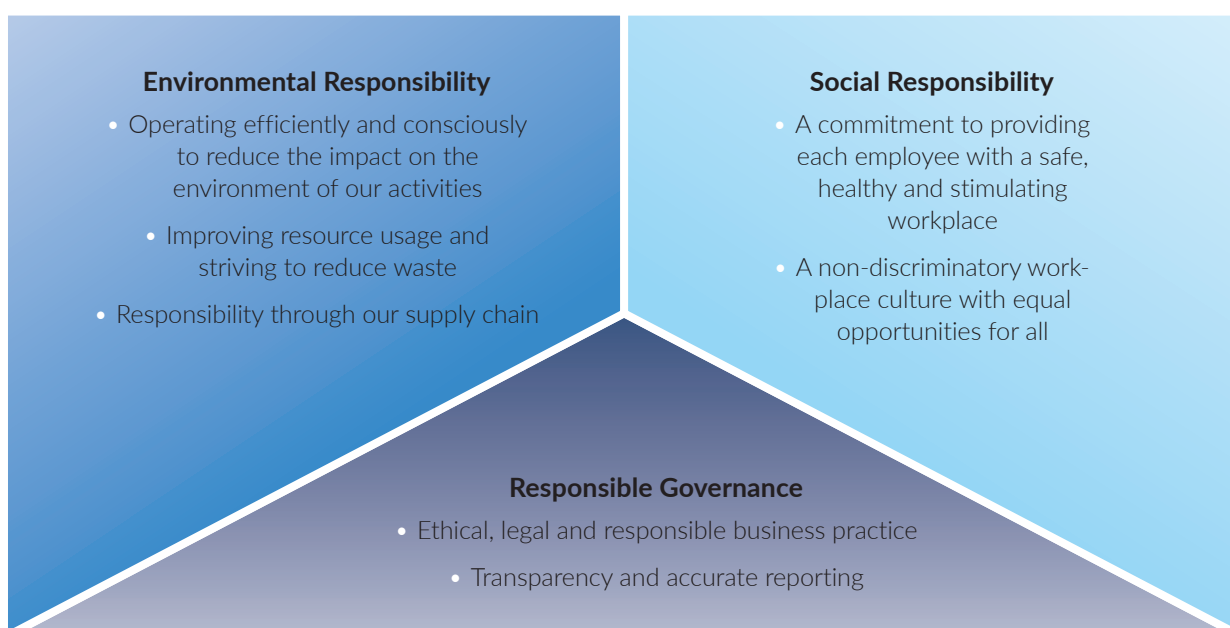
The group carried out an internal ESG analysis of our current processes and policies to identify important sustainability topics, and have outlined Calliditas' sustainability agenda for the coming year.

In 2022 we also welcomed an outside speaker working with sustainability and communications to present to the entire company on the importance and value of ESG, encouraging every Calliditas member to consider how the company should make strides in its ESG policy moving forwards. Moving forward, an overview of Calliditas' ESG strategy, plans and activities will be integrated in the introduction training for all new hires, who will be required to attend an introductory ESG session conducted by our Sustainability Manager. We are committed to ensuring that every Calliditas team member views good ESG practice as an integral part of how we go about our work, and we always encourage input from all our employees on how we can do better.



## A Responsible and Sustainable Business

It is of paramount importance to Calliditas to be a responsible company whose operations are sustainable and reflect the high standard to which we hold ourselves. We take a three-pronged approach to ensure that all the work we carry out reflects this commitment:



## Responsible Governance

A commitment to good business practice underpins all of Calliditas' operations. We have an ethical, value-driven culture based on dialogue and respect and always seek to empower our employees to uphold the company values and to address issues swiftly and transparently. We have a whistle-blower system in place to ensure that every employee can make their voice heard, with the option of anonymity and with a guarantee that there will be no threat of retaliation, and we urge our employees to be alert to and report any suspected business ethics violations or unethical conduct.

Our Code of Business Conduct and Ethics is the foundation of our business and outlines the requirements expected of all Calliditas employees, who are obligated to deal ethically and lawfully with the company's customers, suppliers, competitors, and fellow employees in all business dealings. The Code contains policies covering fraud, bribery, corruption, and money laundering, and also outlines our commitment to uphold the accuracy of our records and of any financial disclosures

or communications to the market. As a public company listed both in Sweden and on the NASDAQ Global Select Market, we take seriously our responsibility to provide our shareholders and the public with complete and accurate information about our financial condition and our operations. Our Code also contains policies related to the prevention of anticompetitive behavior and conflicts of interest, as well as ethical practice in our research and development work. It was updated in 2022 and all employees were required to read and reaffirm their compliance with and understanding of the Code.

This year, Calliditas transitioned from a clinical stage to a commercial stage biotech company, which requires careful compliance with a new set of regulations regarding our sales and marketing efforts as we commercialize TARPEYO® (budesonide) delayed release capsules in the United States. We strictly follow laws and regulations at the federal and state level in all our business activities in the US, including in our interactions with government authorities, healthcare professionals and organizations, and patients. Every Rare

Disease Account Manager receives specific and mandatory training which covers laws and regulations related to pharmaceutical sales and interactions with physicians, and affirms what constitutes ethical behavior. The training content is renewed when needed and conducted at minimum on a yearly basis. We are also stringent in ensuring that our marketing and promotional efforts strictly meet all FDA regulations and legal requirements. We are guided by both in-house and outside legal counsel, who review all material regarding TARPEYO before it is made available to the public.

As a company with a largely outsourced supply chain, we are also mindful of the social and ethical impact that we may have through our suppliers and are thus careful and rigorous in our selection process. Calliditas' direct suppliers are reputable companies located in countries with strong environmental, health, safety and labor legislation. They were chosen through a selection process thoroughly evaluating quality standards, compliance with laws and regulations and all relevant permits. We hold ourselves to higher quality standards than those required by law and will always hold any partners to the same rigorous standards.

### Environmental Responsibility

Calliditas understands the importance of acting in an environmentally conscious way, and we continuously strive to minimize the environmental impact of our operations and that of our suppliers.

It is important for us to strive to reduce our direct environmental impact from our operations in Sweden, the US, and France and Switzerland. Our offices in New York and Stockholm are equipped with energy saving features like smart outlets, energy efficient lightbulbs and motion activated lights in common areas and bathrooms. While business travel is important to our company, with employees based across Europe and the United States, we are always mindful of our environmental impact, and have positioned our offices in areas with excellent transport links to encourage employees to utilize public transport, and in our US-based offices we have implemented a commuter benefit that allows employees to save on a pre-tax basis on their transit expenses for work. We also sort our waste and recycle as much as possible at all of our offices, and offer kitchens with plentiful supplies of glassware and tableware to encourage reusable items and to avoid using plastic.

Our pre-clinical drug development laboratories in Archamps and Plan-les-Ouates comply with all French and Swiss regulations and bioethics policies concerning clinical research. A careful regard for bioethics is embedded in all of our procedures, processes and decision-making in our clinical research. Chemical handling and waste disposal are highly controlled, and Calliditas is committed to continuing to improve the safety standards in our labs.

We also encourage all our suppliers to align with appropriate standards to minimize environmental impact, and ensure that environmental considerations are embedded in our supplier selection process. We remain accountable for understanding the environmental impact of our supply chain and ensuring it is sustainable, and will continue to work with our suppliers to keep environmental considerations in mind as we continue in our partnerships.

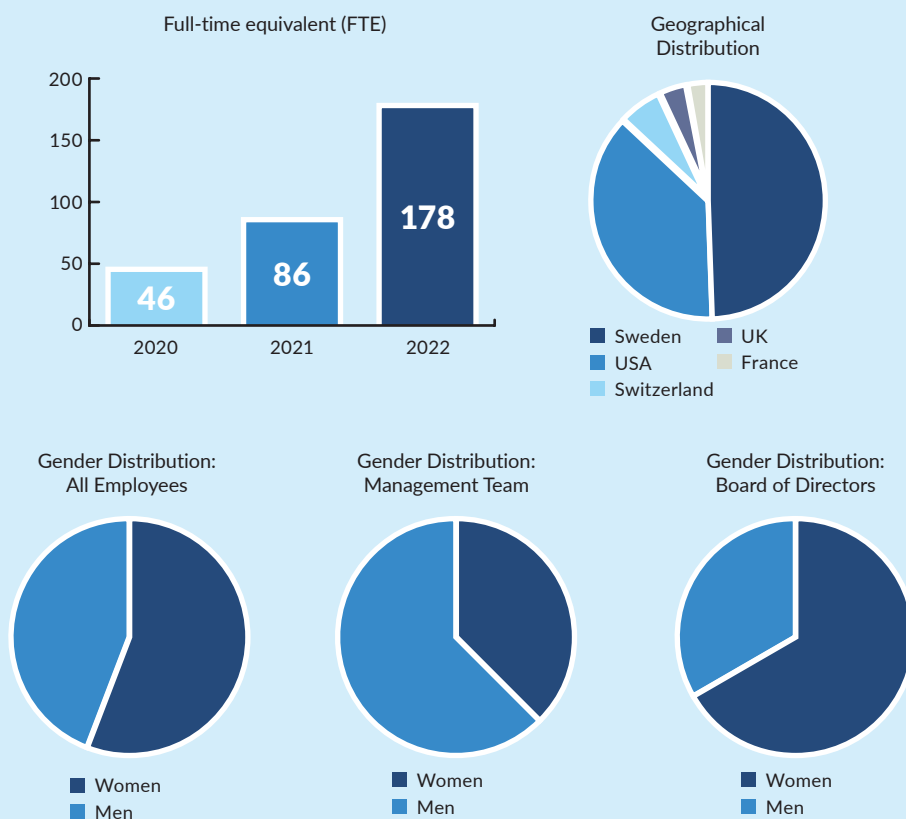
### Social Responsibility

The success and strength of Calliditas Therapeutics depends on our employees. We are committed to providing a safe, productive and inclusive working environment for every Calliditas team member as we work together to earn the trust and respect of our shareholders and patients.

We look to promote ethical behavior through our Code of Business Conduct and Ethics and our Employee Handbook, which are embedded in our daily operations and which reflect our core values and culture as a company. We view our employees as essential to helping us maintain a work environment that meets a high standard, and every member of the Calliditas team is encouraged to seek guidance and report any suspected violations of this code. We believe strongly that diversity, inclusivity and respect are key to ensuring the success of our business, and are proud to have a diverse workforce in terms of gender, nationality and age.

We are also conscious of providing comfortable as well as safe working spaces, and thus ensure that our offices are supplied with abundant natural light and a variety of fit-for-purpose workspaces including adjustable, ergonomic workstations. We strive to maintain healthy employees and a healthy work environment in all of our offices and encourage input from every employee as we continuously look to improve.

## Employee demographics



We also strongly believe in cultivating engagement across the different teams in our company and encouraging open communication. Calliditas now has five offices across four different countries; while we are headquartered in Stockholm, our commercial team is based in New York City and New Jersey in the USA and our pre-clinical research is carried out in France and Switzerland. It is important to us to continue to maintain our company culture even as our team continues to grow, and to ensure that all employees, no matter where they are based, feel that they are a valued part of Calliditas and feel connected to their co-workers across the world. We host an annual Strategy Day corporate strategy retreat where all our employees come together to learn about the work being carried out by each department and to provide input for management on our corporate strategy for the forthcoming year.

All employees have access to the management team and receive regular feedback, including at yearly employee review sessions. The senior leadership team holds quarterly town hall meetings as a forum to share details about the progress we have made and our plans for the future, where we encourage an open dialogue from all employees about the direction and objectives of the company. We are always seeking feedback and input to ensure that every Calliditas team member has the resources and support they need to be successful in their role and to contribute to the company's overall mission.

We are proud to offer a safe, inclusive, and stimulating workplace with equal development opportunities for all, and look forward to continuing to support our employees and maintain our culture as we grow and develop as a company.

# The Share

## Share Performance

### Nasdaq Stockholm

Calliditas was listed on Nasdaq Stockholm Mid-Cap, on June 29, 2018. As of December 31, 2022, the closing rate was SEK 92.5 yielding a decrease of 18% in 2022. During the same period, the OMXSPI decreased by 25%. The highest closing rate during the year was SEK 114.8 and the lowest SEK 64.5.

### 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, 2022, the closing price was USD 17.0, which gave a decrease of 31% during the period January-December 2022. Nasdaq Composite decreased by 33% during the same period. The highest closing price during the year was USD 25.5 and the lowest was USD 11.5.

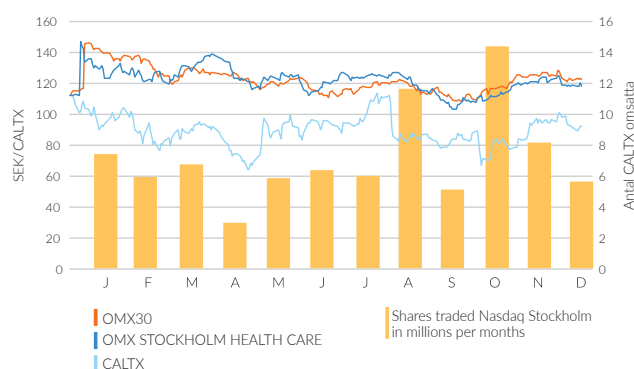
## Turnover

### Nasdaq Stockholm

A total of 79.4 million shares were traded during 2022, with a total value of SEK 7,010 million. On average, 313,866 shares were traded each day.

### Nasdaq USA

During the period January-December 2022, a total of 3.0 million ADSs were traded. On average, 12,151 ADSs were traded per day.



## Shareholders

As of December 31, 2022, Calliditas had 18,585 shareholders. The 15 largest shareholders controlled 53.0% of the capital at year-end. The three largest shareholders, excluding Calliditas Therapeutics, were BVF Partners, Linc AB and Stiftelsen Industrifonden. Foreign shareholders accounted for 32.6% of capital.

## Share Capital

As of December 31, 2022, share capital in Calliditas amounted to SEK 2,383 thousand. The number of shares was 59,572,587 corresponding to a quotient value per share of SEK 0.04. In accordance with the Articles of Association, share capital must be not less than SEK 710 thousand and not more than SEK 2,840 thousand, distributed between at least 17,750,000 shares and not exceed 71,000,000 shares. The proportion of shares available for trade (free float) amounted approximately to 69% at year-end.

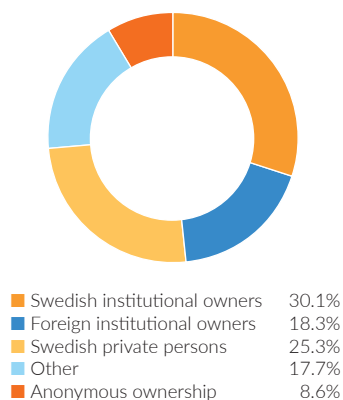
## Investor Relations Work

Investor Relations work in 2022 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.

