



ANNUAL REPORT

2021

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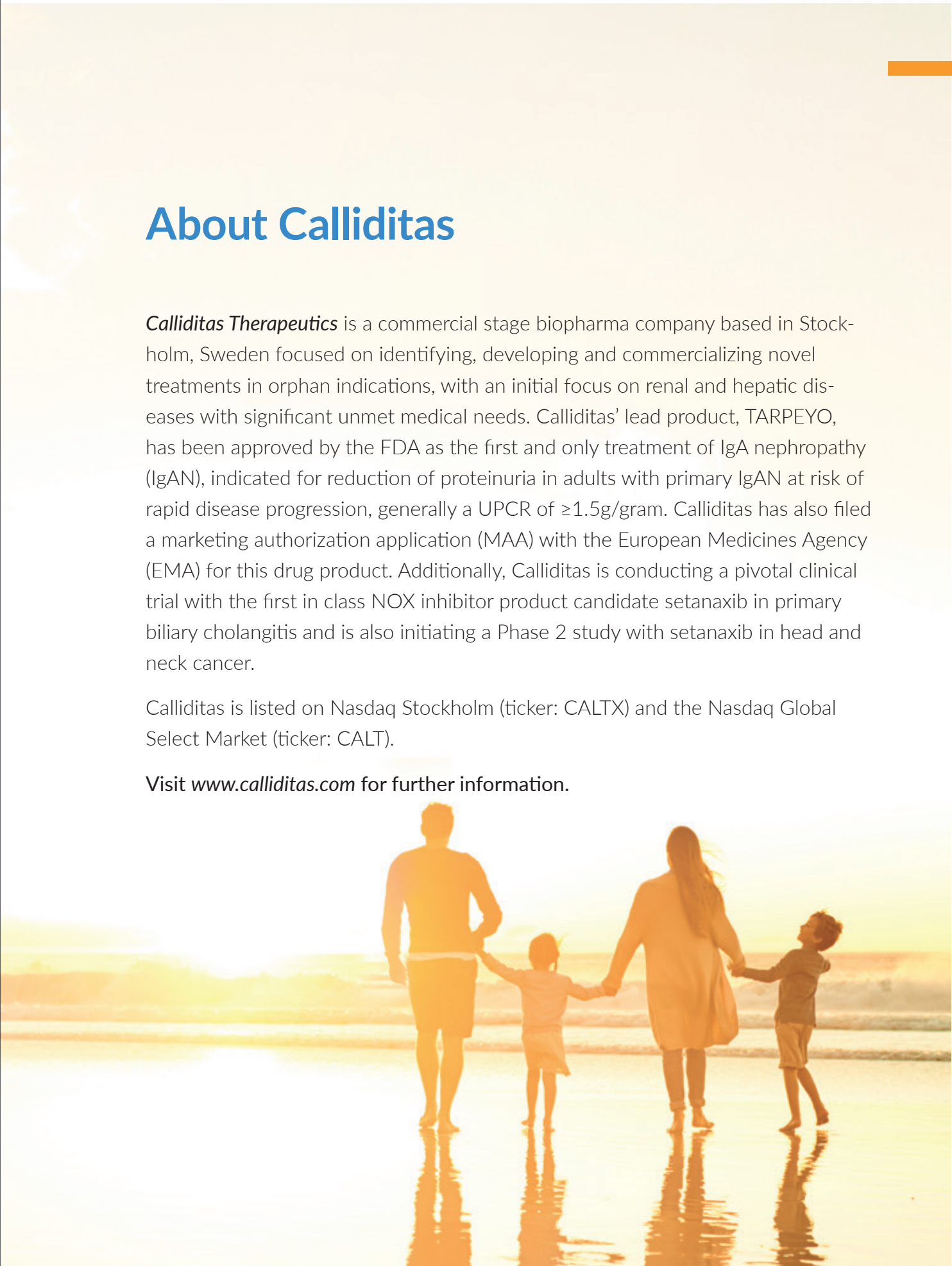
The Annual Report of Calliditas Therapeutics AB (publ), 556659-9766, is comprised of directors report, the Group's and the Parent Company's financial statements with notes and audit report (pages 28-85).

# 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, TARPEYO, has been approved by the FDA as the first and only treatment of IgA nephropathy (IgAN), indicated for reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR of  $\geq 1.5\text{g/gram}$ . Calliditas has also filed a marketing authorization application (MAA) with the European Medicines Agency (EMA) for this drug product. Additionally, Calliditas is conducting a pivotal clinical trial with the first in class NOX inhibitor product candidate setanaxib in primary biliary cholangitis and is also initiating a Phase 2 study with setanaxib in head and neck cancer.

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

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



## Business highlights

» In January 2021, Calliditas announced the clinical development plan for setanaxib and presented additional data from Part A of the NeflgArd study at the company's R&D Day. Calliditas set out plans to initiate a pivotal Phase 2/3 study in PBC. In addition, Calliditas set out plans to initiate a Phase 2 proof-of-concept study in head and neck cancer, which would study administration of setanaxib in conjunction with immunotherapy targeting CAFs (cancer associated fibroblasts). Calliditas also provided some additional information regarding the recently concluded Part A of the Phase 3 study NeflgArd. The data presented included overall baseline characteristics, rate of discontinuation of study treatment (9.5%) and rate of discontinuation from the study (3.5%). It was also confirmed that no adverse clinical effects were seen with regards to weight gain, blood pressure or HbA1c, reflecting a safety profile in keeping with the Phase 2b trial.

**In March 2021**, Calliditas announced the submission of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for Nefecon in patients with primary IgA Nephropathy, seeking accelerated approval under Subpart H for the 505(b)(2) application.

» In April 2021, Calliditas announced that the FDA accepted the submission for the NDA for Nefecon.

» In May 2021, Calliditas announced that the company submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Nefecon.

» In July 2021, Calliditas signed a loan agreement of up to the EUR equivalent of \$75 million with Kreos Capital. The loan facility is divided into three tranches of \$25 million each. Drawdown of the first \$25 million tranche was made in September, 2021. Drawdown of the second tranche of \$25 million can be made until June 30, 2022 and became available when the FDA granted accelerated approval of TARPEYO.

Drawdown of the third and final \$25 million tranche can be made until 31 December 2022 and will be available subject to certain revenue milestones and coverage metrics.

» In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize Nefecon for the treatment of IgAN in the EEA member states, Switzerland and the UK valued at a total of EUR 97.5 million (\$115m) in initial upfront and potential milestone payments, plus tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

» In August 2021, Calliditas received FDA fast track designation for setanaxib in PBC.

» In August 2021, Calliditas completed an accelerated book building procedure and resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of SEK 324.0 million before transaction costs.

**In December 2021**, Calliditas announced that the US Food and Drug Administration (FDA) approved TARPEYO (budesonide) delayed release capsules to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5\text{g/g}$ .

## Financial summary for the Group

	2021	2020	2019	2018	2017
Net sales (SEK in thousands)	229,347	874	184,829	-	-
Loss before income tax (SEK in thousands)	(513,373)	(436,151)	(32,501)	(132,049)	(86,794)
Cash (SEK in thousands)	955,507	996,304	753,540	646,175	57,352
Total assets (SEK in thousands)	1,459,910	1,463,908	845,200	648,417	62,288
Average number of employees	56	23	14	10	10



» The successful approval of NEFECON is the result of the incredibly hard work and dedication of a diverse and extraordinary group of people, working as a team towards the common goal of addressing the unmet medical need of patients with this rare disease.«



## Approval!

2021 was a transformative year for Calliditas, as our lead product NEFECON was granted accelerated approval in the US by the FDA under the brand name of TARPEYO. This was the first time that the FDA's cardio renal division granted an accelerated approval in a nephrology indication, a milestone event that we are very proud to be a part of.

Calliditas has actively been pioneering research and development in this rare kidney disease for well over a decade and we are therefore overjoyed that patients in the US suffering from IgAN now have access to a medication which has been through the FDA's rigorous review process. The full indication granted is reduction of proteinuria (the endpoint of the Phase 3 trial) in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, generally a UPCR of 1.5g/gram. It is well established that patients with higher levels of UPCR have a worse outlook and prognosis with regards to their progression towards end stage renal disease, so it is even more important for these patients to obtain a reduction in proteinuria and to ensure that their kidney function (measured by eGFR) is stabilized as quickly as possible.

Discussions regarding how to target the actual origin of the disease started in the late 1990's between Professors Fellström and Hällgren, who were focused on delivering a drug agent to the ileum where the production of the secretory IgA antibodies are thought to originate. The focus on local treatment remains just as novel and intriguing today as it was then. Calliditas was convinced of the value of this approach and designed a drug development program focused on achieving disease modification by targeting the production of these secretory antibodies, a brave and ambitious decision. Development programs of any kind are inherently complex and can run into various problems along the way, so it was therefore extremely gratifying to see this approach produce such strong clinical results.

The Phase 3 program is still ongoing, as there is an integrated confirmatory part which has the purpose of complementing the existing data with longer term outcome data related to the impact of the treatment on the kidney function over a longer period of time. This final part of the Phase 3 program will form the basis of a submission for full approval.

The successful approval of NEFECON is the result of the incredibly hard work and dedication of a diverse and extraordinary group of people, working as a team towards the common goal of addressing the unmet medical need of patients with this rare disease. To date, clinical trials involving over 365 patients across three separate programs have successfully read out, with over 100 patients still enrolled across our Phase 3 program and our open label extension study. Calliditas' CMC department has provided clinical trial material, and successfully generated and overseen formulation improvements, upscaling of manufacturing and supply chain management to deliver a commercial product in a timely manner. The regulatory group has expertly provided both strategic and tactical insight and support for the entire regulatory process, including recently managing parallel EMA and FDA submissions.

Market access and medical affairs have brought insight from healthcare professionals and the payor universe, conducted hundreds of interactions with groups and individuals to inform the organization and provided relevant input for critical decision making. Marketing and commercial have worked to create and implement all of the systems, resources, structures and materials required for the commercial launch, while legal, HR, IT and finance have all worked in tandem to ensure that our resources, compliance, communication, integration and reporting have kept up with the increasing demands and opportunities of a fast paced and growing organization, one which was transforming from an R&D

focused organization to an integrated, global research and commercial business. It has been a privilege to help guide and participate in this amazing journey over the past 5 years, and I am confident that this is just the beginning of our evolution into a broad-based biopharma business with the requisite talent, resources and science to continue to deliver enduring value to all of our stakeholders.

In addition to the work conducted on the NEFECON development program, we also significantly advanced our other pipeline program, with setanaxib as the lead compound. We received fast track designation in PBC from the FDA in August and completed preparations allowing us to initiate a pivotal program in PBC before the end of the year. In parallel, we also prepared to start a Phase 2 program in head and neck cancer. We are extremely excited about the future of this first in class platform of NOX inhibitors and believe that there is great potential to advance this platform across orphan diseases. Recruitment in an investigator-led Phase 2 clinical trial in IPF is progressing very well despite the challenges presented by the COVID-19 pandemic, and we look forward to the trial potentially being fully recruited already in 2022. We are also targeting the read out of our interim analysis of our Phase 2 trial in head and neck cancer in 2022, as well as the potential conditional approval of NEFECON in Europe and the regulatory submission of NEFECON in China.

Our hard work and preparation in 2021 has put us in a strong position to deliver on our plans in the year to come, as we look forward to our first year as a commercial stage company. It will be another exciting year for Calliditas!

**Renée Aguiar-Lucander, CEO**



## REGULATORY SUBMISSIONS

# 2021: The culmination of a long but exciting regulatory journey

At the end of the year, Calliditas achieved a huge milestone when the FDA approved our drug for IgA nephropathy, an achievement that was the result of over a decade of clinical development and regulatory interaction.

This journey began with discussions on how to target the origins of this autoimmune kidney disease in the 1990s between Professors Fellström and Hällgren, who patented the underlying concept to target the gut, the presumed origin of the disease. Two decades later, Calliditas submitted two landmark regulatory filings with the FDA and EMA, seeking approval in this indication for the first time.

The regulatory undertaking began with a Phase 2a trial in 16 Swedish patients, who were treated for six months followed by a three month follow up period, which read out positive data in 2009. The following year, Calliditas was granted US orphan drug designation for this product, by then named Nefecon. This laid the foundation for the company to initiate the largest, at the time, study ever conducted in IgA nephropathy, a Phase 2b randomized double-blinded, placebo-controlled clinical trial assessing the safety and efficacy of two different doses of Nefecon over a nine-month treatment period. This study, named NEFIGAN, was conducted in 62 centers across 10 European countries;

it originally intended to recruit 90 patients but over-recruitment almost doubled this number, and ultimately the study read out positive data on over 150 patients. It was at the end of Phase 2b meeting in January 2017 that Calliditas received a groundbreaking acceptance of proteinuria as a surrogate marker for accelerated approval, which marked the first time that the FDA allowed the use of this surrogate endpoint for a Phase 3 nephrology study.

Calliditas helped to pioneer this regulatory pathway, collaborating on a meta-analysis – published in 2016 – with Professor Inker at Tufts University and the National Kidney Foundation that examined the correlation between changes in urine protein and clinical endpoints at individual and trial levels.

Calliditas subsequently agreed with the FDA on the design for our Phase 3 NeflgArd study, which is still ongoing with a total of 360 patients as a randomized, double blinded and placebo controlled trial for confirmatory purposes, and closely echoes the NEFIGAN trial.



The first patient was enrolled in November 2018, and two years later Calliditas read out positive topline data from Part A, with statistically significant results both for the primary endpoint of proteinuria reduction, as well as for eGFR at 9 months, which alongside the results of the NEFIGAN trial formed the basis for the submission of an NDA with the FDA, which sought accelerated approval under Subpart H for the 505(b)(2) application. To compile all the data and materials that had been accumulated over a decade of clinical development was an enormous undertaking: thousands of pages, graphs and tables needed to be produced, edited, reviewed and double checked. Our NDA consisted of 1,198 documents which, if printed, would amount to 75,533 pages.