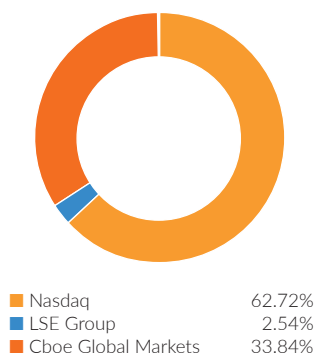
## Analysts

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

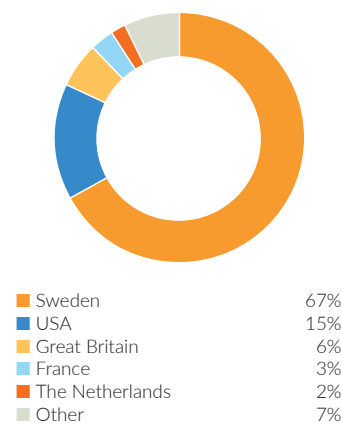
## Ownership per category, %



## Trading platforms, %



## Ownership per country, %



Source: Monitor by Modular Finance AB and Fidessa.

Source: Euroclear



## The 15 largest shareholders as of December 31, 2022

Shareholders	Total number of shares	Holding, %	Votes, %
BVF Partners LP	6,260,311	10.5%	10.5%
Linc AB	5,962,312	10.0%	10.0%
Calliditas Therapeutics AB	5,908,018	9.9%	9.9%
Stiftelsen Industrifonden	3,830,440	6.4%	6.4%
Fjärde AP-fonden	2,663,000	4.5%	4.5%
Avanza Pension	2,079,201	3.5%	3.5%
Handelsbanken Fonder	2,069,220	3.5%	3.5%
Unionen	2,058,342	3.5%	3.5%
Polar Capital	1,500,000	2.5%	2.5%
Sofinnova Partners	1,408,078	2.4%	2.4%
Öhman Fonder	914,598	1.5%	1.5%
Renée Aguiar-Lucander	643,000	1.1%	1.1%
Nordnet Pensionsförsäkring	587,822	1.0%	1.0%
Atlant Fonder	540,000	0.9%	0.9%
Mikael Bender	527,069	0.9%	0.9%
<b>Top 15 largest shareholders</b>	<b>36,951,411</b>	<b>62.0%</b>	<b>62.0%</b>
Other shareholders	22,621,176	38.0%	38.0%
<b>Total share</b>	<b>59,572,587</b>	<b>100%</b>	<b>100%</b>

## CALTX share data 2022

Average daily turnover (SEK)	27,711,770
Average daily turnover rel. Mcap (%)	0.53%
Average daily shares traded	313,866
Number of shares traded	79,408,222
Average trades per day	1,722
Number of trades	435,783
Average value per trade (SEK)	16,088
High	118.0
Low	58.7
Volume-Weighted Average Price (VWAP)	88.3

## Size classes as of December 31, 2022

Size classes	No. of known shareholders	No. of shares	Holding, %	Votes, %	Proportion of known shareholders
1 - 100	9397	351,797	0.59%	0.59%	50.80%
101 - 200	2450	377,801	0.63%	0.63%	13.24%
201 - 500	3018	1,030,854	1.73%	1.73%	16.32%
501 - 1,000	1576	1,231,169	2.07%	2.07%	8.52%
1,001 - 2,000	953	1,440,196	2.42%	2.42%	5.15%
2,001 - 5,000	638	2,056,163	3.45%	3.45%	3.45%
5,001 - 10,000	252	1,834,202	3.08%	3.08%	1.36%
10,001 - 20,000	89	1,311,790	2.21%	2.21%	0.48%
20,001 - 50,000	72	2,274,714	3.83%	3.84%	0.39%
50,001 - 100,000	20	1,367,518	2.31%	2.32%	0.11%
100,001 - 200,000	10	1,471,450	2.47%	2.47%	0.05%
200,001 - 500,000	7	2,217,284	3.73%	3.79%	0.04%
500,001 - 1,000,000	6	3,724,530	6.25%	6.25%	0.03%
1,000,001 - 2,000,000	2	2,908,078	4.90%	5.14%	0.01%
2,000,001 - 5,000,000	5	12,700,203	21.32%	21.32%	0.03%
5,000,001 - 10,000,000	3	18,130,641	30.43%	30.43%	0.02%
Unknown	0	5,144,197	8.58%	8.24%	N/A
<b>Total</b>	<b>18,498</b>	<b>59,572,587</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

# 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 2022. All amounts are expressed in SEK millions unless otherwise stated.

## Multi-Year Summary, Group

	2022	2021	2020	2019	2018
Net sales (SEK in thousands)	802,879	229,347	874	184,829	-
Loss before income tax (SEK in thousands)	(409,417)	(513,373)	(436,151)	(32,501)	(132,049)
Total assets (SEK in thousands)	1,952,973	1,459,910	1,463,908	845,200	648,417
Average number of employees	86	56	23	14	10

## Multi-Year Summary, Parent Company

	2022	2021	2020	2019	2018
Net sales (SEK in thousands)	548,977	229,347	874	184,829	-
Loss before income tax (SEK in thousands)	(208,548)	(354,405)	(407,363)	(36,186)	(131,923)
Total assets (SEK in thousands)	2,173,639	1,528,439	1,318,525	838,249	651,633
Average number of employees	45	29	16	13	10

## 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.

Calliditas' lead product, developed under the name Nefecon, has been granted accelerated approval by the FDA under the trade name TARPEYO® and conditional marketing authorization by the European Commission under the trade name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, setanaxib. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on the Nasdaq Global Select Market (ticker: CALT).

In 2020, Calliditas made a positive reading of top line data from Part A of the NefIgArd study. The results were statistically significant and clinically relevant: proteinuria showed a 31% reduction compared to

baseline, a stronger effect than seen in the phase 2b study (27%). In addition, eGFR was stabilized in the treated patient population, which is ultimately the real treatment goal.

In 2021, Calliditas intensified preparations for commercialization in the United States, and in December 2021, the FDA granted an accelerated approval for Nefecon in the United States under the name TARPEYO (budesonide), for the treatment of adult patients with primary IgA nephritis (IgAN) at risk of rapid disease progression generally considered a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/g. Tarpeyo became the first treatment ever approved for the treatment of IgAN in the United States.

In January 2022, Calliditas announced the commercial availability and initial sales of TARPEYO in the United States and in July 2022, the European Commission (EC) granted conditional marketing authorization for Kinpeygo for the treatment of IgAN in adults at risk of rapid disease progression with a UPCR  $\geq 1.5$  g/gram. Kinpeygo became the first and only approved treatment for IgAN in Europe and Kinpeygo will be marketed in the European Economic Area (EEA), the UK and Switzerland exclusively by Calliditas' European commercial partner STADA Arzneimittel AG.

In December 2022, an exclusive license agreement was signed with Viatris Pharmaceuticals Japan Inc., a subsidiary of Viatris Inc, to register and commercialize Nefecon for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in Japan.

The Group's revenues of SEK 802.9 million in 2022 derives 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 372.2 million and milestones and royalties from our partnerships amounted to SEK 427.4 million for the year ended December 31, 2022.

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. and the Swedish subsidiary Nefecon AB, where there are no ongoing operations.

### **Significant Events During the Year**

#### **U.S TARPEYO commercial availability**

In January 2022, Calliditas announced the commercial availability and initial sales of TARPEYO (budesonide), the first FDA approved treatment for IgA nephropathy (IgAN), indicated for reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally considered a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$ g/g.

#### **First patient randomized in TRANSFORM**

In February 2022, the first patient was randomized in the company's phase 2b/3 TRANSFORM study in patients with primary biliary cholangitis (PBC).

#### **Expansion of the Everest license agreement to South Korea**

In March 2022, Calliditas expanded the licensing agreement with Everest Medicines to extend the territory covered to include South Korea. The extension resulted in an upfront payment of USD 3 million to Calliditas as well as additional payments and royalties related to future potential approvals and commercialization of Nefecon in South Korea.

#### **First patient randomized in the head and neck trial**

In May 2022, Calliditas announced that the first patient had been randomized in the Group's proof-of-concept Phase 2 study in patients with squamous cell carcinoma of the head and neck (SCCHN) with the NOX 1 and 4 inhibitor setanaxib.

#### **European approval of Kinpeygo**

In July 2022, European Commission (EC) granted conditional marketing authorization for Kinpeygo for the treatment of IgAN in adults at risk of rapid disease progression with a UPCR  $\geq 1.5$  g/gram and Kinpeygo will be marketed in the European Economic Area (EEA), the UK and Switzerland exclusively by Calliditas' European commercial partner STADA Arzneimittel AG.

#### **Publication of NeflgArd Part A data in Kidney International**

In October 2022, the successful results from Part A of the NeflgArd pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter study was published in Kidney International.

#### **NDA accepted in China**

In November 2022, Calliditas announced that its China partner Everest Medicine's New Drug Application for Nefecon was accepted by the Chinese regulatory authority National Medical Products Administration (NMPA).

#### **License agreement with Viatris for Japan**

In December 2022, Calliditas entered into an exclusive license agreement with Viatris Pharmaceuticals Japan Inc., a subsidiary of Viatris Inc, to register and commercialize Nefecon for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in Japan. Under the terms of the agreement, Calliditas received an initial upfront payment of USD 20 million upon signing and is entitled to up to an additional USD 80 million in pre-defined development and commercialization milestones. Viatris will also pay mid-teens percentage royalties on net sales.

### **Sales and Earnings**

Net sales amounted to SEK 802.9 million and SEK 229.3 million for the year ended December 31, 2022 and 2021, respectively. Net sales primarily originate from net sales of TARPEYO in the U.S. and milestones from our partnerships in Europe, China and Japan. Net sales from TARPEYO amounted to SEK 372.2 million and milestones and royalties from our partnerships amounted to SEK 427.4 million.

#### **Cost of Sales**

Cost of sales amounted to SEK 15.2 million for the year ended December 31, 2022. For the year ended December 31, 2021, no cost of sales was recognized.

## BOARD OF DIRECTORS' REPORT

### Research and development expenses

Research and development expenses amounted to SEK 414.7 million and SEK 357.5 million for the year ended December 31, 2022 and 2021, respectively. The increase of SEK 57.2 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 515.2 million and SEK 179.6 million for the year ended December 31, 2022 and 2021, respectively. The increase of SEK 335.6 million was primarily related to the costs for sales and marketing of TARPEYO in the U.S., including the costs for the sales force compared to the prior year, where no sales force existed.

### Administrative Expenses

Administrative expenses amounted to SEK 259.5 million and SEK 210.6 million for the year ended December 31, 2022 and 2021, respectively. The increase of SEK 48.9 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 20.2 million) and (SEK 6.1 million) for the year ended December 31, 2022 and 2021, respectively. The increase in other operating income/(expenses), net was primarily related to a more unfavorable exchange rate development on operating liabilities compared to the prior year.

### Financial Income/Expenses

Financial income amounted to SEK 50.2 million and SEK 20.3 million for the year ended December 31, 2022 and 2021, respectively and mainly pertains unrealized currency gains. Financial expenses amounted to SEK 37.7 million and SEK 9.3 million for the year ended December 31, 2022 and 2021, respectively and consist mainly of interest expense.

### Tax

Total income tax/(expense) amounted to (SEK 2.9 million) and SEK 3.8 million for the year ended December 31, 2022 and 2021, 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, 2022 and 2021, the Group had a net loss of SEK 412.3 million and SEK 509.5 million, respectively and the corresponding loss per share before and after dilution amounted to SEK 7.78 and SEK 9.84, respectively.

### Liquidity and Financial Position

Cash amounted to SEK 1,249.1 million and SEK 955.5 million as of December 31, 2022 and 2021, respectively. Shareholders' equity related to the shareholders of the Parent Company amounted to SEK 766.3 million and SEK 1,008.3 million as of December 31, 2022 and 2021, respectively.

### Cash Flow

Cash flow used in operating activities amounted to SEK 311.4 million and SEK 461.6 million for the year ended December 31, 2022 and 2021, respectively. The decrease was primarily explained by the increase in sales for TARPEYO in the U.S. and the outlicensing milestone revenue from Viatris, compared to the prior year.

Cash flow used in investing activities amounted to SEK 5.1 million and SEK 24.3 million for the year ended December 31, 2022 and 2021, respectively. The decrease was mainly derived from a EUR 1.5 million milestone payment for the Budenofalk license, which occurred in the corresponding period of the prior year.

Cash flow from financing activities amounted to SEK 576.0 million and SEK 435.2 million for the year ended December 31, 2022 and 2021, respectively. The increase was primarily due to the USD 25 million each draw down of tranche 2 and 3 of the Kreos loan facility in June and December 2022, compared to the prior year.

Net increase/(decrease) in cash amounted to SEK 259.5 million and (SEK 50.8 million) for the year ended December 31, 2022 and 2021, respectively.

### Personnel

The number of employees in the Group were 102 and 66 employees as of December 31, 2022 and 2021, respectively. The total number of full-time equivalent (FTE), including the consultants, were 178 and 86 as of December 31, 2022 and 2021, respectively. The average number of employees were 86 and 56 for the year ended December 31, 2022 and 2021, respectively of which 59% were women and 41% 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, ESOP 2020, ESOP 2021 and ESOP 2022. 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 2020 can take place at the earliest during the third quarter of 2023. 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. At the end of the year 3,952,166 options were allocated.

Calliditas also has three long-term incentive programs for board members of Calliditas, LTIP 2020, LTIP 2021 and LTIP 2022. Participants in the programs will be allocated performance-based share awards free of charge. The share awards in LTIP 2020 are subject to performance-based earnings based on the development of Calliditas's share price from the date of the Annual General Meeting 2020 through July 1, 2023. 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. In total, there were share awards outstanding corresponding to 94,878 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 59,572,587 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 2022, Calliditas had 18,585 (19,879) shareholders and the ten largest shareholders owned 48.3 (59.1) % of all outstanding shares, excluding shares held by Calliditas. As of December 31, 2022, 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 3,830,440 shares, respectively, corresponding to 10.5%, 10.0% and 6.4%, respectively, of the votes and capital.

For further information regarding the share, please see pages 34-35.

## Issuance and Repurchase of Treasury Shares and Warrants

For the year ended December 31, 2022, Calliditas resolved to carry out an issue of 5,908,018 C-shares at a subscription price of SEK 0.04 per share, which is equivalent to the quotient value, and to subsequently immediately repurchased the 5,908,018 newly issued C-shares for SEK 0.04 per share and subsequently was converted into ordinary shares in accordance with the company's articles of association and held as treasury shares at the year end. The purpose of the issue and repurchase is to secure future potential delivery of shares under the company's at-the-market program. The share issue has increased the share capital by SEK 0.2 million.

The subsidiary Nefecon AB holds 5,000,072 warrants pending any distribution to future participants in the Board LTIP 2020 and 2021 programs and ESOP 2020, 2021 and 2022 programs.

## 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 2023 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 2022, the board met 12 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 92-97.

### 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 solutions

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, which has been approved for marketing in the USA 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 2/3 study for the treatment of primary biliary cholangitis and the Phase 2 study for the treatment of head and neck cancer.

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 549.0 million and



SEK 229.3 million for the year ended December 31, 2022 and 2021, respectively. The increase was primarily derived from an outlicensing transaction to Viartis and sales of TARPEYO compared to the prior year. Operating loss amounted to SEK 215.4 million and SEK 355.7 million for the year ended December 31, 2022 and 2021, 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 887.5 million and SEK 552.9 million as of December 31, 2022 and 2021, respectively. The increase of SEK 334.6 million was primarily derived from intercompany transactions.

The Parent Company had cash of SEK 1,059.7 million and SEK 894.5 million as of December 31, 2022 and 2021, respectively.

### Outlook

Calliditas believes that its drug Nefecon has great market potential. The product has been approved under the brand name TARPEYO by the FDA in the USA which has granted an accelerated approval for TARPEYO (budesonide) targeted release capsules indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally described as a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5\text{g/g}$ . TARPEYO is the first FDA-approved treatment for this indication and has been designed specifically to target the origin of the disease. In July 2022, Nefecon was also granted conditional approval by the European Commission for European Economic Area (EEA). These approvals marks the transition for Calliditas to a commercial phase biopharmaceutical company.

With recently initiated commercial operations in the U.S. and R&D clinical studies ongoing, the business is capital intensive and until Nefecon/TARPEYO/Kinpeygo will bring in steady revenues that exceed the costs, external financing may be required. The Group's cash position of SEK 1,249.1 million as of December 31, 2022, 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	(1,187,391)
<b>Net loss for the year</b>	<b>(208,548)</b>
	<b>1,125,480</b>

The Board of Directors proposes that SEK 1,125,480 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 the development programs, 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 2022 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,		
		2022	2021	2020
Net sales	3	802,879	229,347	874
Cost of sales		(15,201)	-	-
<b>Gross profit</b>		<b>787,678</b>	<b>229,347</b>	<b>874</b>
Research and development expenses	7,8,9,10	(414,749)	(357,485)	(241,371)
Marketing and selling expenses	7,8,9,10	(515,190)	(179,603)	(38,964)
Administrative expenses	6,7,8,9,10	(259,469)	(210,630)	(102,760)
Other operating income	4	2,862	259	2,501
Other operating expenses	5	(23,074)	(6,344)	-
<b>Operating loss</b>	7	<b>(421,943)</b>	<b>(524,456)</b>	<b>(379,720)</b>
Financial income	11	50,195	20,336	547
Financial expenses	12	(37,669)	(9,253)	(56,978)
<b>Loss before income tax</b>		<b>(409,417)</b>	<b>(513,373)</b>	<b>(436,151)</b>
Income tax expense	13	(2,851)	3,836	(360)
<b>Loss for the year</b>		<b>(412,268)</b>	<b>(509,537)</b>	<b>(436,511)</b>
Attributable to:				
Equity holders of the Parent Company		(412,268)	(500,293)	(433,494)
Non-controlling interests		-	(9,244)	(3,017)
		<b>(412,268)</b>	<b>(509,537)</b>	<b>(436,511)</b>
<b>Loss per share</b>				
Before and after dilution to ordinary equity holders of the Parent Company	14	(7.78)	(9.84)	(9.66)

## Consolidated Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31,		
		2022	2021	2020
<b>Loss for the year</b>		<b>(412,268)</b>	<b>(509,537)</b>	<b>(436,511)</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	36,287	(20,111)	(9,352)
<b>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods</b>		<b>36,287</b>	<b>(20,111)</b>	<b>(9,352)</b>
<i>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:</i>				
Remeasurement gain on defined benefit plans	28	2,763	1,993	1,216
<b>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods</b>		<b>2,763</b>	<b>1,993</b>	<b>1,216</b>
<b>Other comprehensive income/(loss) for the year</b>		<b>39,050</b>	<b>(18,118)</b>	<b>(8,137)</b>
<b>Total comprehensive loss for the year</b>		<b>(373,218)</b>	<b>(527,655)</b>	<b>(444,648)</b>
<b>Attributable to:</b>				
Equity holders of the Parent Company		(373,218)	(519,189)	(438,343)
Non-controlling interests		-	(8,466)	(6,305)
		<b>(373,218)</b>	<b>(527,655)</b>	<b>(444,648)</b>

## Consolidated Statements of Financial Position

		December 31,	
(SEK in thousands)	Note	2022	2021
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	15	483,841	399,418
Equipment	16	7,468	6,309
Right-of-use assets	8	24,452	33,300
Non-current financial assets	17,19,33	11,210	3,915
Deferred tax assets	18	13,799	4,196
<b>Total non-current assets</b>		<b>540,770</b>	<b>447,138</b>
<b>Current assets</b>			
Inventories	21	3,647	889
Accounts receivable	20	78,703	-
Other current assets	19	10,018	11,343
Prepaid expenses and accrued income	22	70,741	45,032
Cash	23	1,249,094	955,507
<b>Total current assets</b>		<b>1,412,204</b>	<b>1,012,772</b>
<b>TOTAL ASSETS</b>		<b>1,952,973</b>	<b>1,459,910</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>	25		
Share capital		2,383	2,094
Additional paid-in capital		2,590,890	2,459,741
Reserves		9,307	(26,979)
Retained earnings including net loss for the year		(1,836,317)	(1,426,574)
<b>Equity attributable to equity holders of the Parent Company</b>		<b>766,264</b>	<b>1,008,281</b>
<b>Non-current liabilities</b>			
Provisions	26	11,792	14,530
Contingent consideration	27	75,880	54,399
Pension liabilities	28	884	3,182
Deferred tax liabilities	18	39,752	30,856
Non-current interest-bearing liabilities	20	713,030	189,164
Non-current lease liabilities	8,19	15,792	24,052
Other non-current liabilities	19,29	4,350	-
<b>Total non-current liabilities</b>		<b>861,479</b>	<b>316,183</b>
<b>Current liabilities</b>			
Accounts payable	19,20	160,404	67,971
Current tax liabilities		5,684	1,221
Other current liabilities	8,19	22,697	12,702
Accrued expenses and deferred revenue	30	136,446	53,553
<b>Total current liabilities</b>		<b>325,231</b>	<b>135,446</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>1,952,973</b>	<b>1,459,910</b>



## Consolidated Statements of Changes in Equity

Attributable to the Equity Holders of the Parent Company								
(SEK in thousands)	Note	Share Capital	Additional Paid-in Capital	Translation Reserve	Retained Earnings incl. Net Loss for the Year	Total	Non-Controlling Interests	Total Equity
<b>Opening equity January 1, 2020</b>		<b>1,548</b>	<b>1,274,664</b>	<b>(45)</b>	<b>(488,096)</b>	<b>788,071</b>	<b>-</b>	<b>788,071</b>
Loss for the year		-	-	-	(433,494)	(433,494)	(3,017)	(436,511)
Other comprehensive income/(loss) for the year		-	-	(6,045)	1,196	(4,849)	(3,288)	(8,137)
<b>Total comprehensive loss for the year</b>		<b>-</b>	<b>-</b>	<b>(6,045)</b>	<b>(432,298)</b>	<b>(438,343)</b>	<b>(6,305)</b>	<b>(444,648)</b>
<b>Transactions with owners:</b>								
New share issue		397	890,990	-	-	891,388	-	891,388
Costs attributable to new share issue		-	(97,686)	-	-	(97,686)	-	(97,686)
Exercise of warrants		52	59,199	-	-	59,251	-	59,251
Share-based payments	10	-	6,012	-	-	6,012	-	6,012
Non-controlling interests from business combinations		-	-	-	-	-	136,084	136,084
Purchase of non-controlling interests		-	-	-	1,798	1,798	(83,970)	(82,172)
<b>Total transactions with owners</b>		<b>449</b>	<b>858,516</b>	<b>-</b>	<b>1,798</b>	<b>860,763</b>	<b>52,114</b>	<b>912,877</b>
<b>Closing equity December 31, 2020</b>	10,25	<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>
<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>316,980</b>	<b>(37,343)</b>	<b>279,637</b>
<b>Closing equity December 31, 2021</b>	10,25	<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 income/(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>

## Consolidated Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31,		
		2022	2021	2020
<b>Operating activities</b>				
Operating loss		(421,943)	(524,456)	(379,720)
Adjustments for non-cash items	23	61,260	66,676	15,465
Interest received		3,553	102	1,912
Interest paid		(35,252)	(5,432)	(393)
Income taxes paid		(7,392)	(3,949)	(528)
<b>Cash flow used in operating activities before changes in working capital</b>		<b>(399,774)</b>	<b>(467,058)</b>	<b>(363,264)</b>
<b>Cash flow from changes in working capital</b>				
Changes in inventory		(2,758)	(949)	-
Changes in operating receivables		(91,878)	(11,712)	8,033
Changes in operating liabilities		183,056	18,131	46,050
<b>Cash flow used in operating activities</b>		<b>(311,354)</b>	<b>(461,588)</b>	<b>(309,181)</b>
<b>Investing activities</b>				
Acquisition of a subsidiary, net of cash acquired		-	-	(172,602)
Purchase of equipment	16	(2,512)	(6,588)	-
Investments in non-current financial assets	17	(2,633)	(1,686)	(5)
Purchase of intangible assets	15	-	(16,066)	-
<b>Cash flow used in investing activities</b>		<b>(5,144)</b>	<b>(24,340)</b>	<b>(172,607)</b>
<b>Financing activities</b>				
New share issue		-	324,000	891,388
Costs attributable to new share issue		-	(20,909)	(95,937)
Issuance of treasury shares		236	-	-
Repurchase of treasury shares		(236)	-	-
Exercise of warrants		95,121	-	59,251
Purchase of non-controlling interests		-	(49,303)	(82,172)
Contribution from non-controlling interests		-	2,282	-
New borrowings	20	491,745	199,524	-
Costs attributable to new loans		(1,260)	(14,858)	-
Repayment of lease liabilities		(9,615)	(5,575)	(3,972)
<b>Cash flow from financing activities</b>		<b>575,990</b>	<b>435,162</b>	<b>768,558</b>
<b>Net increase/(decrease) in cash</b>		<b>259,493</b>	<b>(50,766)</b>	<b>286,770</b>
<b>Cash at beginning of the year</b>		<b>955,507</b>	<b>996,304</b>	<b>753,540</b>
Exchange-rate difference in cash		34,094	9,969	(44,006)
<b>Cash at the end of the year</b>	23	<b>1,249,094</b>	<b>955,507</b>	<b>996,304</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, 2022, 2021 and 2020, respectively. 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.

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, 2022, 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 25, 2023, which will be presented for adoption at the Annual General Meeting on May 30, 2023.

## Note 1 Significant Accounting Policies

### Basis for Preparation

These consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) 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 Financial Reporting Board RFR 1, Supplementary Accounting Regulations for Groups.

The accounting policies stated below have, unless otherwise stated, been applied consistently over all periods presented in the consolidated financial statements. The Group's accounting policies have been applied consistently by the Group's companies. The consolidated financial statements provide comparative information in respect of the previous period and an additional comparative period.

### 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).

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

The consolidated financial statements have been prepared on a historical cost basis, except for certain financial assets (including derivative financial instrument) and contingent consideration that have been measured at fair value through profit or loss.

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.

### Basis for Consolidation

The consolidated financial statements comprise the financial statements of the Parent Company and its subsidiaries as of December 31, 2022. Control is achieved when the Parent Company has control over the investee, the Parent Company is exposed to or has rights to variable returns from its involvement in the investee, and the Parent Company has the ability to use its power over the investee to affect the amount of the investor's returns, which normally means that the Parent Company owns more than half of the number of votes for all of the shares and participations.

The Group re-assesses whether or not it controls an investee if facts and circumstances indicate that there are changes of the control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date the Group gains control until the date the Group ceases to control the subsidiary.

All subsidiaries are consolidated using the acquisition method. The cost of an acquisition is measured as the fair value of assets that have been provided as payment along with any liabilities taken over or which have arisen at the acquisition date. With the acquisition method, the fair value of acquired identifiable assets, assumed liabilities and contingent liabilities in a business combination, regardless of the scope of any non-controlling interest, are measured at fair value as of the acquisition date. Any surplus arising from the difference between cost and fair value of identifiable acquired assets, liabilities and contingent liabilities is recognized as goodwill. If the cost amount is less than the fair value of the acquired net assets, it is recognized in the consolidated statements of income.

Subsidiaries that were acquired during the financial year are included in the consolidated financial statements as soon as the controlling interest has been transferred to the Group. Subsidiaries that were disposed during the financial year are included in the consolidated financial statements up until the date when the controlling interest no longer exists.

For each business combination, the Group elects whether to measure the non-controlling interests in the acquiree at fair value or at the proportionate share of the acquiree's identifiable net assets. Acquisition-related costs are expensed as incurred and included in administrative and selling expenses in the consolidated statements of income.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

### 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, 2022 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.

### Revenue

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 final price is related to 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 Viartis 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

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when the agreements with the parties were signed. These contracts with customers consist of fixed remuneration as well as variable remuneration in the form of regulatory and commercial milestones, and sales-based royalties. Variable remuneration (for example, attributable to future regulatory milestones) are initially considered constrained, as there is significant uncertainty as to whether these will occur. Compensation attributable to sales-based milestones or royalties are not recognized until the sale that results in the right to milestones or royalties arises.

## **Royalty Revenue**

Calliditas is entitled to royalties on sold goods, as per agreement. Revenue recognition is based on royalty reports received, which are based on actual net sales statistics of the licensee. Accrued royalty revenue is recognized on the balance sheet under prepaid expenses and accrued income.

## **Financial Income**

Financial income consists of interest income and foreign exchange gains. Interest income is recognized in accordance with the effective interest method. Effective interest is the interest that discounts estimated future receipts and payments during a financial instrument's anticipated duration to the financial assets or liability's recognized net value. The calculation contains all costs included in the effective interest paid by the parties to the contract, transaction costs and all other premiums and discounts. Dividends received are recognized when the right to receive a dividend has been established. Foreign exchange gains and losses are netted.

## **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-licence 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.

## **Employee Benefits**

### **Short-term benefits**

Current employee benefits such as salaries, social security costs, vacation pay and bonuses are expensed during the period in which employees perform the service.

### **Pensions**

The Group has both defined-contribution and defined-benefit pension plans, and most employees are covered by and recognized in the defined-contribution pension plans. Employees in France and Switzerland are covered by defined-benefit pension plans. All other employees were covered by defined-contribution pension plans. See Note 27 Pension Liabilities for more information.

### **Defined-contribution pension plans**

A defined-contribution pension plan is a pension plan according to which the Group pays fixed premiums to a separate legal entity. The Group does not have any legal or informal obligation to pay further premiums if this legal entity does not have sufficient assets to pay the full remuneration to employees

corresponding to their service during the current or previous periods. The Group therefore has no further risk. The Group's obligations relating to fees for defined-contribution plans are expensed in profit or loss as they are accrued due to the employee performing services for the Group over a period.

### **Defined-benefit pension plans**

In defined-benefit plans, the pension is determined as a percentage of the pensionable final salary, based on the employee's length of service and average final salary. The Group is responsible for ensuring that the established benefits are paid out. The defined-benefit pension obligations are recognized in the consolidated statements of financial position as the net total of the estimated present value of the obligations and the fair value of the plan assets, which are recognized as a provision or a non-current financial receivable. For defined-benefit plans, pension expense and commitments are calculated using the applicable principles of IAS 19. This calculation is performed at least annually by independent actuaries. The Group's obligations are measured at the present value of expected future payments.

Actuarial gains and losses may arise in connection with the determination of the present value of the obligations and the fair value of plan assets. These arise either because the fair value differs from the previous assumption, or the assumptions change. Actuarial gains and losses are recognized in the consolidated statements of comprehensive income in the period in which they arise. Interest expense, less the estimated return on plan assets, is classified as a financial expense. Other cost items in the pension expense are charged to operating profit.