Shortly after this submission, we also filed an MAA with the EMA. Though some of the documents used in the NDA filing could be used also for the regulatory process in Europe, many were EU specific and thus had to be created, compiled and checked separately. The MAA ultimately consisted of 576 documents amounting to a total of 38,442 pages, submitted as one electronic document with 18,896 links and 4,055 hyperlinks. Both of these submissions, which were filed on time as planned, represented a hugely significant achievement and reflected the hard work of many different people in the company, guided by our regulatory team.

The FDA's approval of our drug, TARPEYO, on December 15 2021, was the perfect culmination of this long and rigorous regulatory journey, and most importantly finally brought a product to market for IgAN patients who have long been waiting for a drug specifically designed and approved for this rare indication.

The Biotechnology innovation organization Amplion and Biomedtracker recently published the largest study of clinical drug development success rates to date, covering 2006-2015 and a total of 9,985 clinical and regulatory phase transitions. The study aimed to measure clinical development success rates with a broad set of data to strengthen benchmarking metrics for company sponsored, FDA registration enabling drug development programs. It revealed that only 9.6% of drug development programs from start to finish successfully make it to market. In 2021 specifically, there were 95 total approvals by the FDA, and we were incredibly proud to be counted among them. It is truly exciting to be leading the field globally in this indication after many years of development and collaboration within the area of nephrology.



## TARPEYO APPROVAL

# TARPEYO: First ever approved treatment for IgAN

On December 15th, 2021, the US Food and Drug Administration granted accelerated approval of Calliditas' lead product, TARPEYO, indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally defined as a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$ g/g.

»TARPEYO (developed under the project name NEFECON) is the first ever and only approved FDA-approved treatment for IgA Nephropathy«

TARPEYO is an oral, delayed release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism.

TARPEYO is designed as a 4 mg delayed release capsule with an enteric coating so that it remains intact until it reaches the ileum. Each capsule contains beads coated with polymers and budesonide designed to target mucosal B-cells responsible for the production of the galactose-deficient IgA1 antibodies (Gd-Ag1) that are believed to cause IgA nephropathy.

TARPEYO was approved by the FDA under the accelerated approval pathway, based on achieving its primary endpoint of reduction in proteinuria in Part A of the NeflgArd pivotal Phase 3 study, an ongoing, randomized, double-blind, placebo-controlled, multi-center study conducted to evaluate the efficacy and safety of TARPEYO 16 mg once daily vs placebo in adult patients with primary IgAN.

The effect of TARPEYO was assessed in patients with biopsy-proven IgAN, eGFR  $\geq 35$  mL/min/1.73 m<sup>2</sup>, and proteinuria (defined as either  $\geq 1$  g/day or UPCR  $\geq 0.8$  g/g) who were on a stable dose of maximally-tolerated RAS inhibitor therapy. Part A of the study included a 9-month blinded treatment period and a 3-month follow-up period. The primary endpoint was UPCR, and eGFR was a secondary endpoint.



*"As a IGAN patient the approval of Tarpeyo finally gives hope for new treatment. I am thankful for Calliditas to see the need and spend the time to be the first company to get a treatment for FDA approval."*

- John



*"I was ecstatic to hear of the FDA approval of Tarpeyo. It is a beacon of light for the IgAN community, a community that has been waiting for a designated treatment of the illness, not just the symptoms, for so long. We finally have hope, and I cannot wait to see the positive impact this approval will have on our community."*

- Judy

Patients taking TARPEYO showed a statistically significant 34% reduction in proteinuria from baseline vs 5% in the placebo cohort at 9 months. The treatment effects for the primary endpoint of UPCR at 9 months were consistent across key subgroups, including key demographic and baseline disease characteristics.

The second part of the NeflgArd study, Part B, is a confirmatory validation study in which no TARPEYO treatment will be administered and which will assess eGFR at two years. Each patient will be dosed for 9 months and then monitored off-drug for the

remainder of the trial period, generating an aggregate of 15 months of follow-up data. Calliditas intends to complete Part B in early 2023, subject to any impact from the COVID-19 pandemic to our business.

Calliditas has been granted orphan drug designation for the treatment of IgAN in the United States and is commercializing TARPEYO in the US on its own.

# 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

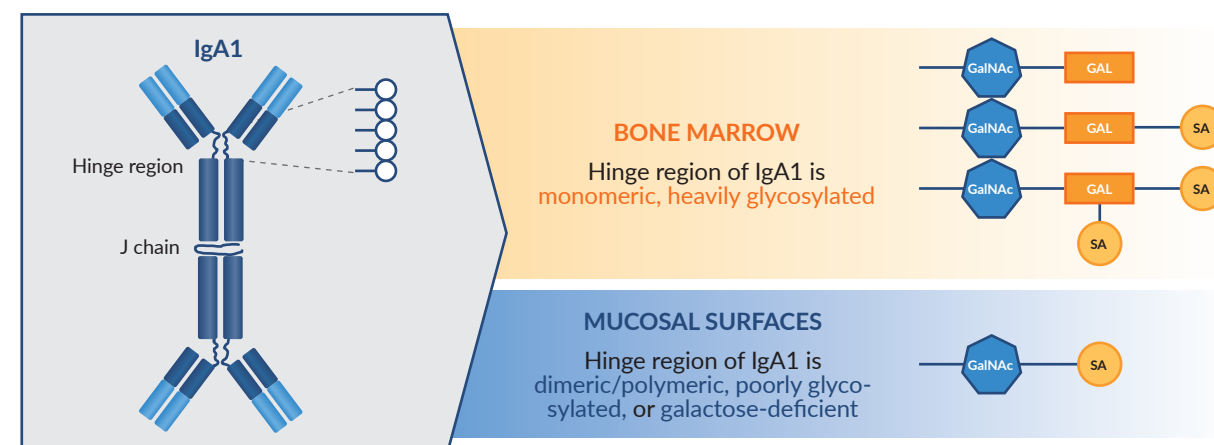
IgAN is a serious progressive autoimmune disease of the kidney, in which up to 50% of patients end up at risk of developing end-stage renal disease (ESRD) within ten to twenty years. The standard of care for ESRD is dialysis or kidney transplant, which represents a significant health economic burden 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 we estimate that IgAN affects approximately 2,000,000 people.

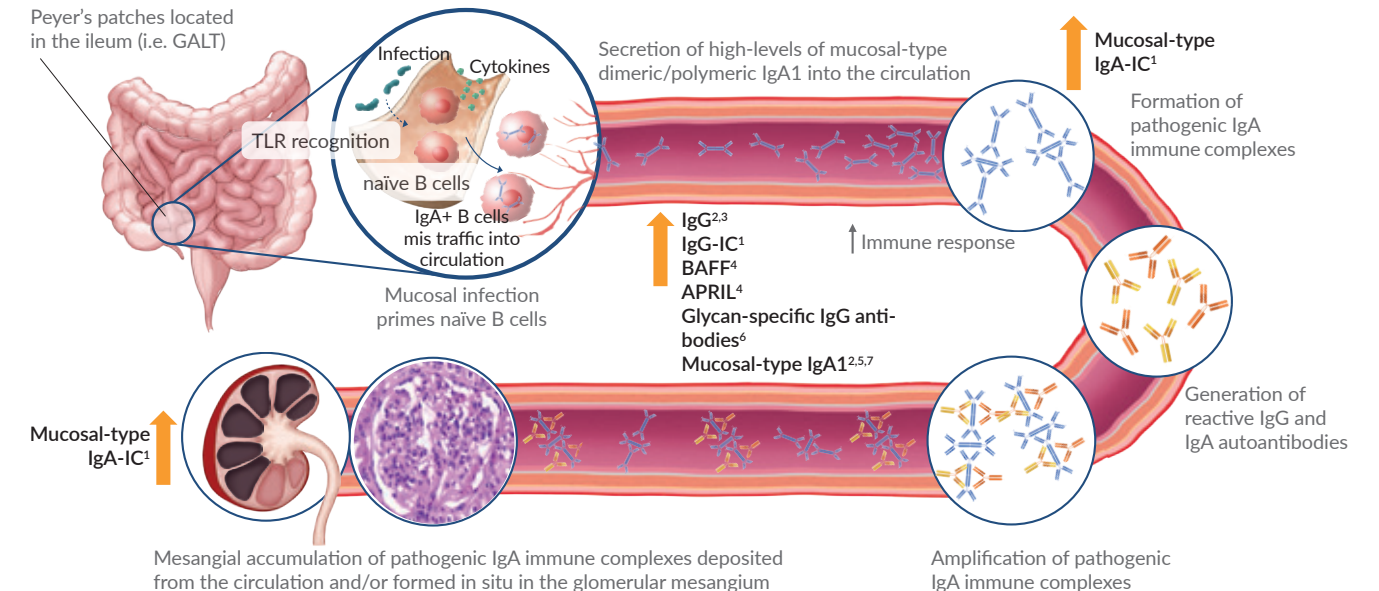
## IgAN Pathophysiology

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 envi-



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



ronmental, 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

With the exception of TARPEYO, which is approved in the United States, there are currently no approved treatment options for IgAN. 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 reduces the pressure in the kidney glomeruli, thereby reducing leakage and protein excretion in urine. Treatment via RAS inhibition is supportive only, and does not address the underlying cause of IgAN.

In the absence of approved treatments, some physicians try to control the disease progression with a variety of off-label treatments that include systemic immunosuppressive agents, usually high doses of systemic corticosteroids. However, research is inconclusive as to whether or not it has any impact on the actual underlying kidney disease as measured by eGFR. In addition, this off label treatment is known to result in serious adverse events. There is therefore a high unmet medical need for a treatment that targets the disease origin and can also be well-tolerated by IgAN patients.



## Commercialization in the US

» During 2021 we secured the necessary partnerships to ensure an efficient, timely and optimal launch strategy.«

### The US Market

Calliditas is commercializing TARPYO in the US with a targeted commercial infrastructure and primary focus on the specialist physicians (nephrologists) treating the IgAN patient population. We estimate the prevalence of IgAN in the US to be between 130,000 – 150,000 with up to 50% of these patients progressing and ending up at risk of developing end stage renal disease (ESRD.)

### Commercial Launch Readiness

In 2021, Calliditas was focused on getting its commercial infrastructure in place in preparation for an FDA approval. Calliditas focused its pre-commercial efforts on disease education, market access and patient advocacy with the goal of facilitating appropriate access to TARPYO for the patients for which it can fulfil an unmet medical need. Prior to approval, the focus was on medical education supported by unbranded disease state education and preparations, as well as market access preparations to ensure the successful commercialization of TARPYO in early Q1 2022.

We have an experienced medical affairs, market access, marketing, and sales leadership team, with an average tenure of over 20 years. In March, we welcomed three additional industry veterans to the Calliditas team responsible for key functional areas of Medical Affairs, Marketing and Sales. Warren Brooks, PhD, our Vice

President of US Medical Affairs, joined Calliditas from Regeneron, where he served as a Senior Director, National Lead in Immunology in Medical Affairs. Teona Johnson, Head of US Marketing, joined Calliditas after spending over 10 years in leadership roles in marketing at Pfizer Inc and bringing over 15 years of marketing experience which includes a proven track record of successfully launching and growing brands in the biopharmaceutical industry. Our Head of Sales, David Ferraro, joined the team from Kyowa Kirin, Inc., a global specialty pharmaceutical company, where he served as the National Sales Director for the Oncology / Rare Disease business unit.



### Medical Affairs:

Our medical science liaison team, which was initially formed in early 2020, continued its work in establishing relationships and collaborating with our advisory boards and with key opinion leaders (KOLs) on how to best address and educate our audience. In 2021, we were also well published and active

at the relevant congresses, attending the International Symposium on IgA Nephropathy (IIGANN), the ERA EDTA Congress and the International Symposium on IgA Nephropathy (IIGANN). Calliditas also published two posters at the American Society of Nephrology

(ASN) Digital Kidney Week 2021 in the 'Glomerular Diseases: Immunology and Inflammation in IgANP, C3GP, TMA, and Nephrotic Diseases' session. Dr Karen Molyneux from the Mayer IgA Nephropathy Laboratory at the University of Leicester presented a poster titled "Targeted Release Formulation Budesonide Selectively Reduces Circulating Levels of Chemokines Critical to Immune Cell Trafficking to Peyer Patches in IgA Nephropathy". In addition, Laura Pérez-Alós presented research on how "Treatment with Targeted Release Formulation Budesonide Modulates the Complement System in Patients with IgA Nephropathy".

### Market Access:



Calliditas has done extensive work in market access over the past several years. During 2021 we developed and implemented the optimal trade and distribution path for TARPYO. This included selecting and partnering with two of the industry's best in ICS from AmerisourceBergen

and our exclusive specialty pharmacy Biologics, a McKesson company.

Our national account managers were in the field in the months leading up to approval, holding and arranging meetings with payers to educate them on IgAN – as this marked the first time that a company approached them to treat this rare disease. TARPYO is priced according to the value it offers patients and towards reducing IgAN disease burden on society. Value was assessed according to clinical, economic, and societal benefits, factoring in both established and innovative treatments that are currently available. We believe health insurance will provide broad coverage of TARPYO, and Calliditas is committed to help ensure that all appropriate patients will have access to this medication.

Upon approval we launched TARPYO Touchpoints™, a full-service patient and provider support program, offering services, assistance and resources designed to accelerate and streamline access to TARPYO for the appropriate patients. The program utilizes Biologics by McKesson's PharmacyElite™ model, which integrates the Hub and exclusive Specialty Pharmacy services under one roof. We have a dedicated team of Care Navigators (dedicated Case Managers), as well as a designated Rare Pod Team which contains nurses, pharmacists, and a fulfilment and distribution team.