### **Severance pay**

An expense for remuneration in connection with termination of employment of personnel is recognized only if the Group is committed, without any realistic possibility of withdrawal, by a formal detailed plan to eliminate a position in advance of when that position would normally expire. When remuneration is paid as an offer to encourage voluntary termination of employment, the cost is recognized if it is probable that the offer will be accepted and the number of employees that will accept the offer can be reliably estimated.

### **Share-based payments**

Share-based payments in the Group refers to option programs and performance-based share award programs, which are regulated by equity instruments. In cases where the fair value of the instrument exceeds what the employee paid, the difference is recognized as a personnel cost. The fair value of options is determined at the grant date using the Black-Scholes model for pricing of options. The valuation of the performance share awards is based on a discounted model with Monte Carlo simulation of the share price's development for the share-related parts and with estimated probabilities for the outcome of the market conditions. The cost is recognized, together with a corresponding increase in equity, during the period in which the service conditions are met, up to and including, the date on which the employees concerned are fully eligible for compensation.

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 resolved.

### **Leases**

#### **Lessee**

The Group assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

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 two to four 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 20 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.

#### **Financial Expenses**

Financial expenses mainly consist of interest expenses, realized and unrealized losses on foreign exchange derivative instruments and unrealized foreign exchange losses. Foreign exchange gains and losses are netted.

#### **Taxes**

Income tax comprises current tax and deferred tax. Income tax is recognized in net profit for the year, except when the underlying transaction is recognized in other comprehensive income or equity with the related tax effect recognized in other comprehensive income and in equity. Current tax is the tax that is to be paid or received in the current year, with the application of the tax rates that have been enacted or substantively enacted by the end of the reporting period. Current tax also includes adjustments of current tax attributable to prior periods.

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.

Deferred tax assets on deductible temporary differences and loss carryforwards are recognized only to the extent that it is probable that it will be possible to utilize these, or to the extent that there are temporary differences which these can be utilized to offset. A provision for deferred tax assets will be recognized when it is no longer deemed probable that they can be utilized.

#### **Intangible Assets**

Intangible assets in the Group consist of licenses and similar rights and goodwill.

#### **Licenses and similar rights**

Intangible assets with a finite useful life are recognized at initial recognition at cost less accumulated amortization and any accumulated impairment losses. Intangible assets with finite lives are amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. When determining the amortized amount of the assets, the residual value of the asset is taken into account, when applicable.

#### **Goodwill**

Goodwill arising in a business combination comprises the difference between the cost of the business combination and the fair value of identifiable assets acquired, liabilities assumed, and any contingent liabilities

recognized at the acquisition date. Goodwill on business combinations is included in intangible assets and measured at cost less any accumulated impairment losses. Goodwill is allocated to the cash-generating units, which is the full Group, and tested annually for impairment requirement, or whenever there is any indication of impairment. There is no amortization of goodwill and impairment of goodwill is not reversed.

#### **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**

Amortization of the intangible assets begins when the asset can be used, that is, when it is in the place and in the condition required to be able to use it in the manner intended by the Group's management.

The Group's expected finite useful life is:

– Licenses and similar rights – 6-15 years

Until full market approval from regulatory authorities has been granted, amortization of "Licenses and Similar Rights" will not commence. As market approval has not yet been obtained, no other costs have been capitalized. Following market approval from regulatory authorities, "Licenses and Similar Rights" will be amortized on a straight-line basis over the expected useful life. Until a market approval of the product has been obtained, the asset is assessed for impairment at least once a year, and when there is an indication that the asset may be impaired.

#### **Equipment**

Equipment is recognized in the consolidated statement of financial position at cost less accumulated depreciation and impairment. Such cost includes the cost price and expenses directly attributable to the asset. Repairs and maintenance costs are expensed as incurred, while expenses for improvements are recognized as investments and added to the cost of the assets.

An item of equipment and any significant part initially recognized is derecognized upon disposal (i.e., at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of income when the asset is derecognized.

#### **Depreciation**

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

The residual values, useful lives, and methods of depreciation of equipment are reviewed at each financial year and adjusted prospectively, if appropriate. If there is an indication that an asset needs to be impaired, the asset is written down to its recoverable amount if this is lower than the carrying amount. The recoverable amount corresponds to the highest of net realizable value and value in use.

#### **Impairment of Non-Financial Assets**

Goodwill and intangible assets not yet available for use, are not amortized but the Group assesses for impairment at each reporting date, and when there is an indication that an asset may be impaired. Equipment that is depreciated is assessed for impairment whenever events or changes in circumstances indicate that the carrying amount is not recoverable.

An impairment loss is made by the amount by which the asset's carrying amount exceeds its recoverable amount. An asset's recoverable amount is the higher of an asset's or cash generating units' ("CGU") fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or CGU exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.



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In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs of disposal, recent market transactions are taken into account. If no such transactions can be identified, an appropriate valuation model is used. These calculations are corroborated by valuation multiples, quoted share prices for publicly traded companies or other available fair value indicators.

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. Impairment losses of continuing operations are recognized in the statement of income in expense categories consistent with the function of the impaired asset. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years.

## Financial Assets and Financial Liabilities

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity. Financial instruments are classified at initial recognition, including on the basis of the purpose for which the instrument was acquired and managed. This classification determines the valuation of the instruments.

### Initial recognition and measurement of financial assets

The Group's financial assets consist of non-current financial assets, accounts receivable and cash, which are recognized at amortized cost.

The instruments are classified into:

- Amortized cost, or
- Fair value through profit or loss

Financial assets at amortized cost are initially measured at fair value with the addition of transaction costs. Following the initial recognition, the assets are measured at amortized cost less a provision for losses on expected credit losses. Assets classified at amortized cost are held according to the business model to collect contractual cash flows that are only payments of capital amount and interest on the outstanding capital amount.

### Initial recognition and measurement of financial liabilities

The Group's financial liabilities consist of contingent consideration, non-current interest-bearing liabilities, other non-current liabilities, lease liabilities, accounts payable and other current liabilities, all of which, except contingent consideration, are recognized as amortized cost. Contingent consideration is recognized at fair value through profit or loss.

The instruments are classified into:

- Amortized cost, or
- Fair value through profit or loss

Financial liabilities at amortized costs are initially measured at fair value, net of transaction costs. Subsequently periods are measured at amortized cost using the effective interest (EIR) method. Financial liabilities classified at fair value are measured both initially and in subsequent periods 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.

### Recognition and derecognition

A financial asset or financial liability is recognized in the consolidated statement of financial position when the Group becomes a party in accordance with the contractual terms of the instrument. Debt is recognized when the counterparty has performed and a contractual obligation exists to pay, even if an invoice has not yet been received.

A financial asset is derecognized from the consolidated statement of financial position when the rights in the agreement are realized, expire or the Group loses control of them. A financial liability is derecognized from the consolidated statement of financial position when the contractual obligation is fulfilled or otherwise extinguished. The same applies to part of a financial asset or financial liability.

Gains and losses from derecognition from the consolidated statement of financial position are recorded in the consolidated statement of income.

A financial asset and financial liability are offset and recognized with a net amount in the consolidated statement of financial position only when there is a legal right to set off the amounts and that there is an intention to settle the items with a net amount or to simultaneously realize the asset and settle the debt.

### Impairment of financial assets

The Group's impairment model is based on expected credit losses and takes into account forward-looking information. The valuation of expected credit losses takes into account any collateral and other credit enhancements in the form of guarantees. See Note 20 Financial Risks for information on considerations relating to accounts receivable and deposits.

### Inventory

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. By continuously monitoring inventory, we ensure that it is dispatched based on its shelf life and moving average basis. When necessary, impairment of inventory is performed within the frame of normal business operations and is recognized in costs of goods sold.

### Accounts Receivable

Accounts receivable are reported at amortized cost. A provision for expected credit losses is recorded based on the Group's forward-looking expected credit losses (ECL). An analysis of expected credit losses is performed, taking into account historical, current and forward looking factors. The effect of recognition of the provision amount is reported in the statement of income.

### Cash

Cash is entirely comprised of cash at banks.

### Equity

Common shares, other contributed capital and retained earnings are classified as equity. Financial instruments that meet the criteria for classification as equity are recognized as equity even if the financial instrument is legally structured as a liability. Transaction costs that are directly attributable to the issue of new shares or options are recognized net after tax in equity as a deduction from the issue proceeds.

When Calliditas shares are repurchased, the amount of the consideration paid is recognized as a deduction from equity. Repurchased shares are classified as treasury shares and are presented as a deduction from total equity. When treasury shares are sold or subsequently reissued, the amount received is recognized as an increase in equity and the resulting surplus or deficit on the transaction is transferred to or from Additional Paid-in Capital.

### Option Program

The Group has issued an option program which constitutes share-based payments. 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.

### Provisions

A provision differs from other liabilities in that there is uncertainty about the time of payment or the amount of the amount to settle the provision. A provision is recognized in the statement of financial position when there is an existing legal or informal obligation arising from past events, and it is likely that an outflow of financial resources will be required to settle the obligation and a reliable estimate of the amount can be made. The amount

recognized is the best estimate of what is required to settle the existing obligation on the balance sheet date. Where the effect of when payment is made in time is significant, provisions are calculated by discounting the expected future cash flow.

#### **Contingent Liabilities**

A contingent liability is disclosed when there is a possible commitment originating from events that have occurred and whose occurrence is confirmed by one or several uncertain future events. An obligation arising from past events whose existence will be confirmed by the occurrence or non-occurrence of one or more uncertain future events is not recognized as a liability or provision.

#### **Foreign Currency**

##### **Transactions in foreign currency**

Transactions in foreign currency are translated to the functional currency at the exchange rate on the date of the transaction. Monetary assets and liabilities in foreign currency are translated to the functional currency at the exchange rate that applies on the closing date. Exchange rate differences arising on translation are recognized in net profit for the year. Foreign exchange gains and losses on operating receivables and liabilities are recognized in operating profit, while foreign exchange gains and losses on financial receivables and liabilities are recognized as financial items.

##### **Translation from foreign operations**

Assets and liabilities in foreign operations are translated from the functional currency of the operations to the Group's presentation currency at the exchange rate applicable on the closing date. Income and expenses in a foreign operation are translated to SEK at the average exchange rate which corresponds to an approximation of the exchange rates prevailing on each individual transaction date. Translation differences arising in the translation of foreign operations' functional currencies are recognized in the consolidated statements of comprehensive income.

#### **Earnings per Share**

The calculation of earnings per share is based on the Group's net loss for the year and on the weighted-average number of common shares outstanding during the year. In calculating earnings per share after dilution, earnings and the average number of shares are adjusted for the dilutive effects of potential common shares. Earnings per share is not adjusted for any dilution that results in a profit per share after dilution that is higher than profit per share before dilution, or loss per share that is lower than loss per share before dilution.

#### **Cash Flow**

The consolidated statement of cash flows is prepared in accordance with the indirect method. The recognized cash flow includes only transactions that involve inflows and outflows, divided into operating activities, investing activities and financing activities. Cash flows from inflows and outflows are recognized at gross amounts, except for transactions comprising large inflows and outflows that pertain to items that are traded quickly and have short terms.

#### **Segment Information**

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 NA Enterprises Inc. The non-current assets are located in Sweden, the U.S., France and Switzerland.

## **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.

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.

#### **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, 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.

Specifically, the significant accounting judgments and estimates within revenue recognition include determining which promises within each contract 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 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 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 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 determined estimates are recorded for 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 is reviewed and adjusted on no less than a quarterly basis.

##### **Intangible Assets**

The Group's intangible assets are essentially attributable to the Group acquiring the rights to the NOX platform, as well as goodwill in connection with the acquisition of Genkyotex SA. As well as to the previous in-licensing agreement of Budenofalk 3mg oral capsule from the German pharmaceutical company Dr Falk Pharma GmbH. 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. See below and Note 15 Intangible Assets and Impairment Testing.

## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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### 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, in accordance with the policy described in Note 1 Significant Accounting Policies. 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, see Note 15 Intangible Assets and Impairment Testing. As of December 31, 2022, the Group's goodwill amounted to SEK 45,784 and other intangible assets amounted to SEK 438,057. There is no impairment for the year ended December 31, 2022.

### 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 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, 2022, 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.

### Allowance for Expected Credit Losses for Accounts Receivable

Management makes allowance for expected credit losses for accounts receivable equal 12 months. 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.

### 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.

### Assumptions for The Valuation of Pension Benefits

The valuation of pension commitments and pension expenses is based on the actuarial assumptions specified in Note 28 Pension Liabilities.

### 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 consolidated 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 Revenue from Contracts with Customers

The Group's revenues in 2022 primarily consisted of net sales of TARPEYO in the U.S., milestone fees from STADA for the conditional approval and commercialization of Kinpeygo in Europe and the milestone fee from Viatrix to register and commercialize Nefecon for the treatment of IgA nephropathy (IgAN) in Japan. In addition, net sales also consisted of the milestone fee from Everest Medicines for the extension of the license agreement for South Korea.

The recognition of revenue is associated with significant accounting judgments and estimates, for additional information see Note 2.

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

Type of goods or service	Year Ended December 31,		
	2022	2021	2020
Product sales	375,515	-	-
Outlicensing of product	421,689	225,252	-
Royalty income	2,287	-	-
Performance of certain regulatory services	3,387	4,095	-
Provision of drugs	-	-	874
<b>Total</b>	<b>802,879</b>	<b>229,347</b>	<b>874</b>

Geographical markets	Year Ended December 31,		
	2022	2021	2020
USA	372,247	-	-
Europe*	143,955	201,878	-
Asia	286,677	27,469	874
<b>Total</b>	<b>802,879</b>	<b>229,347</b>	<b>874</b>

\* No net sales were recorded in Sweden in 2022, 2021 and 2020, respectively.

Revenue from major customers	Year Ended December 31,		
	2022	2021	2020
Customer A	372,247	-	-
Customer B	80,643	27,469	874
Customer C	143,955	201,879	-
Customer D	206,034	-	-
<b>Total</b>	<b>802,879</b>	<b>229,348</b>	<b>874</b>

As of December 31, 2022, the total liability for expected returns and rebates amounts to SEK 24,294, which are recognized in other current liabilities and accrued expenses and deferred revenue. In addition, there are no other performance obligations. No liability for expected returns and rebates was recorded as of December 31, 2021.

Contract assets comprise of accrued royalties and amounts to SEK 2,287 as of December 31, 2022. No contract assets were recorded December 31, 2021. Changes in contract asset balances are entirely attributable to the ordinary operations of the Group where sales have commenced during the year. Contract liabilities comprises of accrued rebates on sales and amounts to SEK 15,849 as of December 31, 2022 and deferred revenue amounts to SEK 3,387 as of December 31, 2021. Opening balance comprise prepaid income which has been recognized as revenue during the year.