### Sales Force Readiness

Our Head of Sales, David Ferraro, has brought on a tenured sales management team, who spent Q2 and Q3 recruiting territory representatives based on rare disease, specialty product, and nephrology market experience. This was extremely important to us as we prepared for both in-person and remote interactions with our target audience. Calliditas had filled all sales territories with contingent offers that became effective upon FDA approval. Our field force of 40 sales representatives is sized and designed to provide the optimal reach and frequency of nephrologists treating the IgAN patient population. Our sophisticated segmentation, targeting and customer relationship management system will prepare the field force to begin face to face promotion in early Q1 2022.

In summary, during 2021 we secured the necessary partnerships to ensure an efficient, timely and optimal launch strategy. Our trade, distribution and patient support services were all operational and our launch campaigns were developed and tested for both in person and remote interactions in advance of approval. We continued to build on our work with an eager, focused, and receptive nephrology and IgAN advocacy community and remained on target for a commercial launch of TARPYO in the US in January 2022. Calliditas officially announced the commercial availability and initial sales of TARPYO on January 28th 2022.





## Interview with Dr. Brad Rovin



Dr Brad Rovin is the Director of the Division of Nephrology and the Vice Chairman of Medicine for Research at the Ohio State University Wexner Medical Centre. He is also the Lee A. Hebert Distinguished Professor of Nephrology at OSU. As a nephrologist, Dr. Rovin specializes in autoimmune kidney diseases, with a focus on how the immune system interacts with the kidney and causes renal inflammation and injury.

### Historically, what have the challenges been when approaching the treatment of IgAN?

The biggest challenge is trying to tell the patient that after many years of study we still don't know how to treat IgAN, and all that can be offered is good blood pressure control, RASi inhibition, and systemic glucocorticoids, with all of their side effects.

### What does it mean broadly for nephrologists and patients to have the first approved medication for this indication?

Several important points. It shows that the nephrology community, the IgAN patient community, and the FDA can all work together to make progress in this disease. I think it also give patients hope and faith in the medical research enterprise.

### What approach do you currently take to treating your IgAN patients?

I generally start all patients on RAS inhibition as soon as the diagnosis is established. My goal is to minimize proteinuria, and while I am happy if I can get the patient below 1 g/d, I really want them below 500 mg/d.

### How do you think the TARPEYO approval will shift your approach to treating your patients?

I am hopeful this will greatly attenuate my use of systemic glucocorticoids for IgAN patients. After giving sufficient time with RAS inhibition, I would pivot and add TARPEYO. Having TARPEYO available affords me the option of thinking about treatment for IgAN as multi-target. For example, if patients do not respond to RASi the way we want, we generally keep pushing the dose up and/or add another RASi, like an aldosterone antagonist. It may be better tolerated and avoid issues like hypotension or increased serum creatinine to use a reasonable dose of RASi, and if blood pressure is controlled appropriately to move directly to a drug with a different mechanism of action to try and generate synergy.

## Commercialisation in Europe: STADA Deal

This year, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize NEFECON for the treatment of the IgA nephropathy in Europe.

In July 2021, Calliditas announced a deal with STADA covering European Economic Area (EEA) member states, Switzerland and the UK valued at a total of 97.5 million EUR (\$115m), plus royalties. Under the terms of the agreement, Calliditas received an initial upfront payment of 20 million EUR (\$24m) upon signing and is entitled to up to an additional 77.5 million EUR (\$91m) in future payments linked to pre-defined regulatory and commercialization milestones. STADA is also due to pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

Calliditas is advancing its delayed release formulation of budesonide under the development name "NEFECON®" outside of the US. Calliditas submitted a Marketing Authorization Application for NEFECON to the European Medicines Agency in May 2021. The submission was based, as was the submission to the FDA, on positive data from Part A of the NefIgArd pivotal Phase 3 study and on the Phase 2b NEFIGAN study, which also met both its primary endpoint of

proteinuria reduction and key secondary endpoint of eGFR stabilization at 9 months.

While Calliditas was initially granted Accelerated Assessment procedure by EMA's Committee for Human Medicinal Products (CHMP), in September 2021 the EMA announced its decision to continue the assessment of the MAA for NEFECON under standard procedure assessment timelines. Calliditas expects a decision from the CHMP in the second quarter of 2022.

IgAN is designated as an orphan disease in both the US and Europe. In Europe, an orphan disease is defined as a disease or condition affecting no more than five in 10,000 European citizens with no satisfactory method of diagnosis, prevention or treatment. Orphan incentives consist of ten years of market exclusivity from the grant date of marketing approval in the EU, protocol assistance and scientific advice, fee reductions on EMA procedural activities and eligibility for EU grants.



»In July, Calliditas announced a deal with STADA covering EEA member states, Switzerland and the UK«



# Important milestones in the development of NEFECON

## 2007–2011

- The Phase 2a study is completed with positive results
- Calliditas obtains orphan designation for NEFECON in the US
- NEFECON becomes the lead product candidate
- Calliditas gains exclusive rights to the TARGIT formulation technology to develop and manufacture NEFECON

## 2014

- NEFECON core patents are granted in the US, Europe, China and Hong Kong

## 2015

- Calliditas collaborates with KHI (American Society of Nephrology) on proteinuria as a surrogate endpoint in IgAN
- Calliditas announces initial results from the Phase 2b study and achieves the primary endpoint in a planned interim analysis, the only placebo-controlled, randomized study in IgAN to achieve this milestone

## 2016

- Calliditas obtains orphan drug designation for NEFECON in Europe
- Tufts Medical Center publishes the meta-analysis study related to changes of proteinuria as a surrogate endpoint in IgAN in American Journal of Kidney Disease

## 2017

- Publication of results from the Phase 2b study in The Lancet
- Calliditas completes a number of End of Phase 2 meetings with the EMA and FDA, achieving acceptance by the FDA in January for the use of reduction in proteinuria as an approvable endpoint for a pivotal Phase 3 study

## 2018

- First patient is randomized in the pivotal clinical Phase 3 study NeflgArd
- Poster from Professor Barratt at IlgANN 2018 demonstrates that Nefecon modifies circulating IgA-IgG immune complex levels and levels of poorly O-Galactosylated IgA
- First patient is enrolled in the pivotal Phase 3 NeflgArd study

## 2019

- All 200 patients are enrolled in Part A (required for market approval) of the NeflgArd study
- After positive interaction with the FDA, the design of Part B of the NeflgArd study is modified, significantly reducing the number of patients required in Part B, as well as reducing the overall study duration
- NEFECON is outlicensed to Everest Medicines, covering Greater China and Singapore

## 2020

- Readout of positive topline data from the Phase 3 pivotal NeflgArd Trial, which confirmed the results of the Phase 2b study, providing a basis for regulatory filings. NeflgArd became the first successful randomized, double-blind, placebo-controlled Phase 3 clinical trial carried out in IgAN
- Poster is presented by Dr Molyneux at ASN Kidney Week demonstrating that Nefecon has a demonstrated impact on circulating pathogenic biomarkers (BAFF, soluble BCMA and TACI) in IgAN

## 2021

- First patient is dosed in open label extension trial of NeflgArd
- Full recruitment of 360 patients for the post-approval confirmatory part of the NeflgArd study
- NDA filing with FDA for accelerated approval in IgAN
- MAA filing with EMA for conditional approval in IgAN
- Posters are presented at ASN Kidney Week demonstrating that NEFECON selectively reduces circulating levels of chemokines critical to immune cell trafficking to Peyer Patches in IgAN and that NEFECON modulates the complement system in patients with IgAN.
- FDA approves Nefecon, branded as TARPEYO in the US



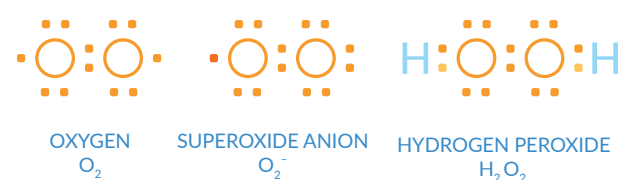
## A NOX Inhibitor Platform

**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 launching 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 ( $O_2^{\cdot-}$ ). NOX4, DUOX1 and DUOX2, meanwhile, mainly produce hydrogen peroxide ( $H_2O_2$ ).



At appropriate concentrations, ROS have essential functions in cellular signalling 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

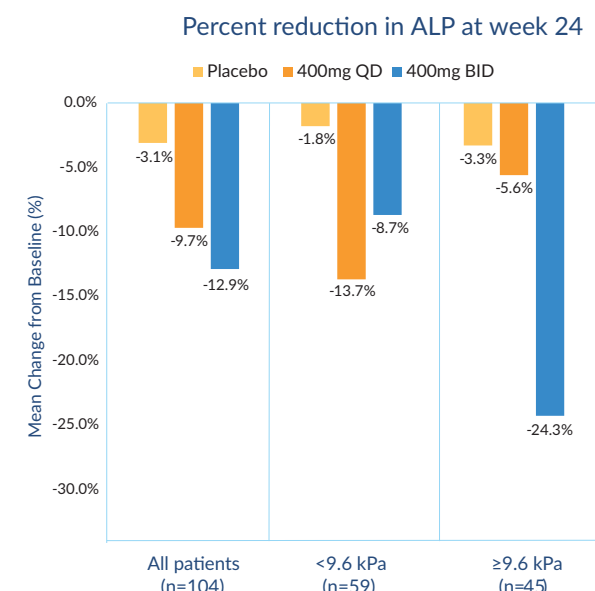
Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, known as Ocaliva, are the only FDA- and EMA-approved treatments for PBC. These drugs are primarily anti-cholestatic. UDCA is a bile acid analogue which is incorporated into the bile acid pool, replacing other more 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

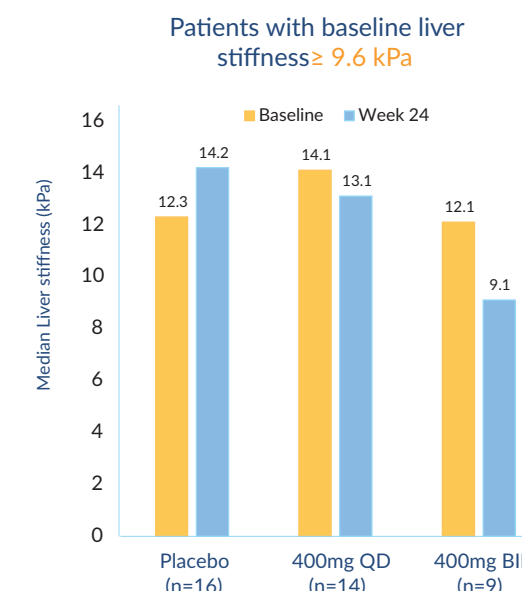
Setanaxib previously has been investigated in a 24 week Phase 2 trial with 111 patients and has received orphan drug designation for the treatment of PBC in the United States and Europe. Although the study did not meet its primary endpoint, it met key secondary endpoints related to change in alkaline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



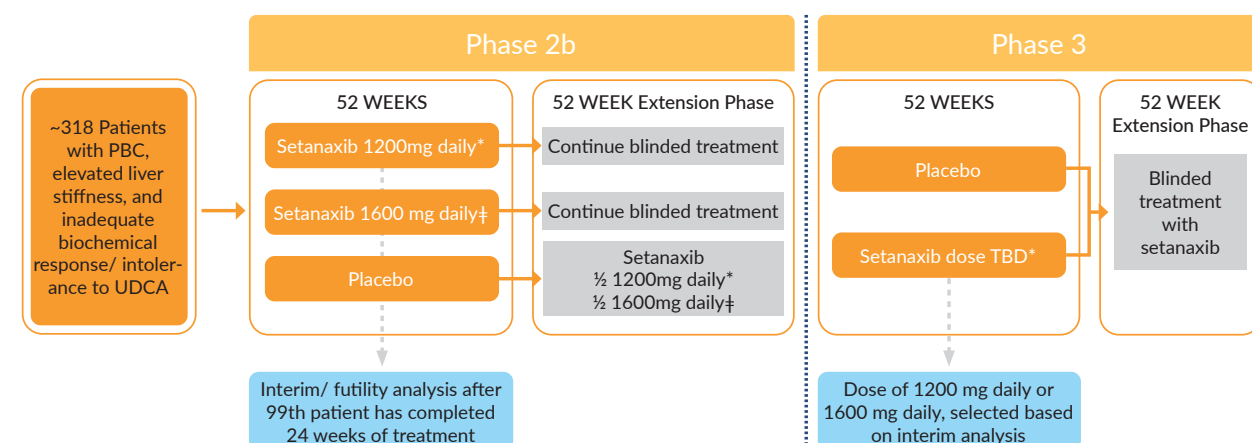
### Phase 2b/3 TRANSFORM Trial

Calliditas has initiated a pivotal 52-week, randomized, placebo-controlled, double-blind, trial with an adaptive Phase 2b/3 design. Calliditas announced that the first patient was randomised in the TRANSFORM study on 15th February 2022.

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 Q2 or Q3 2023, and the trial is expected to read out final data in late 2024 or early 2025.