## Note 4 Other Operating Income

	Year Ended December 31,		
	2022	2021	2020
Exchange rate differences	–	149	2,501
Pass through costs	439	–	–
Net gains on disposal of equipment	–	110	–
Other income	2,423	–	–
<b>Total</b>	<b>2,862</b>	<b>259</b>	<b>2,501</b>

## Note 5 Other Operating Expenses

	Year Ended December 31,		
	2022	2021	2020
Exchange rate differences	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	–
<b>Total</b>	<b>23,074</b>	<b>6,344</b>	<b>–</b>

## Note 6 Auditors' Fee

	Year Ended December 31,		
	2022	2021	2020
<b>EY</b>			
Audit services	13,369	6,235	4,449
Other audit activities	3,370	2,105	3,774
Tax advice	–	73	–
<b>Total</b>	<b>16,739</b>	<b>8,413</b>	<b>8,223</b>
<b>KPMG</b>			
Audit services	–	472	102
Other audit activities	–	1,178	2,552
<b>Total</b>	<b>–</b>	<b>1,650</b>	<b>2,654</b>
<b>Other auditors</b>			
Audit services	–	471	102
Other audit activities	–	79	–
<b>Total</b>	<b>–</b>	<b>550</b>	<b>102</b>
<b>Total Audit Fee</b>	<b>16,739</b>	<b>10,613</b>	<b>10,979</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 7 Costs according to Type of Cost

	Year Ended December 31,		
	2022	2021	2020
Raw materials and consumables	3,179	–	–
Other external expenses	939,566	549,079	311,329
Personnel costs	248,952	164,206	68,943
Depreciation on equipment's and right-of-use assets	12,913	34,433	2,823
Other operating expenses	23,074	6,344	–
<b>Total</b>	<b>1,227,684</b>	<b>754,062</b>	<b>383,095</b>

## Note 8 Leases

	December 31,	
	2022	2021
<b>Right-of-use assets</b>		
Opening balance	37,198	9,595
Additional agreements	–	34,944
Revaluation agreements	(474)	–
Termination of agreement	–	(7,625)
Exchange differences	3,485	284
<b>Closing balance</b>	<b>40,209</b>	<b>37,198</b>
<b>Depreciation</b>		
Opening balance	(3,898)	(4,351)
Depreciation	(10,807)	(5,711)
Revaluation agreements	47	–
Termination of agreement	–	6,456
Exchange differences	(1,099)	(292)
<b>Closing balance</b>	<b>(15,757)</b>	<b>(3,898)</b>
<b>Net book value</b>	<b>24,452</b>	<b>33,300</b>

Depreciation on right-of-use assets is included in the consolidated statements of income under Research and development expenses amounted to SEK 1,073, SEK 997 and SEK 165 in 2022, 2021 and 2020, respectively, under Marketing and selling expenses amounted to SEK 3,743, SEK 1,522 and SEK – in 2022, 2021 and 2020, respectively, and under Administrative expenses amounted to SEK 5,991, SEK 3,192 and SEK 2,621 in 2022, 2021 and 2020, respectively.

	December 31,	
	2022	2021
<b>Lease liabilities</b>		
Non-current lease liabilities	15,792	24,052
Current lease liabilities	10,374	9,591
<b>Total</b>	<b>26,165</b>	<b>33,642</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.

	December 31,	
	2022	2021
<b>Maturity analysis on future lease liabilities</b>		
<12 months	16,467	11,909
1-2 years	12,613	11,231
>2 years	10,053	16,256
<b>Total</b>	<b>39,133</b>	<b>39,396</b>

## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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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 2023 until 2026 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,		
	2022	2021	2020
Interest expenses attributable to lease liabilities	1,604	590	388
Expenses attributable to short-term lease	-	633	731
Expenses attributable to leasing agreements with low value	214	146	103
Expenses attributable to variable lease payments that are not included in lease liabilities	303	446	344
Expenses attributable to lease depreciation	10,807	5,711	2,786
<b>Total expensed during the year</b>	<b>12,928</b>	<b>7,526</b>	<b>4,352</b>
This year's lease payments in the Group	13,231	6,659	4,930

### Note 9 Employees and Personnel Costs

#### Average Number of Employees

	Year Ended December 31,					
	2022		2021		2020	
	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.
<b>Parent Company</b>						
Sweden	45	33%	29	40%	16	44%
	<b>45</b>	<b>33%</b>	<b>29</b>	<b>40%</b>	<b>16</b>	<b>44%</b>
<b>Subsidiaries</b>						
France	2	-	3	26%	-	-
Switzerland	6	53%	6	47%	2	50%
United States	33	52%	18	62%	5	100%
	<b>41</b>	<b>51%</b>	<b>27</b>	<b>55%</b>	<b>7</b>	<b>86%</b>
<b>Total for the Group</b>	<b>86</b>	<b>41%</b>	<b>56</b>	<b>47%</b>	<b>23</b>	<b>57%</b>

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

	Year Ended December 31,		
	2022	2021	2020
<b>Wages and Salaries</b>			
<b>Parent Company</b>			
Board and Executive Management <sup>1)</sup>	33,471	27,792	19,211
Other employees	52,126	33,370	15,598
<b>Subsidiaries</b>			
Board and Executive Management	14,493	4,983	3,184
Other employees	90,055	57,452	11,615
<b>Total</b>	<b>190,145</b>	<b>123,597</b>	<b>49,608</b>

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

	Year Ended December 31,		
	2022	2021	2020
<b>Social Security Costs and Pension Costs</b>			
<b>Parent Company</b>			
Pension costs for the Board and Executive Management	2,167	1,785	1,748
Pension costs to other employees	6,582	4,084	1,666
Social security costs	17,393	17,088	12,330
<b>Subsidiaries</b>			
Pension costs for the Board and Executive Management	616	167	129
Pension costs to other employees	2,647	928	506
Social security costs	6,484	8,596	225
<b>Total</b>	<b>35,889</b>	<b>32,648</b>	<b>16,604</b>

#### Gender Distribution Among the Board and Executive Management

	Year Ended December 31,		
	2022	2021	2020
Percentage of women on the Board	67%	60%	60%
Percentage of men on the Board	33%	40%	40%
Percentage of women among other executive management	38%	33%	33%
Percentage of men among other executive management	62%	67%	67%



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

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>						
Hilde Furberg	413	–	–	–	239	651
Diane Parks	490	–	–	–	239	729
Lennart Hansson (until May, 2022)	200	–	–	–	33	233
Molly Henderson	590	–	–	–	227	817
Henrik Stenqvist (from May, 2022)	275	–	–	–	74	349
Elisabeth Björk (from May, 2022)	188	–	–	–	74	261
<b>Executive Management</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
of which relates to subsidiaries	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
Diane Parks	421	–	–	–	162	583
Molly Henderson	539	–	–	–	124	663
<b>Executive Management</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
of which relates to subsidiaries	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>

Year Ended December 31, 2020						
	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
<b>Chairman of the Board</b>						
Elmar Schnee	834	–	–	–	310	1,144
<b>Board members</b>						
Thomas Eklund (until June, 2020)	72	–	–	–	43	115
Hilde Furberg	273	–	–	–	106	379
Lennart Hansson	281	–	–	–	106	387
Bengt Julander (until June, 2020)	58	–	–	–	–	58
Diane Parks	379	–	–	–	106	485
Molly Henderson (from June, 2020)	345	–	–	–	37	382
<b>Executive Management</b>						
CEO, Renée Aguiar-Lucander	3,401	678	1,357	–	1,094	6,530
Other executive management (5 people)	9,816	1,198	1,760	472	2,018	15,264
of which relates to subsidiaries	2,547	129	636	–	–	3,312
<b>Total</b>	<b>15,459</b>	<b>1,876</b>	<b>3,117</b>	<b>472</b>	<b>3,820</b>	<b>24,744</b>

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### Other Remuneration

Other remuneration comprises of fees for services rendered to the Parent Company. Management services purchased from Cordcom Consultants KB amounted to SEK -, SEK - and SEK 472 in 2022, 2021 and 2020, respectively, and relates to the functions of a Head of Communications and Investor Relations that were outsourced to this entity.

### 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, Vice President Operations, 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 2022 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 92-97.

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.

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, 2021	Change	December 31, 2021	Change	December 31, 2022
Renée Aguiar-Lucander, CEO	225,000	71,000	296,000	295,000	591,000
Other executive management	415,000	120,000	535,000	520,000	1,055,000
Other employees and consultants	449,000	1,009,000	1,458,000	848,166	2,306,166
<b>Total</b>	<b>1,089,000</b>	<b>1,200,000</b>	<b>2,289,000</b>	<b>1,663,166</b>	<b>3,952,166</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	Exercised 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%	836,500
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	145.05	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%	500,000
ESOP 2021:2	September 29, 2021	September 29, 2024	25.72	109.38	47.50%	329,500
ESOP 2021:3	March 17, 2022	March 17, 2025	27.64	93.77	43.84%	650,000
ESOP 2022:1	September 27, 2022	September 27, 2025	26.57	94.66	45.14%	1,101,000
						<b>3,952,166</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 5,000,000 warrants 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,		
	2022	2021	2020
Share-based payments	34,549	24,737	5,304
Provisions attributable to changes in social security costs (Share-based payments)	234	9,992	3,164
<b>Total</b>	<b>34,783</b>	<b>34,729</b>	<b>8,468</b>

## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

### 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.

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

Board LTIP 2019		Share Awards Outstanding as of			
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
Elmar Schnee, Chairman of the Board	23,236	-	23,236	(23,236)	-
Thomas Eklund, Board member (until June, 2020)	2,816	-	2,816	(2,816)	-
Hilde Furberg, Board member	8,449	-	8,449	(8,449)	-
Lennart Hansson, Board member (until May, 2022)	8,449	-	8,449	(8,449)	-
Diane Parks, Board member	8,449	-	8,449	(8,449)	-
<b>Total</b>	<b>51,399</b>	<b>-</b>	<b>51,399</b>	<b>(51,399)</b>	<b>-</b>

Board LTIP 2020		Share Awards Outstanding as of			
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
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	-	4,327	(1,443)	2,884
Diane Parks, Board member	4,327	-	4,327	-	4,327
Molly Henderson, Board member	4,327	-	4,327	-	4,327
<b>Total</b>	<b>31,371</b>	<b>-</b>	<b>31,371</b>	<b>(1,443)</b>	<b>29,928</b>

Board LTIP 2021		Share Awards Outstanding as of			
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
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, 2022)	-	4,086	4,086	(2,724)	1,362
Diane Parks, Board member	-	4,086	4,086	-	4,086
Molly Henderson, Board member	-	4,086	4,086	-	4,086
<b>Total</b>	<b>-</b>	<b>26,968</b>	<b>26,968</b>	<b>(2,724)</b>	<b>24,244</b>

Board LTIP 2022		Share Awards Outstanding as of			
Holder	January 1, 2021	Change	December 31, 2021	Change	December 31, 2022
Elmar Schnee, Chairman of the Board	-	-	-	13,926	13,926
Hilde Furberg, Board member	-	-	-	5,356	5,356
Diane Parks, Board member	-	-	-	5,356	5,356
Molly Henderson, Board member	-	-	-	5,356	5,356
Henrik Stenqvist, Board member	-	-	-	5,356	5,356
Elisabeth Björk, Board member	-	-	-	5,356	5,356
<b>Total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>40,706</b>	<b>40,706</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).

	Exercised Date	Fair Value at Grant Date	Number of Share Awards
Board LTIP 2019	June 1, 2022	22.49	51,399
Board LTIP 2020	July 1, 2023	33.97	29,928
Board LTIP 2021	July 1, 2024	62.95	24,244
Board LTIP 2022	July 1, 2025	51.54	40,706

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,		
	2022	2021	2020
Share-based payments	1,531	876	267
Provisions attributable to changes in social security costs (Share-based payments)	(1,614)	297	207
<b>Total</b>	<b>(83)</b>	<b>1,173</b>	<b>474</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.

For the programs initiated in 2018 and 2019, the observation period was short for the underlying share and the volatility was then based on the observation period with a discount as it normally decreases as the share's history becomes longer. The risk-free interest rate is at the same level as Swedish government bonds with a corresponding term. Dividends are assumed to amount to zero during the period until the date of expiration.

	Warrants Outstanding as of			Inputs used for the Black & Scholes valuation				
Outstanding Warrants per Year	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;

	Warrants Outstanding as of				
Holder	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, 2021	1,089,000	120.94	82,770	-	1,279,086	74.37
Granted	1,331,000	133.48	26,968	-	-	-
Forfeited	(131,000)	121.78	-	-	-	-
<b>Outstanding as of December 31, 2021</b>	<b>2,289,000</b>	<b>128.18</b>	<b>109,738</b>	<b>-</b>	<b>1,279,086</b>	<b>74.37</b>
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>
Weighted average share price at the date of exercise	-	-	102.06	-	91.45	-



## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

### Note 11 Financial Income

	Year Ended December 31,		
	2022	2021	2020
Interest income under the effective interest method	3,553	102	547
Exchange rate differences	46,642	20,234	-
<b>Total</b>	<b>50,195</b>	<b>20,336</b>	<b>547</b>

### Note 12 Financial Expenses

	Year Ended December 31,		
	2022	2021	2020
Interest on lease liabilities	(1,604)	(590)	(388)
Other interest expenses under the effective interest method	(31,191)	(6,518)	(5)
Exchange rate differences	-	-	(53,267)
Changes in FX options measured at fair value	-	-	(3,318)
Other financial expenses	(4,874)	(2,145)	-
<b>Total</b>	<b>(37,669)</b>	<b>(9,253)</b>	<b>(56,978)</b>

### Note 13 Income Tax Expense

	Year Ended December 31,		
	2022	2021	2020
Current income taxes	(11,539)	(4,581)	(1,035)
Deferred tax	8,688	8,417	675
<b>Income tax expense recognized in the consolidated statements of income</b>	<b>(2,851)</b>	<b>3,836</b>	<b>(360)</b>

	Year Ended December 31,		
	2022	2021	2020
<b>Reconciliation of effective tax rate</b>			
Accounting loss before income tax	(409,417)	(513,373)	(436,151)
Tax in accordance with applicable tax rate in Sweden 20.6% (20.6%, 21.4%)	84,340	105,755	93,336
<b>Tax effect of:</b>			
Effect of other tax rates for foreign subsidiaries	(11,857)	11,481	680
Tax attributable to unrecognized deferred tax assets for tax losses carried forward	(64,150)	(101,785)	(91,725)
Non-deductible expenses	(11,184)	(11,615)	(2,652)
Non-taxable income	-	-	1
<b>Income tax expense recognized in the consolidated statements of income</b>	<b>(2,851)</b>	<b>3,836</b>	<b>(360)</b>
<b>At the effective income tax rate</b>	<b>(1%)</b>	<b>1%</b>	<b>-</b>

The Group has costs attributable to new share issue amounted to SEK -, SEK 20,909 and SEK 97,686 in 2022, 2021 and 2020, respectively, which are recognized directly against equity. These costs are deductible for tax purposes.

The Group has SEK 3,562,440 and SEK 3,200,911 of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position as of December 31, 2022 and 2021, respectively. The tax losses carried forward are allocated between Sweden of SEK 1,597,989, France of SEK 1,194,206 and Switzerland of SEK 770,245, 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.

### Note 14 Earnings per Share

	Year Ended December 31,		
	2022	2021	2020
<b>Loss per share before and after dilution</b>			
Net loss for the year attributable to equity holders of the Parent Company	(412,268)	(500,293)	(433,494)
Weighted-average number of common shares outstanding	53,022,550	50,829,255	44,873,448
<b>Loss per share before and after dilution</b>	<b>(7.78)</b>	<b>(9.84)</b>	<b>(9.66)</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 - 2022. 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 3,952,166 shares and for issued share awards with entitlement to receive 94,878 shares, since the Group is in a loss position in 2022, 2021 and 2020, respectively.