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



\*Dose of 1200 mg daily administered as 800 mg AM and 400 mg PM  
†Dose of 1600 mg daily administered as 800 mg AM and 800 mg PM

### Setanaxib in Head and Neck Cancer

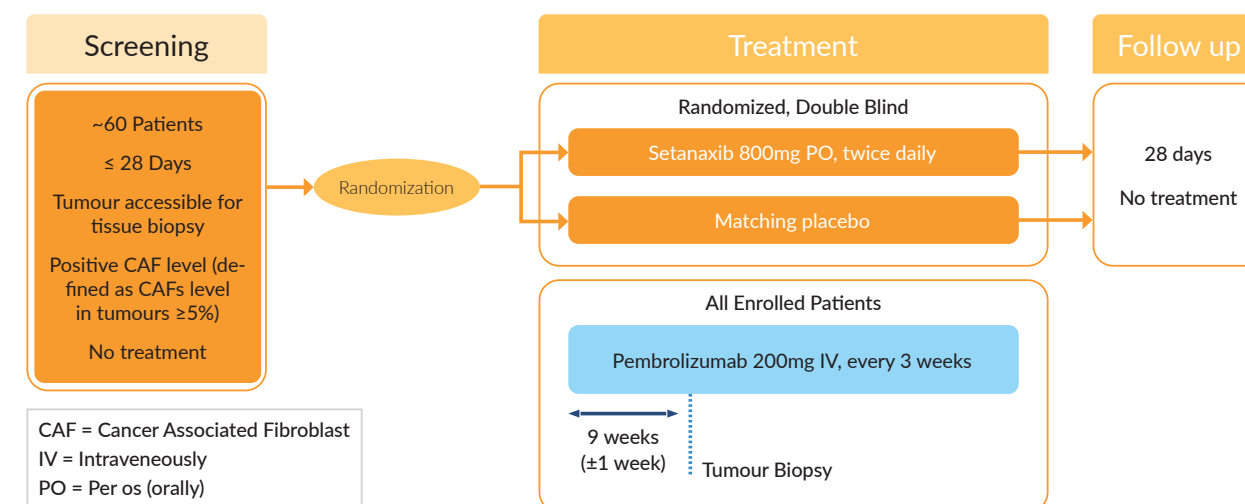
Calliditas is also initiating a Phase 2 clinical trial to evaluate setanaxib in head and neck cancer. The response to immuno-oncology therapies can be affected by the tumour microenvironment, in particular by the numbers of tumour-infiltrating lymphocytes (TILs) and cancer-associated fibroblasts (CAFs)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

This research paper, 'NOX4 Inhibition Potentiates Immunotherapy by Overcoming Cancer-Associated Fibroblast-Mediated CD8 T-cell Exclusion from Tumors' (DOI: 10.1158/0008-5472.CAN-19-3158), was one of the most highly cited Cancer Research articles in 2020 and 2021 and will be featured at the American Association for Cancer Research (AACR) Annual Meeting 2022.



Calliditas is initiating a double-blind, randomized, placebo-controlled, proof-of-concept Phase 2 study, which will investigate the effect of setanaxib 800 mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks, in up to 60 patients with relapsed or metastatic SCCHN and tumours with moderate or high levels of CAFs. A tumour 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.

The target is to start enrollment in Q2 2022, with an interim analysis of biomarker and safety data targeted for Q4 2022 and final data read out expected in H2 2023.

### Our pipeline

Clinical Candidate	Indication / Trial	Research / Preclinical	Phase 1	Phase 2	Phase 3	Marketed
NEFECON*	IgAN/ NeflgArd					
Setanaxib	PBC					
Setanaxib	SCCHN					
Setanaxib	IPF					
	Kidney					
NEFECON	IgAN / OLE†					

Depicts ongoing/planned clinical trial stage:

Depicts Investigator Led Trial:

† Open Label Expansion, intended to primarily support treatment-related considerations.

\* Approved under accelerated approval in the USA under the tradename TARPEYO. TARPEYO™ (budesonide) delayed release capsules is a prescription medicine used to reduce levels of protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN) who are at high risk of rapid disease progression, generally UPCR ≥ 1.5g/g. Calliditas submitted a Marketing Authorization Application for NEFECON to the European Medicines Agency in May 2021.

Setanaxib is also being evaluated in an investigator led trial in DKD (Diabetic Kidney Disease).



# Environmental, Social, and Corporate Governance

Our drive to provide access to treatment for patients with rare diseases with a high unmet medical need is the foundation of our business. As part of our mission to serve patients, we support environmental, social and corporate governance (ESG) initiatives that are aligned with our values and that can help us positively impact our patients, our employees and our planet.

## Our Vision:

To leverage our interdisciplinary expertise in pharmaceutical product development to identify, develop and market high value new medicines in niche indications, in which there is a significant unmet medical need and where the company can partially or completely drive and participate in the commercialization of the product.



We are dedicated to ensuring that we act ethically and responsibly in every area of our business, with a commitment to the highest standards of clinical development and business ethics as well as the highest safety and quality standards.

## Our commitment to our employees

2021 was yet another year where the Calliditas team grew significantly, as the company bolstered its US team in preparation for TARPEYO's accelerated approval and formally completed our acquisition of Genkyotex, which became a wholly owned subsidiary of Calliditas in October. This growth has made our quality systems and our internal policies even more paramount, and we remain passionately committed to cultivating a productive, diverse and inclusive work environment and to maintaining a company culture that we are extremely proud of.

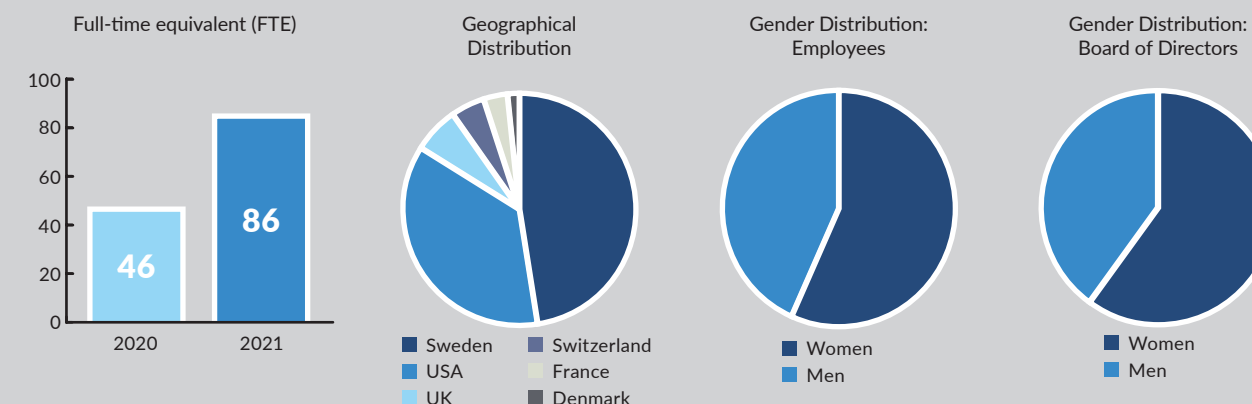
The success of Calliditas Therapeutics is determined by our ability to operate as a unified team as we work to earn the trust and respect of our co-workers, investors, and ultimately our patients. Our company is built on a foundation of creative, productive and dedicated employees and Calliditas is committed to ensuring equal opportunities for everyone to flourish and contribute to our overall mission. We look to promote ethical behaviour amongst our team through our

company values and our employee code of conduct, and we view our employees as essential to helping us maintain a work environment that meets a high ethical standard. Every member of the Calliditas team is expected and encouraged to ask questions, seek guidance and report suspected violations of this code.

We also strongly believe in cultivating engagement across the different teams in our company and encouraging open communication. Employees have access to management, 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 made and plans for the future, and to foster an open dialogue with employees about the direction and objectives of the company. We are always seeking feedback and input to ensure that employees have the resources and support they need to be successful in their role and to contribute to the company's mission. We also encourage an appropriate work-life balance as we aim to maintain healthy employees and a healthy work environment. We are proud to offer a safe, inclusive, and stimulating workplace with equal development opportunities for all.

## Commitment to Safety and Environmental Responsibility

Calliditas understands the importance of acting in



an environmentally conscious way, and we always strive to be mindful of how our business operations could be impacting the planet. 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 so as to encourage employees to utilize public transport.

Calliditas is also committed to rigorous safety standards, both for ourselves and our partners. Calliditas does not own or manage any manufacturing facilities, but we are rigorous and mindful about how we select our suppliers and build partnerships. All of our current appointed commercial suppliers are reputable companies, located in western Europe and USA. They were chosen through a selection process strictly evaluating, among other things, 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.

Our acquisition and integration of Genkyotex has added two new offices, in France and Switzerland, and also means that as a company Calliditas is now engaged in clinical research. We strictly follow bioethics policies defined by French regulations when it comes to clinical research, which includes an internal Animal Welfare Committee and an external Ethics Committee to ensure all animal experiment project requests are acceptable from an ethical point of view. A careful regard for bioethics is embedded in all of our procedures, processes and decision-making in our clinical research.

## Commitment to Our Patients

Since our company was founded, our mission and vision has been to focus on unmet needs in orphan indications and to bring to market treatments for those

suffering from rare diseases. We continue to work with the rare disease community as we endeavour to provide access to novel and innovative treatments and see this cooperation as vital for our future development as a company, particularly now that we have an approved product on the market.

We draw inspiration from our advocacy partners and all our patients, and are proud to support patient advocacy and disease state educational efforts in IgAN. We continued our support of the IgA Nephropathy Foundation, sponsoring an IgAN patient toolkit, and joined IgAN patients in events such as the American Association of Kidney Patients' walk to raise awareness. We were also the lead sponsor of the SPARK 2021 national patient/caregiver symposium. We have a robust plan to continue to build on our partnerships with patient advocacy groups in the future and to invest in these relationships and in our patients. We also ensured we were ready to support our patients the moment that TARPEYO was approved, establishing our comprehensive patient and provider support program, TARPEYO Touchpoints™. This program offers services, assistance, and resources designed to help patients access treatment as easily as possible. Calliditas is committed to working with payers and healthcare providers across the United States to ensure that all patients prescribed TARPEYO have access to it, and we look forward to helping as many IgAN patients as possible.

We pride ourselves on being pioneers in our field and are looking forward to continuing our work to bring novel medications to our patients. Having commercially launched the first ever approved treatment for IgAN in the USA, we are excited about the possibility of also bringing an approved product to address the unmet medical need in IgAN in Europe and China, as well as the potential of our NOX inhibitor platform and first-in-class compound setanaxib, which we will be conducting two late stage clinical trial programs with in 2022. We will continue to be guided and motivated by our passion to provide medications for patients with unmet medical needs across the world.

# The Share

## Share Performance

### Nasdaq Stockholm

Calliditas was listed on Nasdaq Stockholm Mid-Cap, on June 29, 2018. As of December 31, 2021, the closing rate was SEK 112.8 yielding an decrease of 19% in 2021. During the same period, the OMXSPI increased by 34%. The highest closing rate during the year was SEK 143.6 and the lowest SEK 62.0.

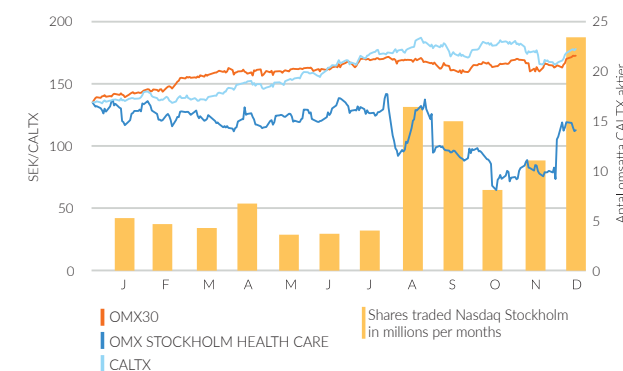
### Nasdaq USA

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, 2021, the closing price was USD 24.8, which gave a decrease of 26 percent during the period January-December 2021. Nasdaq Composite increased by 31 percent during the same period. The highest closing price during the year was USD 33.2 and the lowest was USD 15.0

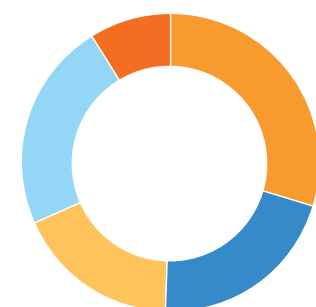
## Turnover

### Nasdaq Stockholm

A total of 94.6 million shares were traded during the year, with a total value of SEK 10,162 million. On average, 373,999 shares were traded each day.

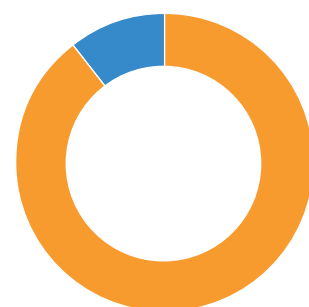


## Ownership per category, %



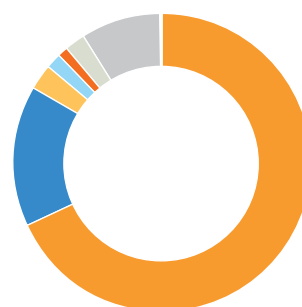
Swedish institutional owners	29.8%
Foreign institutional owners	20.9%
Other	17.7%
Swedish private persons	22.9%
Anonymous ownership	8.7%

## Trading platforms, %



Nasdaq	89.37%
Cboe Global Markets	10.45%

## Ownership per country, %



Sweden	68.3%
USA	15.2%
France	2.7%
Great Britain	1.7%
Norway	1.2%
Other	2.3%
Anonymous ownership	8.7%

Source: Monitor by Modular Finance AB and Fidessa.

## Nasdaq USA

During the period January-December 2021, a total of 17.2 million ADSs were traded. On average, 68,390 ADSs were traded per day.

## Shareholders

As of December 31, 2021, Calliditas had 19,879 shareholders. The 15 largest shareholders controlled 64.6% of the capital and voting rights at year-end. The three largest shareholders were BVF Partners, Stiftelsen Industrifonden and Linc AB. Foreign shareholders accounted for 31.7% of voting rights and capital.

## Share Capital

As of December 31, 2021, share capital in Calliditas amounted to SEK 2,094 thousand. The number of shares was 52,341,584 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 65.8% at year-end.

## Investor Relations Work

Investor Relations work in 2021 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 primarily virtual. Calliditas has also conducted a large number of 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 Carnegie, Stifel, Kempen, Citi, Jefferies, Life Sci Capital, HC Wainwright, SEB and Penser.

## The 15 largest shareholders as of December 31, 2021

Shareholders	Total number of shares	Holding, %	Votes, %
BVF Partners LP	6,331,562	12.7%	12.7%
Stiftelsen Industrifonden	5,772,995	11.0%	11.0%
Linc AB	5,486,108	10.5%	10.5%
Fjärde AP-fonden	2,675,000	5.1%	5.1%
Swedbank Robur Fonder	2,638,107	5.0%	5.0%
Unionen	1,858,342	3.6%	3.6%
Handelsbanken Fonder	1,767,236	3.4%	3.4%
Avanza Pension	1,601,182	3.1%	3.1%
Sofinnova Partners	1,318,078	2.6%	2.6%
Mikael Bender	1,100,459	2.1%	2.1%
Öhman Fonder	827,419	1.6%	1.6%
Polar Capital	750,000	1.4%	1.4%
BlackRock	499,867	1.0%	1.0%
Renée Aguiar-Lucander	418,000	0.8%	0.8%
Atlant Fonder	390,588	0.7%	0.7%
<b>Total share of the 15 largest shareholders</b>	<b>33,434,943</b>	<b>64.6%</b>	<b>64.6%</b>
Other shareholders	18,906,641	35.4%	35.4%
<b>Total</b>	<b>52,341,584</b>	<b>100.0%</b>	<b>100.0%</b>

## CALTX share data 2021

Daily average turnover, SEK	40,164,091
Low, SEK	62.0
High, SEK	143.6
VWAP, SEK	107.4
Number of shares traded	94,621,760
Average number of shares traded per day	373,999
Average number of trades per day	1,995
Number of trades	504,693
Average value per trade, SEK	20,134
Daily turnover rel. Mcap, %	0.71%
Part Nasdaq (ordinary trade), %	89.3%
Cboe Global Markets %	10.7%

## Size classes as of December 31, 2021

Size classes	No. of known shareholders	No. of shares	Holding, %	Votes, %	Proportion of known shareholders
1 - 100	11,264	413,748	0.8%	0.8%	45.7%
101 - 200	2,570	396,484	0.8%	0.8%	12.0%
201 - 500	2,918	995,116	1.9%	1.9%	18.9%
501 - 1000	1,463	1,156,636	2.2%	2.2%	10.0%
1001 - 2000	831	1,273,079	2.4%	2.4%	5.6%
2001 - 5000	505	1,638,479	3.1%	3.1%	4.4%
5001 - 10000	161	1,173,940	2.2%	2.2%	1.5%
10001 - 20000	75	1,085,463	2.1%	2.1%	0.7%
20001 - 50000	43	1,424,350	2.7%	2.7%	0.4%
50001 - 100000	17	1,117,749	2.2%	2.2%	0.2%
100001 - 200000	12	1,725,739	3.4%	3.4%	0.2%
200001 - 500000	8	2,809,799	5.4%	5.4%	0.2%
500001 - 1000000	2	1,577,419	3.0%	3.0%	0.1%
1000001 - 4000000	7	12,958,404	24.9%	24.9%	0.1%
4000001 -	3	17,590,665	34.2%	34.2%	0.0%
Anonymous ownership		5,004,514	8.7%	8.7%	
<b>TOTAL</b>	<b>19,879</b>	<b>52,341,584</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</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 2021. All amounts are expressed in SEK millions unless otherwise stated.

### Multi-Year Summary, Group

	2021	2020	2019	2018	2017
Net sales (SEK in thousands)	229,347	874	184,829	-	-
Loss before income tax (SEK in thousands)	(513,373)	(436,151)	(32,501)	(132,049)	(86,794)
Total assets (SEK in thousands)	1,459,910	1,463,908	845,200	648,417	62,288
Average number of employees	56	23	14	10	10

### Multi-Year Summary, Parent Company

	2021	2020	2019	2018	2017
Net sales (SEK in thousands)	229,347	874	184,829	-	-
Loss before income tax (SEK in thousands)	(354,405)	(407,363)	(36,186)	(131,923)	(86,848)
Total assets (SEK in thousands)	1,528,439	1,318,525	838,249	651,633	65,366
Average number of employees	29	15	13	10	9

### 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, TARPEYO, has been approved by the FDA as the first and only treatment of IgA nephropathy (IgAN), indicated for reduction of proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR of  $\geq 1.5\text{g}/\text{gram}$ . Calliditas has also filed a marketing authorization application (MAA) with the European Medicines Agency (EMA) for this drug product. Additionally, Calliditas has initiated a clinical trial in primary biliary cholangitis and a trial in head and neck cancer, with NOX inhibitor product candidate setanaxib. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq US Global Select Market (ticker: CALT).

In 2020, Calliditas made a positive reading of top line data from Part A of the NeflgArd 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. With the positive results from Part A of the Phase 3 clin-

ical study top-line readout, Calliditas focused in 2021 mainly on applying for approval for Nefecon in the US and the EU as well as preparing for commercialization in the US and outlicensing Nefecon in the EU.

In March 2021, Calliditas submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for Nefecon for the treatment of primary IgA nephropathy (IgAN) and applied for accelerated approval under Chapter H, Section 505 (b) (2), and in May 2021 submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA).

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. Tarpeyo became the first treatment ever approved for the treatment of IgAN. During the year, Calliditas also entered into a licensing agreement with Stada Arzneimittel AG to register and commercialize Nefecon for IgAN in the European Economic Area (EEA), Switzerland and the United Kingdom, as well as an agreement for a loan facility of 75 million divided into 3 parts of 25 million USD each with Kreos. During the fourth quarter of 2021, Calliditas also

completed the acquisition of the French listed company Genkyotex SA, which now is fully owned by Calliditas.

The Group's revenues in 2021 derives mainly from milestone payments from Calliditas partnerships with Stada and Everest, which amounted to SEK 229.3 million and the Group may be dependent on external financing until Nefecon/Tarpeyo starts generating substantial revenues to ensure continued operations. During the year, a new share issue was carried out which raised a total of SEK 324.0 million before issue costs.

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

### Significant Events During the Year

#### Development plan for setanaxib

In January 2021, Calliditas announced the clinical development plan for setanaxib and additional data from Part A of NeflgArd study at the company's R&D Day. Calliditas set out plans to initiate a pivotal Phase 2/3 study in PBC in 2H 2021. In addition, Calliditas set out plans to initiate a Phase 2 proof-of-concept study in head and neck cancer which would study administration of setanaxib in conjunction with immunotherapy targeting CAFs (cancer associated fibroblasts).

Calliditas also provided selected data from the recently concluded Part A of the Phase 3 study NeflgArd. The data presented included overall baseline characteristics, rate of discontinuation of study treatment (9.5%) and rate of discontinuation from the study (3.5%). It was also confirmed that no adverse clinical effects were seen with regards to weight gain, blood pressure or HbA1c, reflecting a safety profile in keeping with the Phase 2b trial.

#### FDA New Drug Application

In March 2021, Calliditas submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for NEFECON in patients with primary IgAN. Calliditas was seeking accelerated approval under Subpart H for the 505(b)(2) application.

#### EMA Market Authorisation Application

In May 2021, Calliditas submitted a Marketing Authorisation Application (MAA) to the EMA for NEFECON.

#### Credit facility of 75 million USD

In July 2021, Calliditas signed a loan agreement of up to the EUR equivalent of \$75 million with Kreos Capital. The loan facility is divided into three tranches of \$25 million each. Drawdown of the first \$25 million tranche was made in the third quarter 2021. Drawdown of the second tranche of \$25 million can be made until 30 June 2022. Drawdown of the third and final \$25 million tranche can be made until 31 December 2022 and will be available subject to certain revenue milestones and coverage metrics.

#### Licensing agreement with STADA

In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize NEFECON for the treatment of IgAN in the EEA member states, Switzerland and the UK valued at a total of EUR 97.5 million (\$115m) in initial upfront and potential milestone payments, plus tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

#### setanaxib

In August 2021, Calliditas received FDA fast track designation for setanaxib in PBC and announced that Calliditas is initiating a 52-week, randomized, placebo-controlled, double-blind study with an adaptive phase 2b/3 design with setanaxib for a total of approximately 318 patients with primary biliary cholangitis (PBC) and a proof-of-concept phase 2 study of head and neck cancer that will investigate the administration of setanaxib in conjunction with immunotherapy targeting cancer-associated fibroblasts.

#### New share issue

In August 2021, Calliditas completed an accelerated book building procedure and resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of SEK 324.0 million before transaction costs.

#### FDA approval in US

In December 2021, Calliditas announced that the US Food and Drug Administration (FDA) had granted accelerated approval for TARPEYO (budesonide) delayed release capsules indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5\text{g}/\text{g}$ . TARPEYO is the first and only FDA-approved treatment for this disease and was designed specifically to target the origin of IgA nephropathy. This approval marked the successful transition for Calliditas to a commercial-stage biopharmaceutical company.

### Sales and Earnings

Sales amounted to SEK 229.3 million and SEK 0.9 million for the years ended December 31, 2021 and 2020, respectively. The sales derive mainly from milestone payments during the year from the out-licensing of Nefecon to Everest and Stada for China and the EU, respectively.

### Research and development expenses

Expenses for research and development amounted to SEK 357.5 million and SEK 241.4 million for the years ended December 31, 2021 and 2020, respectively. The cost increase for the full year 2021 is mainly attributable to the setanaxib studies and the development of setanaxib as well as a write-down of the SIIL platform compared with the same period last year.

### Administrative and selling expenses

Administrative and selling expenses amounted to SEK 390.2 million and SEK 141.7 million for the years ended December 31, 2021 and 2020, respectively. The increase compared with the previous year is mainly due to the commercial preparations for the launch of TARPEYO in the USA.

### Other operating income / expenses

Other operating income amounted to SEK 0.3 million and SEK 2.5 million for the years ended December 31, 2021 and 2020, respectively and mainly pertains to currency gains on operating receivables. Other operating expenses amounted to SEK 6.3 million the year ended December 31, 2021, and mainly pertains to currency losses on operating liabilities and change in value of contingent consideration.

### Financial income / expenses

Financial income amounted to SEK 20.3 million and SEK 0.5 for the years ended December 31, 2021 and 2020, respectively and mainly pertains unrealized currency gains. Financial expenses amounted to SEK 9.3 million and SEK 57.0 for the years ended December 31, 2021 and 2020, respectively and consist mainly of interest expense and unrealized exchange rate losses.

### Tax

Income tax expenses, in all material respects, primarily relates to the U.S. subsidiaries of Calliditas Therapeutics. Deferred tax assets of SEK 5.1 million have been recognized in the twelve months ended December 31, 2021 due to future temporary differences that such losses can be used to offset and are related to Genkyotex. The Group's tax losses accumulated have otherwise not

been valued and not recognized as deferred tax assets. 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.

### Earnings

For the years ended December 31, 2021 and December 31, 2019, the Group had a net loss of SEK 509.5 million and SEK 436.5 million, respectively and corresponding loss per share before and after dilution amounted to SEK 9.84 and SEK 9.66 for the years, respectively.

### Liquidity and Financial Position

Cash amounted to SEK 955.5 million and SEK 996.3 as of December 31, 2021 and 2020, respectively. In mid-2021, a new issue of 2.4 million shares was carried out. The total issue amount was SEK 324.0 million before issue costs.

Shareholders' equity related to the shareholders of the parent company amounted to SEK 1,008.3 million and SEK 1,210.5 million as of December 31, 2021 and 2020, respectively.

### Cash Flow

Net cash used for operating activities was SEK 461.6 million and SEK 309.2 million for the years ended December 31, 2021 and 2020, respectively.

Cash flow used in investing activities was SEK 24.3 million and 172.6 million for the years ended December 31, 2021 and 2020, respectively and derives mainly from a SEK 16.1 million milestone payment for the Budenofalk license and SEK 6.6 million in purchase of equipment.

Net cash provided by financing activities was SEK 435.2 million and SEK 768.6 million for the years ended December 31, 2021 and 2020, respectively, and arises mainly from the new share issue in August of a net SEK 304.0 million and the utilization in September of the first part of Kreos loan facility of SEK 199.5 million reduced by the purchase of the remaining shares in Genkyotex SA.

Net increase/(decrease) in cash amounted to (SEK 50.8 million) and SEK 286.8 million for the years ended December 31, 2021 and 2020, respectively.

### Personnel

The number of employees in the Group were 66 and

34 employees as of December 31, 2021 and 2020, respectively. The total number of full-time equivalent (FTE), including the consultants, were 86 and 46 people as of December 31, 2021 and 2020, respectively. The average number of employees were 56 and 23 for the year ended December 31, 2021 and 2020, respectively of which 53% were women and 47% were men for 2021.

### Environment

Calliditas works proactively to reduce its adverse environmental impact and to evolve as a sustainable company. Since Calliditas had no product sales during 2021, Calliditas' products have no 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 had at December 31, 2021 two warrant programs outstanding, issued in 2018 and 2019. The warrant program issued in 2018 was addressed to employees and consultants and expired in March 2022 and the program issued 2019 was addressed to employees and consultants and expires in December 2022. At the time of issuance, the warrants were priced at market value in accordance with the Black & Scholes pricing model. In the program from 2018 and 2019 the participants cannot exercise the warrants until the first quarter of 2022 and fourth quarter 2022, respectively. As of December 31, 2021, the total number of warrants outstanding, if fully subscribed, corresponded to 1,279,086 shares.

The Group also has two outstanding option programs, ESOP 2020 and ESOP 2021. 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 allotment 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 third quarter of 2024. At

the end of the year, 2,289,000 options were allocated. Calliditas also has three long-term incentive programs for board members of Calliditas, LTIP 2019, LTIP 2020 and LTIP 2021. Participants in the programs will be allocated performance-based share rights free of charge. The share rights in LTIP 2019 are subject to performance-based earnings based on the development of Calliditas' share price during the period from the date of the 2019 Annual General Meeting to June 1, 2022. The share rights in LTIP 2020 are subject to performance-based earnings based on the development of Calliditas' share price during the period from Annual General Meeting 2020 through June 1, 2023. The share rights in LTIP 2021 are subject to performance-based earnings based on the development of Calliditas' share price during the period from Annual General Meeting 2021 through June 1, 2024.