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

## Note 15 Intangible Assets and Impairment Testing

	December 31,	
	2022	2021
<b>Licenses and similar rights</b>		
Cost at opening balance	390,166	380,836
Acquisition for the year	–	16,066
Exchange differences on translation	78,545	(6,736)
<b>Cost at closing balance</b>	<b>468,711</b>	<b>390,166</b>
<b>Impairment</b>		
Cost at opening balance	(27,975)	–
Impairment	–	(27,975)
Exchange differences on translation	(2,679)	–
<b>Accumulated impairment at closing balance</b>	<b>(30,654)</b>	<b>(27,975)</b>
<b>Goodwill</b>		
Cost at opening balance	37,227	37,989
Exchange differences on translation	8,557	(762)
<b>Cost at closing balance</b>	<b>45,784</b>	<b>37,227</b>
<b>Net book value</b>	<b>483,841</b>	<b>399,418</b>

Intangible assets consist of licenses and similar rights of SEK 438,057 and goodwill of SEK 45,784 as of December 31, 2022.

Intangible assets are mainly from the acquisition of the NOX platform and associated goodwill. The net book value of the NOX platform amounts to SEK 405,925 as of December 31, 2022. 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.

### Impairment Testing of Intangible Assets

#### 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, 2022, the Group's goodwill amounted to SEK 45,784. There is no impairment for the year ended December 31, 2022.

The following table shows the discount rate used before tax:

Parameter, %	Year Ended December 31,	
	2022	2021
Discount rate	12.0	11.0

#### Intangible assets, not yet available for use

These significantly consist of the NOX platform and Budenofalk 3 mg oral capsule, which are tested, at least, annually for impairment requirement. The technology and the rights were reviewed for impairment individually. The assessment of the value of the technology and the rights is based on the fair value less cost of disposals of each individual asset. 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,	
	2022	2021
Discount rate NOX platform	12.0	17.7
Discount rate Budenofalk 3 mg oral capsule	12.0	12.4

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.

## Note 16 Equipment

	December 31,	
	2022	2021
Cost at opening balance	7,073	214
Acquisition for the year	2,512	6,588
Disposal for the year	–	(118)
Exchange differences	1,582	389
<b>Cost at closing balance</b>	<b>11,167</b>	<b>7,073</b>
Depreciation at opening balance	(764)	(51)
Depreciation for the year	(2,106)	(465)
Disposal for the year	–	51
Exchange differences	(830)	(299)
<b>Depreciation at closing balance</b>	<b>(3,700)</b>	<b>(764)</b>
<b>Net book value</b>	<b>7,468</b>	<b>6,309</b>

Depreciation on equipment is included in the consolidated statement of income under Research and development expenses amounted to SEK 579, SEK 59 and SEK - in 2022, 2021 and 2020, respectively, under Marketing and selling expenses amounted to SEK 806, SEK 176 and SEK - in 2022, 2021 and 2020, respectively and under Administrative expenses amounted to SEK 721, SEK 230 and SEK 37 in 2022, 2021 and 2020, respectively.

## Note 17 Non-Current Financial Assets

	December 31,	
	2022	2021
Cost at opening balance	3,915	2,225
Additional acquisition	7,064	1,686
Exchange differences	231	4
<b>Net book value</b>	<b>11,210</b>	<b>3,915</b>

Non-current financial assets comprise of bank guarantees/deposits amounted to SEK 6,851 and SEK 3,915 as of December 31, 2022 and 2021, respectively and other non-current receivables amounted to SEK 4,359 as of December 31, 2022, and no other non-current receivables were recognized as of December 31, 2021.

## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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### Note 18 Deferred Tax Assets and Deferred Tax Liabilities

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 items net value	382	–	382
Liabilities	3,218	–	3,218
Personnel-related items	10,654	–	10,654
Tax loss carried forward	17,037	–	17,037
Other items	311	–	311
<b>Total</b>	<b>31,601</b>	<b>(57,555)</b>	<b>(25,953)</b>
Offsetting	(17,803)	17,803	–
<b>Tax assets/liabilities, net</b>	<b>13,799</b>	<b>(39,752)</b>	<b>(25,953)</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.

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 items net value	270	68	44	382
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>(25,953)</b>

Deferred tax assets and liabilities as of December 31, 2021	Deferred Tax Assets	Deferred Tax Liabilities	Net
Intangible assets	–	(46,175)	(46,175)
Tangible assets	–	(238)	(238)
Lease items net value	270	–	270
Personnel-related items	4,141	–	4,141
Tax loss carried forward	15,319	–	15,319
Other items	23	–	23
<b>Total</b>	<b>19,753</b>	<b>(46,413)</b>	<b>(26,661)</b>
Offsetting	(15,557)	15,557	–
<b>Tax assets/liabilities, net</b>	<b>4,196</b>	<b>(30,856)</b>	<b>(26,661)</b>

Tax losses carried forward of SEK 15,319 have been recognized as deferred tax assets in the statement of financial position as of December 31, 2021 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, 2021	Cost at Opening Balance	Recognized in Profit or Loss	Exchange Differences	Cost at Closing Balance
Intangible assets	(47,120)	–	945	(46,175)
Tangible assets	–	(226)	(12)	(238)
Lease items net value	–	256	14	270
Personnel-related items	596	3,304	240	4,140
Tax loss carried forward	9,666	5,065	588	15,319
Other items	4	18	1	23
<b>Total</b>	<b>(36,854)</b>	<b>8,417</b>	<b>1,776</b>	<b>(26,661)</b>

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

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

	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
Accounts receivable	–	78,703	–	78,703
Prepaid expenses and accrued income	–	2,287	–	2,287
Cash	–	1,249,094	–	1,249,094
	<b>–</b>	<b>1,341,295</b>	<b>–</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 and non-financial assets and liabilities as of December 31, 2021

	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	–	3,915	–	3,915
Cash	–	955,507	–	955,507
	<b>–</b>	<b>959,422</b>	<b>–</b>	<b>959,422</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	54,399	–	–	54,399
Non-current interest-bearing liabilities	–	189,164	–	189,164
Non-current lease liabilities	–	24,052	–	24,052
Accounts payable	–	67,971	–	67,971
Other current liabilities	–	9,591	3,111	12,702
Accrued expenses and deferred revenue	–	25,168	28,385	53,553
	<b>54,399</b>	<b>315,946</b>	<b>31,496</b>	<b>401,841</b>

Financial liabilities valued through profit or loss constitutes of contingent consideration of SEK 75,880 and SEK 54,399 as of December 31, 2022 and 2021, respectively. The fair value of contingent consideration is measured at Level 3 of the fair value hierarchy.

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.

# GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

## Note 20 Financial Risks

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 and liquidity 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.

Days past due, but not impaired, receivables on the closing balance is given below. Of accounts receivable net, SEK 71,825 is to an individual major customer as of December 31, 2022.

	December 31,	
Accounts receivable	2022	2021
Gross accounts receivable	79,873	-
Provisions, expected credit losses	(1,170)	-
<b>Net accounts receivable</b>	<b>78,703</b>	<b>-</b>
<b>Maturity structure accounts receivable</b>		
Accounts receivable, not yet due	79,873	-
Provisions, expected credit losses	(1,170)	-
<b>Net book value</b>	<b>78,703</b>	<b>-</b>
<b>Provisions for expected credit losses</b>		
Opening balance, expected credit loss provisions	-	-
This years provisions	(1,170)	-
<b>Closing balance, expected credit loss provisions</b>	<b>(1,170)</b>	<b>-</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.

### 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, 2022 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 sales and 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 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%

Currency exposure 2020 (%)	Revenue	Operating expenses
USD	100%	35%
EUR	-	36%
GBP	-	6%
SEK	-	23%

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 23,132, SEK 909 and SEK 10,247 in 2022, 2021 and 2020, 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 9,624, SEK 22,402 and pos. SEK 9,979 in 2022, 2021 and 2020, respectively.

### 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 48,771 and SEK 18,270 as of December 31, 2022 and 2021, respectively. A 10% stronger Swedish Krona against the U.S. dollar would have a positive impact on equity of approximately SEK 4,877 and SEK 1,827 as of December 31, 2022 and 2021, respectively. Translation against Euros amounted to SEK -322,135 and SEK -93,814 as of December 31, 2022 and 2021, respectively. A 10% stronger Swedish Krona against Euros would have a negative impact on equity of approximately SEK 32,214 and SEK 9,381 as of December 31, 2022 and 2021, 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 19,377 and SEK 29,236 as of December 31, 2022 and 2021, respectively, and in U.S. dollars SEK 80,655 and SEK 10,707 in Euros as of December 31, 2022 and 2021, 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 1,938 and SEK 2,924 as of December 31, 2022 and 2021, respectively. A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 8,065 and SEK 1,071 as of December 31, 2022 and 2021, 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.

December 31, 2022			
Maturity analysis	<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, 2021			
Maturity analysis	<6 months	6-12 months	2-5 years
Contingent consideration	-	-	54,399
Non-current interest-bearing liabilities	-	-	189,164
Non-current lease liabilities	-	-	24,052
Accounts payable	67,971	-	-
Other current liabilities	7,906	4,796	-
Accrued expenses	47,753	5,800	-

December 31,		
Non-current interest-bearing liabilities	2022	2021
Opening balance	189,164	-
New borrowings, net	491,745	199,524
Transaction costs paid	(1,260)	(14,858)
Interest expense	4,874	2,145
Exchange difference on translation	28,507	2,353
Closing balance	713,030	189,164

In July 2021, Calliditas signed a loan agreement of up to the euro equivalent of USD 75 million with Kreos Capital. The loan facility is divided into three tranches of USD 25 million each. Draw down of the first USD 25 million tranche was made in 2021. Draw down of the second tranche of USD 25 million was made in June 2022 and draw down of the third and final USD 25 million tranche was made December 2022. The interest rate on the loan is 9% per annum with a maturity to December 2025, which is recognized in Financial expenses. The loan has no financial covenants.

## Note 21 Inventories

December 31,		
	2022	2021
Raw materials	1,855	889
Work in progress	937	-
Finished goods	855	-
Total	3,647	889

Inventories recognized as cost of sales amounted to SEK 3,179 in 2022. No inventories were recognized as cost of sales in 2021 and 2020, respectively. No write-downs of inventories have occurred.

## Note 22 Prepaid Expenses and Accrued Income

December 31,		
	2022	2021
Accrued royalties	2,287	-
Prepaid insurance premiums	9,148	10,813
Prepaid interest costs	3,693	-
Prepaid expenses for research and development	45,454	27,888
Prepaid expenses for marketing and selling	8,194	-
Other prepaid expenses	1,964	6,331
Total	70,741	45,032

## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

### Note 23 Cash

	December 31,	
	2022	2021
Cash at Banks	1,249,094	955,507
<b>Total</b>	<b>1,249,094</b>	<b>955,507</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,		
	2022	2021	2020
Depreciations and impairments	12,913	34,433	2,823
Change in Provisions	(3,346)	5,856	6,634
Share-based payments	35,791	21,960	6,012
Change in Contingent consideration	15,941	4,470	-
Other items	(39)	(43)	(4)
<b>Total</b>	<b>61,260</b>	<b>66,676</b>	<b>15,465</b>

#### Reconciliation of liabilities from financing activities

	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>

	January 1, 2021	Cash-Flow	Non-Cash-Items	December 31, 2021
Non-current interest-bearing liabilities	-	184,667	4,497	189,164
Lease liabilities	4,786	(5,575)	34,431	33,642
	<b>4,786</b>	<b>179,092</b>	<b>38,928</b>	<b>222,806</b>

### Note 24 Group Companies

			% Equity Interest		
Company	Principal Activities	Country of Incorporation	2022	2021	2020
Parent Company					
Calliditas Therapeutics AB	Research and development of pharmaceuticals	Sweden	-	-	-
Subsidiaries					
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%	-
Calliditas Therapeutics France SAS	Research and development of pharmaceuticals	France	100%	100%	86.2%
Calliditas Therapeutics Suisse SA	Research and development of pharmaceuticals	Switzerland	100%	100%	86.2%

## Note 25 Equity

	Year Ended December 31,		
	2022	2021	2020
Total registered shares at the beginning of the year	52,341,584	49,941,584	38,707,638
New share issue*	-	2,400,000	9,937,446
Exercise of warrants	1,322,985	-	1,296,500
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>52,341,584</b>	<b>49,941,584</b>
<b>Shares</b>			
Ordinary shares	59,580,087	52,341,584	49,941,584
<b>Total</b>	<b>59,580,087</b>	<b>52,341,584</b>	<b>49,941,584</b>
- of which shares are held by Calliditas	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>52,341,584</b>	<b>49,941,584</b>

Share Capital	December 31,		
	2022	2021	2020
Opening balance	2,094	1,998	1,548
New share issue*	-	96	397
Exercise of warrants	53	-	52
Issuance of treasury shares	236	-	-
<b>Closing balance</b>	<b>2,383</b>	<b>2,094</b>	<b>1,998</b>

\* Initial public offering on The Nasdaq Global Select Market in the United States in June 2020 and the following exercise of the partial over-allotment option from the IPO in July 2020.

\* 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, with the exception of treasury shares held by Calliditas. The quotient value is SEK 0.04 per share.

### Transactions in Treasury Shares

Since 2020, Calliditas has had ordinary shares, in the form of American Depositary Shares ("ADSs"), listed in the United States on The Nasdaq Global Select Market. In 2022 Calliditas has implemented and launched an At-The-Market program ("ATM Program"). The purpose of the ATM Program is to efficiently and cost-effectively raise capital, if necessary, in the U.S. market and to ensure delivery of shares to be sold under the company's ATM Program.

In 2022, 5,908,018 series C shares were issued, which were repurchased and converted to ordinary shares by Calliditas. These transactions are in accordance with the granting mandate. In 2022, no shares were sold in the ATM Program.

### 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.

	December 31,		
	2022	2021	2020
Opening balance	(26,979)	(6,090)	(45)
Change of the year	36,286	(20,889)	(6,045)
<b>Closing balance</b>	<b>9,307</b>	<b>(26,979)</b>	<b>(6,090)</b>

## GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

### Note 26 Provisions

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>

Provisions as of December 31, 2021	Social Security Costs on Share-Based Payment	Other Provisions	Provisions, net
Opening balance	4,972	1,419	6,391
Provisions for the year	8,112	-	8,112
Exchange differences	-	27	27
<b>Total</b>	<b>13,084</b>	<b>1,446</b>	<b>14,530</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 share awards are used.