In total, there were share rights outstanding corresponding to 109,738 shares at full earnings 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 2.1 million, divided into 52,341,584 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. 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 USA. At the end of 2021, Calliditas had 19,879 (6,609 ) shareholders and the ten largest shareholders owned 59.1 (58.4)% of all outstanding shares. On December 31, 2021, BVF Partners LC, Stiftelsen Industrifonden, and Linc AB were the single largest shareholders in the company, with a total of 6,331,562, 5,772,995 and 5,486,108 shares, respectively, corresponding to 12.7%, 11.0% and 10.5%, respectively, of the votes and capital.

For further information regarding the share, please see pages 26-27.

### Holdings of Treasury Shares and Warrants

No shares were held in treasury by Calliditas in 2021. The subsidiary Nefecon AB holds 3,142,000 warrants pending any distribution to future participants in the Board LTIP 2019, 2020, 2021 programs and ESOP 2020 and 2021 programs.



### Work of the Board of Directors

Calliditas' Board of Directors consists of five Board members including the Chairman, who is elected for the period until the 2022 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 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 2021, the board met 16 times. In addition to the board meetings, the chairman of the board and the CEO have a continuous dialogue about the company's management.

In connection with the Board meeting, the Board of Directors also establishes the instructions for the CEO, including financial reporting.

For additional information of the work of the Board of Directors, please see the Corporate Governance Report on pages 86-91.

### 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 2021. These guidelines do not apply to any remuneration decided or approved by the general meeting. For the most recently adopted guidelines for remuneration to executive management, see Note 9 Employees and Personnel Costs.

#### *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 market, branded as TARPEYO, and have also signed partnerships in other regions. 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 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 certain 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/remuneration-2323/>.

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, which has been approved for marketing in the USA. 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 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. Given that Calliditas currently does not have its own earning ability, 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

A financial policy for managing financial risks has been formulated by the Board and forms a framework of guidelines and rules in the form of risk mandates and limits for financial operations. Calliditas is mainly affected by the exchange rate risk. Calliditas has most of its expected future costs in the U.S. dollars and Euros. During 2021, Calliditas held parts of the cash and cash equivalents in Euro and US dollars to reduce future currency exposure to EURO and US dollars. The finance policy is updated at least once a year.

### Parent Company

The Group's Parent Company is Calliditas Therapeutics AB. Operations and accounting in the Parent Company is aligned in all material respects with the operations and accounting of the Group. Net profit for the year and the financial position of the Parent Company are aligned in all material respects with the Group's which is why the comments for the Group are in all material respects also valid for the Parent Company. For the years ended December 31, 2021 and December 31, 2020, the Parent Company had a net loss of SEK 354.4 million and SEK 407.4 million, respectively.

The Parent Company had cash of SEK 894.5 million and SEK 978.2 million as of December 31, 2021 and 2020, respectively.

### Outlook

Calliditas 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)  $\geq 1.5$  g / g. TARPEYO is the first and only FDA-approved treatment for this indication and has been designed specifically to target the origin of the disease. This approval marks the transition for Calliditas to a commercial phase biopharmaceutical company.

Nefecon is also in a Phase 3 clinical study for IgA nephropathy where Part B of the NeflgArd study is ongoing. With studies in PBC and head and neck cancer with setanaxib initiated, the business is capital intensive and until Nefecon/TARPEYO will bring in steady revenues that exceed the costs, external

financing may be required. Calliditas cash position of SEK 955.5 million as of December 31, 2021, together with available loan facilities and subject to 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	2,420,698
Retained earnings	(863,175)
<b>Net loss for the year</b>	<b>(354,405)</b>
	<b>1,203,117</b>

The Board of Directors proposes that SEK 1,203,117 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 2021 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.



## GROUP

## Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31,		
		2021	2020	2019
Net sales	3	229,347	874	184,829
Research and development expenses	9,10	(357,485)	(241,371)	(149,826)
Administrative and selling expenses	6,8,9,10	(390,232)	(141,724)	(62,882)
Other operating income	4	259	2,501	4,385
Other operating expenses	5	(6,344)	-	(4,525)
<b>Operating loss</b>	<b>7</b>	<b>(524,456)</b>	<b>(379,720)</b>	<b>(28,019)</b>
Financial income	11	20,336	547	926
Financial expenses	12	(9,253)	(56,978)	(5,408)
<b>Loss before income tax</b>		<b>(513,373)</b>	<b>(436,151)</b>	<b>(32,501)</b>
Income tax expense	13	3,836	(360)	(77)
<b>Loss for the year</b>		<b>(509,537)</b>	<b>(436,511)</b>	<b>(32,578)</b>
<b>Attributable to:</b>				
Equity holders of the Parent Company		(500,293)	(433,494)	(32,578)
Non-controlling interests		(9,244)	(3,017)	-
		<b>(509,537)</b>	<b>(436,511)</b>	<b>(32,578)</b>
<b>Loss per share</b>				
Before and after dilution to ordinary equity holders of the Parent Company	14	(9.84)	(9.66)	(0.88)

## GROUP

## Consolidated Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31,		
		2021	2020	2019
<b>Loss for the year</b>		<b>(509,537)</b>	<b>(436,511)</b>	<b>(32,578)</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	21, 25	(20,111)	(9,352)	(11)
<b>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods</b>		<b>(20,111)</b>	<b>(9,352)</b>	<b>(11)</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	27	1,993	1,216	-
<b>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods</b>		<b>1,993</b>	<b>1,216</b>	<b>-</b>
<b>Other comprehensive income/(loss) for the year</b>		<b>(18,118)</b>	<b>(8,137)</b>	<b>(11)</b>
<b>Total comprehensive loss for the year</b>		<b>(527,655)</b>	<b>(444,648)</b>	<b>(32,589)</b>
<b>Attributable to:</b>				
Equity holders of the Parent Company		(519,189)	(438,343)	(32,589)
Non-controlling interests		(8,466)	(6,305)	-
		<b>(527,655)</b>	<b>(444,648)</b>	<b>(32,589)</b>

## GROUP

## Consolidated Statements of Financial Position

		December 31,	
(SEK in thousands)	Note	2021	2020
ASSETS			
Non-current assets			
Intangible assets	15,16	399,418	418,825
Equipment	17	6,309	163
Right-of-use assets	8	33,300	5,244
Non-current financial assets	18,20, 31	3,915	2,221
Deferred tax assets	19	4,196	600
Total non-current assets		447,138	427,057
Current assets			
Inventory	29	889	-
Other current assets	20	11,343	22,801
Prepaid expenses	22	45,032	17,746
Cash	23	955,507	996,304
Total current assets		1,012,772	1,036,851
TOTAL ASSETS		1,459,910	1,463,908
EQUITY AND LIABILITIES			
Equity			
	25		
Share capital		2,094	1,998
Additional paid-in capital		2,459,741	2,133,179
Reserves		(26,979)	(6,090)
Retained earnings including net loss for the year		(1,426,574)	(918,596)
Equity attributable to equity holders of the Parent Company		1,008,281	1,210,491
Non-controlling interests		-	45,809
Total equity		1,008,281	1,256,300
Non-current liabilities			
Provisions	26	14,530	6,391
Contingent consideration	15,30	54,399	48,969
Pension liabilities	27	3,182	8,296
Deferred tax liabilities	15,19	30,856	37,454
Non-current interest-bearing liabilities	21	189,164	-
Non-current lease liabilities	8,20	24,052	878
Total non-current liabilities		316,184	101,989
Current liabilities			
Accounts payable	20,21	67,971	53,827
Current tax liabilities		1,221	518
Other current liabilities	8,20	12,702	9,888
Accrued expenses and deferred revenue	28	53,553	41,386
Total current liabilities		135,446	105,619
TOTAL EQUITY AND LIABILITIES		1,459,910	1,463,908

## GROUP

## Consolidated Statements of Changes in Equity

(SEK in thousands)	Note	Attributable to the Equity Holders of the Parent Company					Non-Con- trolling Interests	Total Equity
		Share Capital	Additional Paid-in Capital	Translation Reserve	Retained Earnings incl. Net Loss for the Year	Total		
<b>Opening equity January 1, 2019</b>		<b>1,408</b>	<b>1,072,319</b>	<b>(34)</b>	<b>(455,518)</b>	<b>618 175</b>	<b>-</b>	<b>618,175</b>
Loss for the year		-	-	-	(32,578)	(32,578)	-	(32,578)
Other comprehensive income/(loss) for the year		-	-	(11)	-	(11)	-	(11)
<b>Total comprehensive loss for the year</b>		<b>-</b>	<b>-</b>	<b>(11)</b>	<b>(32,578)</b>	<b>(32,589)</b>	<b>-</b>	<b>(32,589)</b>
<b>Transactions with owners:</b>								
New share issue		140	210,177	-	-	210,317	-	210,317
Costs attributable to new share issue		-	(10,915)	-	-	(10,915)	-	(10,915)
Premiums from warrants issuance	10	-	2,834	-	-	2,834	-	2,834
Share-based payments	10	-	249	-	-	249	-	249
<b>Total transactions with owners</b>		<b>140</b>	<b>202,345</b>	<b>-</b>	<b>-</b>	<b>202,485</b>	<b>-</b>	<b>202,485</b>
<b>Closing equity December 31, 2019</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>
<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	15	-	-	-	-	-	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>	<b>10,15,25</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>
<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
Contribution from non-controlling interest			-	-	-	-	2,282	2,282
Costs attributable to new share issue		-	(20,909)	-	-	(20,909)	-	(20,909)
Share-based payments	15	-	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>	<b>10,15,25</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>



Consolidated Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31,		
		2021	2020	2019
Operating activities				
Operating loss		(524,456)	(379,720)	(28,019)
Adjustments for non-cash items	23	66,676	15,465	2,308
Interest received		102	1,912	926
Interest paid		(5,432)	(393)	(325)
Income taxes paid		(3,949)	(528)	-
Cash flow from operating activities before changes in working capital		(467,058)	(363,264)	(25,110)
Cash flow from changes in working capital				
Changes in inventory		(949)	-	-
Changes in operating receivables		(11,712)	8,033	(53,546)
Changes in operating liabilities		18,131	46,050	7,645
Cash flow from operating activities		(461,588)	(309,181)	(71,011)
Investing activities				
Acquisition of a subsidiary, net of cash acquired	15	-	(172,602)	-
Purchase of equipment	17	(6,588)	-	(118)
Investments in non-current financial assets	18	(1,686)	(5)	(1,888)
Purchase of intangible assets	16	(16,066)	-	(16,066)
Cash flow from investing activities		(24,340)	(172,607)	(18,072)
Financing activities				
New share issue		324,000	891,388	210,317
Costs attributable to new share issue		(20,909)	(95,937)	(12,663)
Exercise of warrants		-	59,251	-
Premiums from warrants issuance		-	-	2,834
Purchase of non-controlling interests		(49,303)	(82,172)	-
Contribution from non-controlling intereset		2,282	-	-
New borrowings	21	199,524	-	-
Costs attributable to new loans		(14,858)	-	-
Repayment of lease liabilities		(5,575)	(3,972)	(1,652)
Cash flow from financing activities		435,162	768,558	198,835
Net increase/(decrease) in cash		(50,766)	286,770	109,752
Cash at beginning of the year		996,304	753,540	646,175
Exchange-rate difference in cash		9,969	(44,006)	(2,387)
Cash at the end of the year	23	955,507	996,304	753,540

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, 2021, December 31,2020 and December 31, 2019. 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 clinical-stage biopharmaceutical 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, 2021, 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 pre-commercialization and 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 27, 2022, which will be presented for adoption at the Annual General Meeting on May 19, 2022.

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.

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, 2021. 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 good-will. 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, 2021 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. Revenue from contracts with customers is recognised when control of the goods or services are transferred to the customer at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services. During 2021, the Group generated revenue from contracts for outlicensing Nefecon to Everest Medicines for the Chinese region and Singapore, a contract initially entered into in 2019, and to Stada Arzneimittel for the EEA member states, Switzerland and the UK, a contract initially entered into in 2021.

The Group recognizes revenue as the identified performance obligations are performed. Outlicensing contracts consists of multiple performance obligations, as they contain multiple goods or services that could be sold on a stand-alone basis, and that are distinct within the context of the contract. Accordingly, the Group allocates the transaction price based on the relative stand-alone selling prices of the performance obligations, which requires identifying the performance obligations in the contracts, and allocating the transaction price between these. The allocation of the transaction price has a significant impact on the Group's revenue recognition, as the revenue recognition patterns differ between the performance obligations. The identification of performance obligations and the allocation of the transaction price between these is hence a significant accounting judgment and estimate. See Note 2 Significant Accounting Judgements, Estimates and Assumptions for more information.

## » GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

The Group's revenues for the financial year 2021 is allocated based on the following identified performance obligations:

- 1) Outlicensing of Nefecon to Everest Medicines for the Chinese region and Singapore, and to Stada Arzneimittel for the EEA region.
- 2) Certain regulatory services to Stada Arzneimittel related to the EU regulatory approval process.

Revenue for the outlicensing of Nefecon for the Chinese region and Singapore, as well as the EEA region, is recognized at the point in time when control of the intellectual property is transferred. The revenue allocated to the performance obligation 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. Revenue for the provision of certain regulatory services to Stada is reported over time as the services are performed, and the allocation of revenue to the performance obligation is based on the expected costs to provide the service, and a profit margin based on comparable companies. In the prior year, the Group recognized revenue for a performance obligation to provide pharmaceutical goods for clinical trials to Everest Medicines. The revenue allocated to this performance obligation was based on the expected costs to provide the goods, and a profit margin based on comparable companies.

These contracts with customers consists 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 is not recognized until the sale that results in the right to the royalties have occurred.

### 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.

### 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 asset's 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.

### 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.

### Administrative and Selling

Administrative and selling expenses consist of salaries and other related costs for personnel in the Group's executive, finance, corporate, market access, commercialization and business development and administrative functions. Administrative and selling 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 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 allotment 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 three 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 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

The acquisition of Genkyotex SA resulted in the Group acquiring the rights to the NOX platform as well as goodwill.

The NOX platform, 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.

In the prior year the Group had acquired the product candidate Budenofalk 3 mg oral capsule from the German pharmaceutical company Dr Falk Pharma GmbH for development of the pipeline portfolio related to orphan liver disease, such as AIH, in the United States.

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 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, or 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.



» **GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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**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, or 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.

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 long-term receivables, other current receivables and cash, all of which are classified 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 related to business combinations, accounts payable and other current liabilities, all of which, except contingent consideration, are classified as amortized cost. Contingent consideration related to business combinations is classified 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 21 Financial Risks for information on considerations relating to accounts receivable and deposits.

**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.

**Warrants**

The Group has only issued warrants that were transferred at fair value. Premiums received for warrants granted to acquire shares in companies within the Group are recorded as additions to equity, based on the warrant premium, at the date when the warrant was transferred to the counterparty.

**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 the non-current assets are located in Sweden, 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 periods if the change affects both the current period and future periods.

**Revenue Recognition**

As described in Note 1, the Group recognizes revenue as identified performance obligations are performed. The outlicensing contracts which the company has entered into consists of multiple performance obligations, as they contain multiple goods or services that could be sold on a stand-alone basis, and that are distinct within the context of the contract. Accordingly, the Group allocates the transaction price based on the relative stand-alone selling prices of the performance obligations, which requires identifying the performance obligations in the contracts, and allocating the transaction price between these.

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.

**Purchase Price Allocation**

The valuation of identifiable assets and liabilities in connection with the acquisition of subsidiaries involves that items in the acquired company's balance sheet as well as items that have not been recognized in the acquired company's balance sheet should be valued at fair value. The valuation of NOX platform is based on the Multiple Excess Earnings Method (MEEM).

## » GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

### 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. In addition, 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 16 Intangible Assets and Impairment Testing.

#### 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 16 Intangible Assets and Impairment Testing. As of December 31, 2021, the Group's goodwill amounted to SEK 37 227 and other intangible assets amounted to SEK 362 191. The impairment testing resulted in impairment of SEK 27 975 related to the vaccine platform (SILL-agreement) where the development of the product can not be expected to generate future cash flows.

#### 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, 2021 and was thus expensed. Capitalization of expenditures are generally made in late stage of the development, for example after 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 approved TARPEYO in the US under accelerated approval. It is expected that TARPEYO will be available in the U.S. early in the first quarter of 2022. 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.

#### 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, 2021, 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 27 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 for the financial year 2021 are related to remuneration within the framework of outlicensing Nefecon to Everest for the Chinese region and Singapore and to Stada Arzneimittel in the EEA member states, Switzerland and the UK. Revenues for the provision of certain regulatory services to Stada are reported over time as the services are performed, plus a fair market margin.

The Group has identified two performance obligations within the agreement with Stada:  
1) Out-licensing of the product candidate Nefecon in existing condition at the signing of the agreement, and  
2) Performance of certain regulatory services related to the MMA for EU.

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:

	Year Ended December 31,		
	2021	2020	2019
<b>Type of goods or service</b>			
Out-licensing of the product candidate	225,252	–	184,829
Performance of certain regulatory services	4,095	–	–
Provision of drugs	–	874	–
<b>Total</b>	<b>229,347</b>	<b>874</b>	<b>184,829</b>
<b>Geographical markets</b>			
Europe	201,878	–	–
China, Hong Kong, Macau, Taiwan and Singapore	27,469	874	184,829
<b>Total</b>	<b>229,347</b>	<b>874</b>	<b>184,829</b>

The total value of outstanding performance obligation to be performed in future periods amounted to SEK 4,095 as of December 31, 2021. No outstanding performance obligations existed as of December 31, 2020.

### Note 4 Other Operating Income

	Year Ended December 31,		
	2021	2020	2019
Exchange rate differences	149	2,501	4,385
Net gains on disposal of equipment	110	–	–
<b>Total</b>	<b>259</b>	<b>2,501</b>	<b>4,385</b>

### Note 5 Other Operating Expenses

	Year Ended December 31,		
	2021	2020	2019
Exchange rate differences	1,807	–	4,464
Net loss on disposal of equipment	67	–	61
Change in value of the contingent consideration at fair value	4,470	–	–
<b>Total</b>	<b>6,344</b>	<b>–</b>	<b>4,525</b>

### Note 6 Auditors' Fee

	Year Ended December 31,		
	2021	2020	2019
<b>EY</b>			
Audit services	6,235	4,449	645
Other audit activities	2,105	3,774	3,343
Tax advice	73	–	–
Other services	–	–	98
<b>Total</b>	<b>8,413</b>	<b>8,223</b>	<b>4,086</b>
<b>KPMG</b>			
Audit services	472	102	–
Other audit activities	1,178	2,552	–
<b>Total</b>	<b>1,650</b>	<b>2,654</b>	<b>–</b>
<b>Other auditors</b>			
Audit services	471	102	–
Other audit activities	79	–	–
<b>Total</b>	<b>550</b>	<b>102</b>	<b>–</b>
<b>Total audit fee</b>	<b>10,613</b>	<b>10,979</b>	<b>4,086</b>

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

Other auditing activities are those services in accordance with a special agreement on financial statements. Other services include advice on accounting issues and advice on processes and internal control.

### Note 7 Costs according to Type of Cost

	Year Ended December 31,		
	2021	2020	2019
Other external expenses	549,079	311,329	176,729
Personnel costs	164,206	68,943	34,157
Depreciation on equipment's and right-of-use assets	34,433	2,823	1,822
Other operating expenses	6,344	–	4,525
<b>Total</b>	<b>754,062</b>	<b>383,095</b>	<b>217,233</b>

### Note 8 Leases

#### Right-of-use assets

	December 31,	
	2021	2020
Opening balance	9,595	7,527
Additional agreements	34,944	98
Termination of agreement	(7,625)	–
Exchange differences	284	(8)
Additional agreements, through acquisition	–	1,978
<b>Closing balance</b>	<b>37,198</b>	<b>9,595</b>

#### Depreciation

Opening balance	(4,351)	(1,568)
Depreciation	(5,711)	(2,786)
Termination of agreement	6,456	–
Exchange differences	(292)	3
<b>Closing balance</b>	<b>(3,898)</b>	<b>(4,351)</b>

#### Net book value

<b>33,300</b>	<b>5,244</b>
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Depreciation on right-of-use assets are included in the consolidated statements of income under Research and development expenses amounted to SEK 997 (SEK 165) for the year ended December 31, 2021 and 2020, respectively, and Administrative and selling expenses amounted to SEK 4,714 (SEK 2,621) for the year ended December 31, 2021 and 2020, respectively.

#### Lease liabilities

	December 31,	
	2021	2020
Non-current lease liabilities	24,052	878
Current lease liabilities	9,591	3,908
<b>Total</b>	<b>33,642</b>	<b>4,786</b>

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

#### Maturity analysis on future lease liabilities

	December 31,	
	2021	2020
<12 months	11,909	4,521
1-2 years	11,231	1,105
>2 years	16,256	–
	<b>39,396</b>	<b>5,626</b>

Future lease payments in accordance with the above are undiscounted and include variable fees.

The leases primarily comprise of leased premises for the Group. The lease agreements for leased premises have terms ending 2022 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,



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

**Note 9 Employees and Personnel Costs**

**Average Number of Employees**

	Year Ended December 31,					
	2021		2020		2019	
	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.	Number of Empl.	% of Male Empl.
<b>Parent Company</b>						
Sweden	29	40%	16	44%	13	38%
	<b>29</b>	<b>40%</b>	<b>16</b>	<b>44%</b>	<b>13</b>	<b>38%</b>
<b>Subsidiaries</b>						
France	3	26%	-	-	-	-
Switzerland	6	47%	2	50%	-	-
United States	18	62%	5	100%	1	100%
	<b>27</b>	<b>55%</b>	<b>7</b>	<b>86%</b>	<b>1</b>	<b>100%</b>
<b>Total for the Group</b>	<b>56</b>	<b>47%</b>	<b>23</b>	<b>57%</b>	<b>14</b>	<b>43%</b>

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

**Wages and Salaries**

	Year Ended December 31,		
	2021	2020	2019
<b>Parent Company</b>			
Board and executive management <sup>1)</sup>	27,792	19,211	13,109
Other employees	33,370	15,598	6,091
<b>Subsidiaries</b>			
Board and executive management	4,983	3,184	2,973
Other employees	57,452	11,615	-
<b>Total</b>	<b>123,597</b>	<b>49,608</b>	<b>22,173</b>

<sup>1)</sup> Executive management includes CEO and other executive management.

**Social Security Costs and Pension Costs**

	Year Ended December 31,		
	2021	2020	2019
<b>Parent Company</b>			
Pension costs for the Board and executive management	1,785	1,748	1,644
Pension costs to other employees	4,084	1,666	1,180
Social security costs	17,088	12,330	3,008
<b>Subsidiaries</b>			
Pension costs for the Board and executive management	167	129	-
Pension costs to other employees	928	506	-
Social security costs	8,596	225	299
<b>Total</b>	<b>32,648</b>	<b>16,604</b>	<b>6,131</b>

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

	Year Ended December 31,		
	2021	2020	2019
Percentage of women on the Board	60%	60%	33%
Percentage of men on the Board	40%	40%	67%
Percentage of women among other executive management	33%	33%	33%
Percentage of men among other executive management	67%	67%	67%

**Disclosures Regarding Total Remuneration of the Board and Executive Management**

	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	499
Lennart Hansson	360	-	-	-	162	522
Diane Parks	421	-	-	-	162	584
Molly Henderson	539	-	-	-	124	664
<b>Executive management</b>						
CEO	4,860	760	1,840	-	3,270	10,730
Other executive management (5 people)	11,279	1,193	2,335	-	5,561	20,367
of which relates to subsidiaries	2,775	167	694	-	1,515	5,151
<b>Total</b>	<b>18,694</b>	<b>1,953</b>	<b>4,175</b>	<b>-</b>	<b>9,906</b>	<b>34,728</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	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>

	Year Ended December 31, 2019					
	Basic Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-based Payments	Total
<b>Chairman of the Board</b>						
Elmar Schnee	402	-	-	-	101	503
<b>Board members</b>						
Thomas Eklund	280	-	-	-	37	317
Hilde Furberg	180	-	-	-	37	217
Lennart Hansson	102	-	-	-	37	139
Bengt Julander	102	-	-	-	-	102
Diane Parks	201	-	-	-	37	238
Olav Hellebø (until May, 2019)	58	-	-	-	-	58
<b>Executive management</b>						
CEO	2,634	510	956	-	-	4,100
Other executive management (8 people)	8,927	1,134	1,991	4,701	-	16,753
of which relates to subsidiaries	2,382	-	591	-	-	2,973
<b>Total</b>	<b>12,886</b>	<b>1,644</b>	<b>2,947</b>	<b>4,701</b>	<b>249</b>	<b>22,427</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 0 (SEK 472, SEK 853) for the year ended December 31, 2021, 2020 and 2019, respectively, and relates to the functions of a Head of Communications and Investor Relations that were outsourced to this entity. There were no services provided from Jedako Consult AB for the year ended December 31, 2021 and 2020, respectively, but for the year ended December 31, 2019 the Group purchased SEK 3,848. The services provided related to the function of a Chief Medical Officer that were outsourced to this entity.

Remuneration of Executive Management

Remuneration of the CEO and other executive management comprises base salary, pension benefits, variable remuneration and remuneration in the form of consultancy fees. Other executive management comprise the 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 and Vice President Operations.

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 2021 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 86-91.

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

Warrants

The Group has two warrants programs, whereby personnel and certain other employees have purchased warrants at fair value with rights to acquire shares in the Parent Company. When warrant is exercised, the holder pays a subscription price and then receives one common share in the Parent Company. For the programs initiated in 2018 and 2019, the warrants can be exercised between January 1, 2022 and March 31, 2022 and between October 1, 2022 and December 31, 2022, respectively. If the warrant holder leaves the Group prior to exercise, the Group has the option to repurchase a certain number of warrants, depending on the time of leaving, at the lesser of fair value or the purchase price.

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 Program 2018/2022

In 2018, a total of 856,586 warrants were issued to employees and key consultants in the Group. The warrants in the warrants program 2018/2022 can be exercised between January 1, 2022 and March 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the company at a subscription price of SEK 74.30 per share.

Warrants Program 2019/2022

In 2019, a total of 422,500 warrants were issued to employees and key consultants in the Group. The warrants in the warrants program 2019/2022 can be exercised between October 1, 2022 and December 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the company at a subscription price of SEK 74.50 per share.

Allotted Warrants	Accumulated No. of Outstanding	Weighted Average Exercise Price, SEK
As of December 31, 2019	2,575,586	58
Exercised during the period	(1,296,500)	42
As of December 31, 2020	1,279,086	74
Exercised during the period	-	-
As of December 31, 2021	1,279,086	74

The allocated weighted-average exercise price for warrants that are outstanding amounts to SEK 74, SEK 74 and SEK 58 as of December 31, 2021, 2020 and 2019, respectively. During 2020, 5,186 warrants were exercised under the Warrant Program 2017/2020, where one warrant entitles to the subscription of 250 shares. The registration of the issue of shares amounted to 1,296,500 common shares.