### Note 27 Contingent Consideration

	December 31,	
	2022	2021
Opening balance	54,399	48,969
Change for the year	15,942	4,470
Exchange differences	5,539	960
<b>Net book value</b>	<b>75,880</b>	<b>54,399</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 12.0 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 20.8% and 15.21% as of December 31, 2022 and 2021, respectively. A 10% higher probability of success in the clinical trials would have a negative impact on profit after tax of approximately SEK 7,588 and SEK 5,440 as of December 31, 2022 and 2021, 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

#### 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.

	December 31,	
Net obligation per country	2022	2021
Switzerland	(789)	(3,071)
France	(94)	(111)
<b>Total</b>	<b>(884)</b>	<b>(3,182)</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, 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 statement of consolidated operations</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 items of 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>

	Defined Benefit Plan Obligation (Switzerland)	Defined Benefit Plan Obligation (France)	Fair Value of Plan Assets (Switzerland)	Employee Benefit Obligations
<b>January 1, 2021</b>	<b>(19,193)</b>	<b>(172)</b>	<b>11,069</b>	<b>(8,296)</b>
Service costs	(2,165)	(13)	–	(2,178)
Interest expense	(17)	–	10	(7)
Curtailment*	12,011	–	(7,805)	4,206
Employee contribution	–	–	704	704
<b>Subtotal included in the statement of consolidated operations</b>	<b>9,829</b>	<b>(13)</b>	<b>(7,091)</b>	<b>2,725</b>
Amounts paid/received	291	–	(291)	–
Return on assets (excluding interest expenses)	–	–	64	64
Actuarial gains/(losses) related to changes in demographic assumptions	349	77	–	426
Actuarial gains/(losses) related to changes in financial assumptions	1,120	–	–	1,120
Other actuarial gains/(losses)	360	–	–	360
<b>Subtotal included in other items of comprehensive income</b>	<b>1,829</b>	<b>77</b>	<b>64</b>	<b>1,970</b>
Employer contributions	–	–	704	704
Currency translation effect	(698)	(3)	416	(285)
<b>December 31, 2021</b>	<b>(7,942)</b>	<b>(111)</b>	<b>4,871</b>	<b>(3,182)</b>

\*The change in the Curtailment refer to retirement obligation settlement connected to the departure of senior management member of Switzerland employees.



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

Distribution by Plan Assets (Switzerland)	December 31,	
	2022	2021
Cash	137	205
Bonds	3,048	2,801
Mortgage loans	655	667
Shares	126	92
Real estate	901	760
Other investments	372	346
<b>Total</b>	<b>5,238</b>	<b>4,871</b>

Of the plan assets above, SEK 3,048 and SEK 2,801 as of December 31, 2022 and 2021, 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,	
	2022	2021
<b>Swiss pension plan</b>		
Discount rate	2.30 %	0.35 %
Mortality table	LPP 2020 generation	LPP 2020 generation
Salary revaluation rate	1.00%	1.00%
Retirement pension inflation rate	0.50%	0.50%
Deposit rate on savings accounts	1.00%	1.00%
Turnover rate	10.00%	10.00%
Remaining life expectancy after retirement	18.6 years	22.3 years
Retirement age	65 years	65 years

Sensitivity Analysis	December 31,	
	2022	2021
Pension commitments under current assumptions for Swiss pension plans	6,027	7,942
Discount rate, -0,5%	6,615	8,904
Discount rate, +0,5%	5,518	7,130
Retirement pension inflation rate, -0,5%	5,797	7,575
Retirement pension inflation rate, +0,5%	6,281	8,353
Salary revaluation rate, -0,5%	5,927	7,792
Salary revaluation rate, +0,5%	6,131	8,100

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 813 and SEK 555 in 2022 and 2021, respectively. The weighted average maturity of the obligation is an estimated 18.6 and 22.3 years in 2022 and 2021, respectively.

## Note 29 Other Non-Current Liabilities

	December 31,	
	2022	2021
Opening balance	-	-
Additional liabilities	4,350	-
<b>Closing balance</b>	<b>4,350</b>	<b>-</b>

Additional liabilities are related to advance payments from customers.

## Note 30 Accrued Expenses and Deferred Revenue

	December 31,	
	2022	2021
Vacation pay liabilities	8,310	6,107
Accrued salaries and Board fees	28,186	16,786
Social security costs	7,065	5,492
Deferred revenue	-	3,387
Accrued rebates on sales	15,849	-
Accrued expenses for royalty	12,023	-
Accrued expenses for research and development	34,637	4,230
Accrued expenses for marketing and selling	21,543	1,242
Accrued expenses for administration	8,832	16,309
<b>Total</b>	<b>136,446</b>	<b>53,553</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 Change of presentation of expenses

From January 1, 2022, Calliditas has switched to presenting marketing and selling expenses separately from administrative expenses. The purpose of the change is to provide more relevant information about the Group's and the Parent Company's financial results and follow the practice in the industry for a company in commercial stage. The change constitutes a voluntary change and is applied with full retroactivity.

	Year Ended December 31,			Year Ended December 31,		
	2021	Re-classification	2021	2020	Re-classification	2020
Net sales	229,347	-	229,347	874	-	874
<b>Operating expenses</b>						
Research and development expenses	(357,485)	-	(357,485)	(241,371)	-	(241,371)
Marketing and selling expenses	-	(179,603)	(179,603)	-	(38,964)	(38,964)
Administrative expenses	(390,232)	179,603	(210,629)	(141,724)	38,964	(102,760)
Other operating income/expenses	(6,085)	-	(6,085)	2,501	-	2,501
<b>Operating loss</b>	<b>(524,456)</b>	<b>-</b>	<b>(524,456)</b>	<b>(379,720)</b>	<b>-</b>	<b>(379,720)</b>
Net financial income/(expenses)	11,083	-	11,083	(56,431)	-	(56,431)
<b>Loss before income tax</b>	<b>(513,373)</b>	<b>-</b>	<b>(513,373)</b>	<b>(436,151)</b>	<b>-</b>	<b>(436,151)</b>
Income tax	3,836	-	3,836	(360)	-	(360)
<b>Loss for the year</b>	<b>(509,537)</b>	<b>-</b>	<b>(509,537)</b>	<b>(436,511)</b>	<b>-</b>	<b>(436,511)</b>

## Note 33 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 in the future. 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.

The Group has pledged assets amounted to SEK 6,859 and SEK 3,915 as of December 31, 2022 and 2021, respectively, which consist of restricted bank accounts and lease deposits. The assets are pledged for the benefit of certain lessors and other suppliers. The Group has no other obligations.

## Note 34 Events After the Reporting Period

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 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 and the eGFR benefit was observed across the entire study population, irrespective of urine protein-to-creatinine ratio (UPCR) baseline, which the company believes supports a regulatory filing for full approval in the study population. The UPCR reductions observed were durable, reflecting a long-lasting treatment effect during the 15-month follow-up period off treatment.

## Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31,	
		2022	2021
Net sales	2	548,977	229,347
Cost of sales		(15,141)	-
<b>Gross profit</b>		<b>533,836</b>	<b>229,347</b>
Research and development expenses	7	(384,453)	(275,950)
Marketing and selling expenses	7	(310,372)	(151,125)
Administrative expenses	5,6,7	(212,971)	(226,349)
Other operating income	3	165,697	70,234
Other operating expenses	4	(7,101)	(1,874)
<b>Operating loss</b>		<b>(215,364)</b>	<b>(355,717)</b>
<i>Profit/(loss) from financial income/(expenses)</i>			
Other interest received and similar items	8	43,259	9,895
Interest expense and similar items	9	(36,443)	(8,583)
<b>Loss before income tax</b>		<b>(208,548)</b>	<b>(354,405)</b>
Income tax expense	10	-	-
<b>Loss for the year</b>		<b>(208,548)</b>	<b>(354,405)</b>

## Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31,	
		2022	2021
<b>Loss for the year</b>		<b>(208,548)</b>	<b>(354,405)</b>
Other comprehensive income/(loss) for the year		-	-
<b>Total comprehensive loss for the year</b>		<b>(208,548)</b>	<b>(354,405)</b>

## Balance Sheet

(SEK in thousands)	Note	December 31,	
		2022	2021
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible Assets</i>			
Licenses and similar rights	11	32,132	32,132
		<b>32,132</b>	<b>32,132</b>
<i>Tangible Assets</i>			
Equipment	12	567	514
		<b>567</b>	<b>514</b>
<i>Non-Current Financial Assets</i>			
Participations in Group companies	13	425,589	406,438
Receivables from Group companies	14	453,537	142,724
Other non-current financial assets	15	8,329	3,762
		<b>887,456</b>	<b>552,924</b>
<b>Total non-current assets</b>		<b>920,154</b>	<b>585,571</b>
<b>Current assets</b>			
Inventories	16	3,647	889
Accounts receivable		6,877	-
Receivables from Group companies		115,676	-
Other current assets		6,537	5,699
Prepaid expenses and accrued income	17	61,092	41,825
		<b>193,830</b>	<b>48,413</b>
<i>Cash</i>	18	1,059,655	894,455
<b>Total current assets</b>		<b>1,253,485</b>	<b>942,868</b>
<b>TOTAL ASSETS</b>		<b>2,173,639</b>	<b>1,528,439</b>

## Balance Sheet

(SEK in thousands)	Note	December 31,	
		2022	2021
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	19		
Restricted shareholders' equity			
Share capital		2,383	2,094
Statutory reserve		3,092	3,092
		5,475	5,186
Non-restricted shareholders' equity			
Share premium reserve		2,521,419	2,420,698
Retained earnings		(1,187,391)	(863,175)
Net loss for the year		(208,548)	(354,405)
		1,125,480	1,203,117
Total shareholders' equity		1,130,956	1,208,303
Non-current liabilities			
Provisions	20	9,512	9,075
Non-current interest-bearing liabilities	21	713,030	189,164
Liabilities to Group companies	24	105	105
Other non-current liabilities		4,350	-
Total non-current liabilities		726,997	198,344
Current liabilities			
Accounts payable		100,469	51,711
Liabilities to Group companies	24	138,173	31,121
Other current liabilities		3,577	2,345
Accrued expenses and deferred revenue	22	73,468	36,615
Total current liabilities		315,686	121,792
TOTAL SHAREHOLDERS EQUITY AND LIABILITIES		2,173,639	1,528,439



## 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, 2021</b>	<b>1,998</b>	<b>3,092</b>	<b>2,116,721</b>	<b>(479,378)</b>	<b>(407,363)</b>	<b>1,235,069</b>
Transfer of previous year's loss	-	-	-	(407,363)	407,363	-
	-	-	-	-	-	-
Loss for the year	-	-	-	-	(354,405)	(354,405)
Other comprehensive income/(loss) for the year	-	-	-	-	-	-
<b>Total comprehensive loss for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(354,405)</b>	<b>(354,405)</b>
<b>Transactions with owners:</b>						
New share issue	96	-	323,904	-	-	324,000
Costs attributable to new share issue	-	-	(19,927)	-	-	(19,927)
Share-based payments	-	-	-	23,566	-	23,566
<b>Total transactions with owners</b>	<b>96</b>	<b>-</b>	<b>303,977</b>	<b>23,566</b>	<b>-</b>	<b>327,639</b>
<b>Closing equity December 31, 2021</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>
<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) for the year	-	-	-	-	-	-
<b>Total comprehensive loss for the year</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)	-	95,120
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>131,200</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>

## Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31,	
		2022	2021
<b>Operating activities</b>			
Operating loss		(215,364)	(355,717)
Adjustments for non-cash items	18	17,584	19,805
Interest received		3,551	103
Interest paid		(33,648)	(4,837)
<b>Cash flow from operating activities before changes in working capital</b>		<b>(227,877)</b>	<b>(340,647)</b>
<b>Cash flow from changes in working capital</b>			
Changes in inventory		(2,758)	(949)
Changes in operating receivables		(144,845)	(91,290)
Changes in operating liabilities		212,279	40,076
<b>Cash flow from operating activities</b>		<b>(163,201)</b>	<b>(392,811)</b>
<b>Investing activities</b>			
Acquisition of participations in Group companies	13	-	(100,091)
Purchase of equipment	12	(269)	(526)
Investments in non-current financial assets	14	(282,391)	(70,966)
Repayment of non-current financial assets	14	1,948	-
Purchase of intangible assets	11	-	(16,066)
<b>Cash flow from investing activities</b>		<b>(280,712)</b>	<b>(187,648)</b>
<b>Financing activities</b>			
New share issue		-	324,000
Costs attributable to new share issue		-	(19,927)
Issuance of treasury shares		236	-
Repurchase of treasury shares		(236)	-
Exercise of warrants		95,121	-
New borrowings	21	491,744	199,524
Costs attributable to new loans		(1,260)	(14,857)
<b>Cash flow from financing activities</b>		<b>585,605</b>	<b>488,739</b>
<b>Net increase/(decrease) in cash</b>		<b>141,691</b>	<b>(91,720)</b>
<b>Cash at beginning of the year</b>		<b>894,455</b>	<b>978,208</b>
Exchange-rate difference in cash		23,509	7,967
<b>Cash at the end of the year</b>	18	<b>1,059,655</b>	<b>894,455</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 Financial 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 valued to the lower of cost or market.

### Leases

The Parent Company applies the exemption contained in RFR 2 for legal entities and record 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

	Year Ended December 31,	
	2022	2021
<b>Type of goods or service</b>		
Product sales	121,613	-
Outlicensing of product	421,689	225,252
Royalty income	2,287	-
Performance of certain regulatory services	3,387	4,096
<b>Total</b>	<b>548,977</b>	<b>229,347</b>
<b>Geographical markets</b>		
USA	118,345	-
Europe	143,955	201,878
Asia	286,677	27,469
<b>Total</b>	<b>548,977</b>	<b>229,347</b>

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

## Note 3 Other Operating Income

	Year Ended December 31,	
	2022	2021
Pass through costs	163,318	70,218
Exchange rate differences	-	16
Other income	2,379	-
<b>Total</b>	<b>165,697</b>	<b>70,234</b>

## Note 4 Other Operating Expense

	Year Ended December 31,	
	2022	2021
Exchange rate differences	7,101	1,807
Net loss on disposal of equipment	-	67
<b>Total</b>	<b>7,101</b>	<b>1,874</b>

## Note 5 Auditors' Fee

	Year Ended December 31,	
	2022	2021
<b>EY</b>		
Audit services	12,215	6,235
Other audit activities	3,370	2,105
Tax advice	-	73
<b>Total</b>	<b>15,585</b>	<b>8,413</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 6,310 and SEK 3,565 for the year ended December 31, 2022 and 2021, respectively. Future payment commitments for operating leases are specified as follows:

	Year Ended December 31,	
	2022	2021
<b>Future minimum lease payments</b>		
Within 1 year	9,445	6,540
Between 1-2 years	5,070	6,540
More than 2 years	-	5,755
<b>Total</b>	<b>14,515</b>	<b>18,835</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,	
	2022	2021
Interest income from Group companies	9,296	886
Other interest income	3,551	102
Exchange rate differences	30,412	8,907
<b>Total</b>	<b>43,259</b>	<b>9,895</b>

### Note 9 Interest Expense and Similar Items

	Year Ended December 31,	
	2022	2021
Interest expense	31,569	6,438
Other financial expenses	4,874	2,145
<b>Total</b>	<b>36,443</b>	<b>8,583</b>

### Note 10 Income Tax Expense

	Year Ended December 31,	
	2022	2021
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	(208,548)	(354,405)
Tax in accordance with applicable tax rate for the Parent Company 20,6%	42,961	73,007
<i>Tax effect on:</i>		
Tax attributable to unrecognized deferred tax assets for tax losses carried forward	(34,371)	(69,425)
Non-deductible expenses	(8,590)	(3,582)
<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 costs attributable to new share issue amounted to SEK - and SEK 19,927 in 2022 and 2021, respectively, which are recognized directly against equity. These costs are deductible for tax purposes.

The Parent Company has SEK 1,594,293 and SEK 1,432,462 of tax losses carried forward for which deferred tax assets have not been recognized in the statements of financial position as of December 31, 2022 and 2021, respectively. 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,	
	2022	2021
<b>Licenses and similar rights</b>		
<i>Cost at opening balance</i>	32,132	16 066
Acquisition for the year	-	16,066
<b>Cost at closing balance</b>	<b>32,132</b>	<b>32,132</b>
<b>Net book value</b>	<b>32,132</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,	
	2022	2021
<i>Cost at opening balance</i>	526	118
Acquisition for the year	269	526
Disposal for the year	-	(118)
<b>Cost at closing balance</b>	<b>795</b>	<b>526</b>
<i>Depreciation at opening balance</i>	(12)	(38)
Depreciation for the year	(216)	(25)
Disposal for the year	-	51
<b>Depreciation at closing balance</b>	<b>(228)</b>	<b>(12)</b>
<b>Net book value</b>	<b>567</b>	<b>514</b>

## Note 13 Participations in Group Companies

	December 31,	
	2022	2021
Cost at opening balance	410,177	298,998
Acquisition for the year	-	98,993
Shareholders' contributions	19,151	12,187
<b>Cost at closing balance</b>	<b>429,328</b>	<b>410,177</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>425,589</b>	<b>406,438</b>

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

Company / Corporate Registration Number / Registered office	December 31,	
	2022	2021
<b>Nefecon AB, 556604-9069, Stockholm</b>		
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>
<b>Calliditas Therapeutics NA Enterprises Inc., 83-4094951, USA</b>		
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>27,107</b>	<b>11,356</b>
<b>Calliditas Therapeutics US Inc., 86-3169403 USA</b>		
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>3,313</b>	<b>707</b>
<b>Calliditas Therapeutics France SAS, 439 489 022, France</b>		
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>395,069</b>	<b>394,275</b>

## Note 14 Receivables from Group Companies

	December 31,	
	2022	2021
Opening balance	142,724	1,485
Additional receivables	296,928	140,682
Repayment of receivables	(1,948)	-
Reclassification	(5,526)	-
Exchange differences	21,360	557
<b>Net book value</b>	<b>453,537</b>	<b>142,724</b>

## Note 15 Other Non-Current Financial Assets

	December 31,	
	2022	2021
Opening balance	3,762	1,939
Additional acquisition	4,349	1,823
Exchange differences	218	-
<b>Net book value</b>	<b>8,329</b>	<b>3,762</b>

## Note 16 Inventories

	December 31,	
	2022	2021
Raw materials	1,855	889
Work in progress	937	-
Finished goods	855	-
<b>Total</b>	<b>3,647</b>	<b>889</b>

## Note 17 Prepaid Expenses and Accrued Income

	December 31,	
	2022	2021
Accrued royalties	2,287	-
Prepaid rental charges	1,876	1,179
Prepaid insurance premiums	8,827	10,246
Prepaid interest costs	3,693	-
Prepaid expenses for research and development	43,472	27,465
Other prepaid expenses	937	2,935
<b>Total</b>	<b>61,092</b>	<b>41,824</b>



# PARENT COMPANY - NOTES TO FINANCIAL STATEMENTS

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

## Note 18 Cash

	December 31,	
	2022	2021
Cash at Banks	1,059,655	894,455
<b>Total</b>	<b>1,059,655</b>	<b>894,455</b>

### Adjustments for non-cash items:

	Year Ended December 31,	
	2022	2021
Depreciation	217	25
Change in Provisions	438	5,454
Share-based payments	16,929	14,259
Other	–	67
<b>Total</b>	<b>17,584</b>	<b>19,805</b>

### Reconciliation of liabilities from financing activities:

	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>

	January 1, 2021	Cash Flow	Non-Cash- Items	December 31, 2021
Non-current interest-bearing liabilities	–	184,667	4,497	189,164
<b>Total</b>	<b>–</b>	<b>184,667</b>	<b>4,497</b>	<b>189,164</b>

## Note 19 Shareholders' Equity

As of December 31, 2022, share capital consists of 59,580,087 shares, of which 5,908,018 shares are held by Calliditas. As of December 31, 2021 share capital consists of 52,341,584 shares. The quotient value of SEK 0.04 and SEK 0.04 as of December 31, 2022 and 2021, respectively. All shares hold has 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 profits. 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,	
	2022	2021
Share premium reserve	2,521,419	2,420,698
Retained earnings	(1,187,391)	(863,175)
Net loss for the year	(208,548)	(354,405)
	<b>1,125,480</b>	<b>1,203,117</b>
To be distributed as follows:		
<b>To be carried forward</b>	<b>1,125,480</b>	<b>1,203,117</b>

## Note 20 Provisions

	December 31,	
	2022	2021
Opening balance	9,075	4,972
Provisions for the year	641	4,103
Amounts claimed for the year	(204)	–
<b>Total</b>	<b>9,512</b>	<b>9,075</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,	
	2022	2021
<i>Due for payment between 1 and 5 years</i>		
Non-current interest-bearing liabilities	713,030	189,164
<b>Total</b>	<b>713,030</b>	<b>189,164</b>

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

## Note 22 Accrued Expenses and Deferred Revenue

	December 31,	
	2022	2021
Accrued salaries and Board fees	10,094	9,586
Vacation pay liability	5,475	4,155
Social security costs	6,875	2,769
Deferred revenue	–	3,387
Accrued expenses for royalty	12,023	–
Accrued expenses for research and development	33,642	2,049
Accrued expenses for marketing and selling	418	–
Accrued expenses for administration	4,941	14,670
<b>Total</b>	<b>73,468</b>	<b>36,615</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 33 Assets Pledged, Contingent Liabilities and Other Obligations. In the Parent Company restricted bank accounts amounts to SEK 3,978 and SEK 3,762 as of December 31, 2022 and 2021, respectively.

## Note 24 Related-Party Transactions

	Sales of Goods/ Services	Purchase of Goods/ Services	Other	Receivables on Closing Balance	Liabilities on Closing Balance
<b>Subsidiaries</b>					
2022	282,288	332,971	–	569,213	138,278
2021	70,218	91,786	–	142,724	31,226

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 International Financial Reporting Standards (IFRS), 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 25, 2023

Elmar Schnee  
*Board Chairman*

Renée Aguiar-Lucander  
*CEO*

Diane Parks  
*Board member*

Hilde Furberg  
*Board member*

Molly Henderson  
*Board member*

Henrik Stenqvist  
*Board member*

Elisabeth Björk  
*Board member*

Our audit report was submitted in April 26, 2023

Ernst & Young AB

Anna Svanberg  
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 2022. The annual accounts and consolidated accounts of the company are included on pages 36-83 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 2022 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 2022 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.

### 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, for the year ended December 31, 2022 the Group's revenues from product sales were 375,515 KSEK, and as is stated in Note 1 and Note 3, revenue from the sale of goods is calculated net of deductions including actual and estimated rebates to public payers and provisions for potential returns and prompt payment discounts. These estimates of variable consideration are affected by judgments made by management. A description of the judgments on which revenue recognition is based is provided in Note 2 "Significant Accounting Judgments, Estimates and Assumptions".

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 subjective management assumptions about expected future events, including return rates, rebates to public payers and prompt payment discounts. Changes in those assumptions can have a material effect on the amount of revenue recognized.

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

To test the estimate of variable consideration, our audit procedures included, among others, evaluating management's methodology and significant assumptions, and performing analytical procedures to compare the estimates of the rebate distributions between different payor categories, expected future returns and prompt payment discounts, against actual results where available. We also tested the completeness and accuracy of dispensing data and inputs used by the Company in its determination of the estimated payor mix, by agreeing it to third-party data. In addition, we involved our government pricing subject matter professionals to assist in evaluating management's methodology and calculations used to measure government rebates.

Finally, we have also reviewed the disclosures provided in the annual report.

### Valuation of intangible assets

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#### *Description*

Intangible assets for the Group and Parent Company amount to SEK 483,841 thousand and SEK 32,132 thousand, respectively, as of December 31, 2022. As explained in Note 1, Note 2 and Note 15 of the consolidated financial statements, the Company performs an impairment assessment of intangible assets not yet available for use and goodwill, on an annual basis or when there is an indication that an asset may be impaired. The Company's evaluation of the carrying value 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, taking into account the development risk. Changes in assumptions used by management could have a significant impact on the recoverable amount.

We determined the valuation of intangible assets to be a key audit matter, as auditing the valuation of intangible assets was complex due to the significant judgments made by management to estimate the recoverable amount, including the determination of the likely 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 valuation 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 so doing, 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 discount rates used, by preparing independent estimates based on market and peer company observable data and comparing to those used by management.

Finally, we have also 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 1-35 and 92-107. 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.



- 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 2022 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated (loss be dealt with) 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 2022.

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 ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and 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 19, 2022 and has been the company's auditor since April 15, 2004.

Stockholm, April 26, 2023  
Ernst & Young AB

Anna Svanberg  
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 2022 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 2022, Calliditas had 18,585 (19,879) shareholders and the ten largest shareholders owned 48.3 (59.1) % of all outstanding shares, excluding shares held by Calliditas. As of December 31, 2022, BVF Partners LP, Linc AB and Stiftelsen Industrifonden were the single largest shareholders in the company, excluding shares held by Calliditas, with 10.5%, 10.0% and 6.4%, respectively, of the votes and 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 until the future revenues substantially exceeds the cost of the development programs, 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.

## 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 2023

Calliditas' 2023 AGM will be held on Thursday, May 30, 2023, 10:00 at Klara, Klarabergsviadukten 90, Stockholm, Sweden.

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 2023 consists of:

- Patrik Sobocki, appointed by Stiftelsen Industrifonden
- Jan Särilvik, appointed by Fjärde AP-fonden
- 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 shareholder 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 2023 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 2022 AGM elected the registered firm of accountants Ernst & Young AB as auditor, up to



## CORPORATE GOVERNANCE REPORT

the 2023 AGM. The Auditor-in-Charge is Anna Svanberg. 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 2022, 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 2022

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	12/12	-	4/4	1,622
Lennart Hansson (until May 2022)	Board Member	2009	Yes	Yes	4/4	2/2	2/2	233
Hilde Furberg	Board Member	2014	Yes	Yes	12/12	7/7	-	651
Diane Parks	Board Member	2019	Yes	Yes	11/12	-	4/4	729
Molly Henderson	Board Member	2020	Yes	Yes	12/12	5/7	-	817
Henrik Stenqvist (from May 2022)	Board Member	2022	Yes	Yes	4/8	2/5	-	349
Elisabeth Björk (from May 2022)	Board Member	2022	Yes	Yes	7/8	-	2/2	261

## Work of the Board in 2022

During 2022, the Board of Directors held a total of 12 meetings, of which 6 were ordinary and 6 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 900,000 to the chairman of the Board of Directors and SEK 350,000 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), Molly Henderson 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 seven meetings in 2022. The company's auditors took part in four 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 four meetings in 2022. 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 19, 2022.

## Remuneration of the CEO and Executive Management 2022

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 60% 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 percent 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 consists of seven individuals and includes, 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 executive management 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 100-103 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.

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## 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 2022 on pages 92-97 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 26, 2023  
Ernst & Young AB

Anna Svanberg  
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 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, 14,063 share awards in LTIP 2020, 10,624 share awards in LTIP 2021 and 13,926 share awards in LTIP 2022. 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 in Engineering 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 fields of rare diseases, 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 Manager/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:** Hilde is currently an industrial advisor to Investinor and Board member of PCI Biotech, OncoZenGe, Herantis Pharma, Sedana Medical and Bio-Me.

**Holdings in the Company:** Hilde Furberg holds 53,199 shares in the Company, 4,327 share awards in board LTIP 2020, 4,086 share awards in LTIP 2021 and 5,356 share awards in LTIP 2022. 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:** Henrik is also a Board member in Midsona AB.

**Holdings in the Company:** Henrik Stenqvist holds 10,000 shares in the Company and 5,356 share awards in LTIP 2022. 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 CTI BioPharma, TriSalus Life Sciences, Kura Oncology, Soligenix and Celularity.

**Holdings in the Company:** Diane Parks holds 8,449 shares in the Company, 4,327 share awards in board LTIP 2020, 4,086 share awards in LTIP 2021 and 5,356 share awards in LTIP 2022. Independent in relation to the Company and its management and in relation to major shareholders.



## Molly Henderson

### Non-executive Director

Born 1970.  
Board member since 2020.

**Education:** M.B.A. and B.S. degree from the State University of New York at Buffalo.

**Board Committees:** Member of the Audit Committee.

**Experience:** Molly Henderson has served as the CFO of several listed life science companies for over 17 years. Currently, she is the CFO of Phathom Pharmaceutical, Inc. She was previously the CFO of Urogen and Executive Vice President of Advaxis, Inc., the CFO of Iovance Biotherapeutics, Inc. (formerly Lion Biotechnologies, Inc.) and before that the Chief Business and Financial Officer and Senior Vice President of VirtualScopics, Inc. Molly has also advised start-up companies in Switzerland, and was a Manager in the audit division of PricewaterhouseCoopers LLP.

**Other current assignments:** CFO of Phathom Pharmaceuticals, Inc.

**Holdings in the Company:** Molly Henderson holds 100 shares in the Company, 4,327 share awards in board LTIP 2020, 4,086 share awards in LTIP 2021 and 5,356 share awards in LTIP 2022. 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 is 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. 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, Chalmers University of Technology, Chalmers Ventures.

**Holdings in the Company:** Elisabeth Björk holds 5,356 share awards in LTIP 2022. 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.

**Holdings in the Company:** Renée Aguiar-Lucander holds 643,000 shares in the Company and 591,000 options<sup>1</sup>.



**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 205,000 options<sup>1</sup>.

<sup>1</sup> Holding in ESOP 2020, ESOP 2021 and/or ESOP 2022



## 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 share in the Company and 95,000 options<sup>1</sup>.



## Andrew Udell

### *President, North America*

Born 1970.  
Head of North America Commercial since 2019.

**Education:** BSc from Lehigh University. MBA from the University of Connecticut.

**Experience:** Andrew Udell has more than 20 years of commercial experience in the pharmaceutical industry. Before joining Calliditas, Andrew worked as Vice President of North America Commercial at NeuroDerm. Andrew began his career in the pharmaceutical industry at Purdue Pharma and held several sales and marketing positions, including responsible for the company's brands and led a multifunctional team for a multi-billion pain medication franchise.

**Holding in the Company:** Andrew Udell holds 26,000 share in the Company and 235,000 options<sup>1</sup>.

# 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. Member 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 biotech. 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.

**Holding in the Company:** Richard Philipson holds 185,000 options<sup>1</sup>.



**Jonathan Schur**

*Group General Counsel*

Born 1953.  
Group General Counsel since 2020.

**Education:** Bachelor's Degree in 1975 from Harvard University, J.D from Harvard Law School.

**Experience:** Jonathan Schur has over 40 years of experience as a lawyer, is a member of the New York Bar, and a former member of the Paris Bar. Prior to joining Calliditas, Mr. Schur was a Partner in the Life Sciences practice group at Goodwin Procter LLP, and before that a partner and co-managing partner of the Paris Office of Dechert LLP.

**Holding in the Company:** Jonathan Schur holds 165,000 options<sup>1</sup>.

<sup>1</sup> Holding in ESOP 2020, ESOP 2021 and/or ESOP 2022



## 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.

**Holding in the Company:** Sandra Frithiof holds 75,000 options<sup>1</sup>.



# 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, 2023	May 16, 2023
Annual General Meeting 2023	May 30, 2023
Interim Report for the period January 1–June 30, 2023	August 17, 2023
Interim Report for the period January 1–September 30, 2023	November 16, 2023
Year-End Report for the period January 1–December 31, 2023	February 22, 2024



# 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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