Outstanding Warrants per Year	Warrants Outstanding as of			Inputs used for the Black & Scholes valuation					
	December 31, 2019	December 31, 2020	December 31, 2021	Exercise Price, SEK	Price per Warrant in SEK	Value per Share in SEK	Risk-Free Rate	Volatility	Expiration Date
Warrant program 2017/2020	1,296,500	-	-	42.36	0.28	21.18	(0.42%)	27%	2020-06-30
Warrant program 2018/2022	856,586	856,586	856,586	74.30	3.29	46.50	(0.28%)	33%	2022-03-31
Warrant program 2019/2022	422,500	422,500	422,500	74.50	6.69*	54.39*	(0.55%)*	36%*	2022-12-31
Total	2,575,586	1,279,086	1 279,086						

\* Average value

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

Holder	Warrants Outstanding as of						
	January 1, 2019	Change	December 31, 2019	Change	December 31, 2020	Change	December 31, 2021
CEO Renée Lucander	719,500	195,000	914,500	(369,500)	545,000	-	545,000
Board member Thomas Eklund (until June, 2020)	111,250	-	111,250	(111,250)	-	-	-
Board member Hilde Furberg	29,500	-	29,500	(29,500)	-	-	-
Other executive management	727,086	107,500	834,586	(397,086)	437,500	-	437,500
Other employees, consultants and external parties	930,750	(245,000)	685,750	(389,164)	296,586	-	296,586
Total	2,518,086	57,500	2,575,586	(1,296,500)	1,279,086	-	1 279,086

Option Program

In 2020 and 2021, respectively, Calliditas implemented option programs for employees and key consultants in Calliditas. The options were allotted free of charge to participants of the program. The options have a three-year vesting period calculated from the allotment 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 allotment date. The options have, at the time of issue, been valued according to the Black & Scholes valuation model.

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

Holder	Options Outstanding as of						
	January 1, 2019	Change	December 31, 2019	Change	December 31, 2020	Change	December 31, 2021
Renée Aguiar-Lucander, CEO	-	-	-	225,000	225,000	71,000	296,000
Other executive management	-	-	-	415,000	415,000	120,000	535,000
Other employees and consultants	-	-	-	449,000	449,000	1,009 000	1,458,000
Total	-	-	-	1,089,000	1,089,000	1,200,000	2,289,000

Calculation of fair value of option program

The fair value on the allotment 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 allotment date and expected volatility in the share price, and risk-free interest for the term of the options.

	Grant Date	Exercise Date	Fair Value upon Issue of the Options, SEK	Exercise Price, SEK	Volatility	No. of Shares covered by Options
ESOP 2020:1	July 1, 2020	July 1, 2023	22.14	121.43	39.6%	859,000
ESOP 2020:2	September 17, 2020	September 17, 2023	22.50	116.78	41.6%	99,000
ESOP 2020:3	February 4,2021	February 4,2024	30.41	145.05	44.3%	60,000
ESOP 2020:4	Mars 9, 2021	Mars 9, 2024	30.41	141.26	45.2%	421,000
ESOP 2021:1	Jun 14, 2021	Jun 14, 2024	35.88	140.71	46.0%	510,000
ESOP 2021:2	September 29, 2021	September 29, 2024	25.72	109.38	47.5%	340,000
						2,289,000



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The total cost of the outstanding option program is presented below. These costs do not affect the Groups consolidated statement of cash flows. The Group has 3,000,000 warrants which are set aside to secure the delivery of shares in connection with the utilization of the option program. For additional information see Note 25 Equity.

	Year Ended December 31,		
	2021	2020	2019
Share-based payments	24,737	5,304	-
Provisions attributable to changes in social security costs (Share-based payments)	9,992	3,164	-
<b>Total</b>	<b>34,729</b>	<b>8,468</b>	<b>-</b>

Share-Based Payments

Board LTIP 2019

This is a performance-based long-term incentive program for certain members of the Board of Directors in Calliditas. A total of 51,399 share awards is outstanding for the incentive program 2019. The share awards are gradually vested over three years until the AGM 2022 or June 1, 2022, whichever is the earliest, based on the development of Calliditas share price during the period from May 8, 2019 through on June 1, 2022. 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, 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:

Holder	Share Awards Outstanding as of						
	January 1, 2019	Change	December 31, 2019	Change	December 31, 2020	Change	December 31, 2021
Elmar Schnee, Chairman of the Board	-	23,236	23,236	-	23,236	-	23,236
Thomas Eklund, Board member (until June, 2020)	-	8,449	8,449	(5,633)	2,816	-	2,816
Hilde Furberg, Board member	-	8,449	8,449	-	8,449	-	8,449
Lennart Hansson, Board member	-	8,449	8,449	-	8,449	-	8,449
Diane Parks, Board member	-	8,449	8,449	-	8,449	-	8,449
<b>Total</b>	<b>-</b>	<b>57,032</b>	<b>57,032</b>	<b>(5,633)</b>	<b>51,399</b>	<b>-</b>	<b>51,399</b>

Calculation of fair value of share-based payments (Board LTIP 2019)

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

The total cost of the outstanding share-based payments is presented below. These costs do not affect the Groups consolidated statement of cash flows. The Group has 70,000 warrants which are set aside to secure the delivery of shares in connection with the utilization of the Board LTIP 2019. For additional information see Note 25 Equity.

	Year Ended December 31,		
	2021	2020	2019
Share-based payments	396	440	249
Provisions attributable to changes in social security costs (Share-based payments)	-	1,426	175
<b>Total</b>	<b>396</b>	<b>1,866</b>	<b>424</b>

Board LTIP 2020

This is a performance-based long-term incentive program for certain members of the Board of Directors in Calliditas. A total of 31,371 share awards is outstanding for the incentive program 2020. The share awards are gradually vested over three years until the AGM 2023 or July 1, 2023, whichever is the earliest, based on the development of Calliditas share price during the period from the date the share awards are allocated (grant date) up to and including the day before the vesting date. 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, 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:

Holder	Share Awards Outstanding as of						
	January 1, 2019	Change	December 31, 2019	Change	December 31, 2020	Change	December 31, 2021
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	-	-	-	4,327	4,327	-	4,327
Diane Parks, Board member	-	-	-	4,327	4,327	-	4,327
Molly Henderson, Board member	-	-	-	4,327	4,327	-	4,327
<b>Total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>31,371</b>	<b>31,371</b>	<b>-</b>	<b>31,371</b>

Calculation of fair value of share-based payments (Board LTIP 2020)

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 2020	July 1, 2023	33.97	31,371

The total cost of the outstanding share-based payments is presented below. These costs do not affect the Groups consolidated statement of cash flows. The Group has 40,000 warrants which are set aside to secure the delivery of shares in connection with the utilization of the Board LTIP 2020. For additional information see Note 25 Equity.

	Year Ended December 31,		
	2021	2020	2019
Share-based payments	445	267	-
Provisions attributable to changes in social security costs (Share-based payments)	171	207	-
<b>Total</b>	<b>616</b>	<b>474</b>	<b>-</b>

Board LTIP 2021

This is a performance-based long-term incentive program for certain members of the Board of Directors in Calliditas. A total of 31,371 share awards is outstanding for the incentive program 2021. The share awards are gradually vested over three years until the AGM 2024 or July 1, 2024, whichever is the earliest, based on the development of Calliditas share price during the period from the date the share awards are allocated (grant date) up to and including the day before the vesting date. 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, 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:

Holder	Share Awards Outstanding as of						
	January 1, 2019	Change	December 31, 2019	Change	December 31, 2020	Change	December 31, 2021
Elmar Schnee, Chairman of the Board	-	-	-	-	-	10,624	10,624
Hilde Furberg, Board member	-	-	-	-	-	4,086	4,086
Lennart Hansson, Board member	-	-	-	-	-	4,086	4,086
Diane Parks, Board member	-	-	-	-	-	4,086	4,086
Molly Henderson, Board member	-	-	-	-	-	4,086	4,086
<b>Total</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>26,968</b>	<b>26,968</b>

Calculation of fair value of share-based payments (Board LTIP 2021)

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).

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	Exercised Date	Fair Value at Grant Date	Number of Share Awards
Board LTIP 2021	July 1, 2024	62.34	26,968

The total cost of the outstanding share-based payments is presented below. These costs do not affect the Groups consolidated statement of cash flows. The Group has 40,000 warrants which are set aside to secure the delivery of shares in connection with the utilization of the Board LTIP 2020. For additional information see Note 25 Equity.

	Year Ended December 31,		
	2021	2020	2019
Share-based payments	431	-	-
Provisions attributable to changes in social security costs (Share-based payments)	126	-	-
<b>Total</b>	<b>557</b>	<b>-</b>	<b>-</b>

**Note 11 Financial Income**

	Year Ended December 31,		
	2021	2020	2019
Interest income	102	547	926
Exchange rate differences	20,234	-	-
<b>Total</b>	<b>20 336</b>	<b>547</b>	<b>926</b>

**Note 12 Financial Expenses**

	Year Ended December 31,		
	2021	2020	2019
Interest on lease liabilities	(590)	(388)	(307)
Other interest expenses	(6,518)	(5)	(18)
Exchange rate differences	-	(53,267)	(2,383)
Changes in FX options measured at fair value	-	(3,318)	(2,700)
Other financial expenses	(2,145)	-	-
<b>Total</b>	<b>(9,253)</b>	<b>(56,978)</b>	<b>(5,408)</b>

**Note 13 Income Tax Expense**

	Year Ended December 31,		
	2021	2020	2019
Current income taxes	(4,581)	(1,035)	(77)
Deferred tax	8,417	675	-
<b>Income tax expense recognized in the consolidated statements of income</b>	<b>3,836</b>	<b>(360)</b>	<b>(77)</b>

	Year Ended December 31,		
	2021	2020	2019
<b>Reconciliation of effective tax rate</b>			
Accounting loss before income tax	(513,373)	(436,151)	(32,501)
Tax in accordance with applicable tax rate in Sweden 20,6% (21,4% ,21,4%)	105,755	93,336	6,955
<i>Tax effect of:</i>			
Effect of other tax rates for foreign subsidiaries	11,481	680	2
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(101,785)	(91,725)	(6,316)
Non-deductible expenses	(11,615)	(2,652)	(782)
Non-taxable income	0	1	64
<b>Income tax expense recognized in the consolidated statements of income</b>	<b>3,836</b>	<b>(360)</b>	<b>(77)</b>
<b>At the effective income tax rate</b>	<b>1%</b>	<b>0%</b>	<b>0%</b>

The Group has costs attributable to new share issue amounted to SEK 20,909 (SEK 97,686 and SEK 10,915) for the year ended December 31, 2021,2020 and 2019, respectively, which are recognized directly against equity. These costs are deductible for tax purposes.

The Group has SEK 3,200,911 (SEK 2,704,803, SEK 578,117) of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position as of December 31, 2021, 2020, and 2019, respectively. The tax losses carried forward are allocated between Sweden of SEK 1,436,157, France of SEK 1,080,573 and Switzerland of SEK 684,181, 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,		
	2021	2020	2019
<b>Loss per share before and after dilution</b>			
Net loss for the year attributable to equity holders of the Parent Company	(500,293)	(433,494)	(32,578)
Weighted-average number of common shares outstanding	50,829,255	44,873,448	36,940,587
<b>Loss per share before and after dilution</b>	<b>(9.84)</b>	<b>(9.66)</b>	<b>(0.88)</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. 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 2018 – 2021. 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 warrants and options with entitlement to subscribe to 3,568,086 shares, since the Group is in a loss position for the year ended December 31, 2021, December 31, 2020 and December 31, 2019, respectively. Further, there is no dilution effect for issued share awards with entitlement to receive 109,738 shares, due to performance-based vesting.

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

**Note 15 Business Combinations**

On November 3, 2020, Calliditas acquired a controlling interest in Genkyotex SA, a biopharmaceutical company specializing in NOX therapies with offices in France and Switzerland. Its unique platform 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 purpose of the acquisition is that it adds a late-stage orphan pipeline asset and platform in inflammation and fibrosis to the Groups product portfolio in orphan diseases.

The fair value of the acquired assets and assessed liabilities for the acquisition of Genkyotex SA in 2020 was preliminarily established for the first 12 months and have thereafter been finalized. The fair value of the acquisitions of Genkyotex have changed due to allocation of assets and liabilities to Switzerland and therefore IFRS adjustments were made to the acquisition values.

There were no business acquisitions during the financial year 2021.

	Preliminary	Adjustments	Final
<b>The assets and liabilities recognized in conjunction with the acquisition are as follows:</b>			
Intangible assets: NOX Platform	382,521	(34,349)	348,124
Intangible assets: Other licenses	28,893	-	28,893
Non-current assets	2,438	-	2,438
Other current assets	10,022	-	10,022
Cash	32,265	-	32,265
Pension liabilities	(9,410)	-	(9,410)
Deferred tax liabilities	(82,683)	43,971	(38,712)
Other non-current liabilities	(643)	-	(643)
Other current liabilities	(20,677)	-	(20,677)
<b>Acquired identified assets</b>	<b>342,726</b>	<b>9,574</b>	<b>352,300</b>
Non-controlling interests	(136,084)	-	(136,084)
Goodwill	48,839	(9,574)	39,265
<b>Acquired net assets</b>	<b>255,481</b>	<b>-</b>	<b>255,481</b>

The gross amounts of acquired receivables does not differ significantly from fair value.

The below table describes the adjustments to the Group opening balance sheet from the finalization of the fair value.

(SEK in thousands)	December 31,		
	2020	Adjustment	2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	461,367	(42,542)	418,825
Equipment	163	-	163
Right-of-use assets	5,244	-	5,244
Non-current financial assets	2,225	-	2,225
Deferred tax assets	600	-	600
<b>Total non-current assets</b>	<b>469,599</b>	<b>(42,542)</b>	<b>427,057</b>
<b>Current assets</b>			
<b>Total current assets</b>	<b>1,036,851</b>	<b>-</b>	<b>1,036,851</b>
<b>TOTAL ASSETS</b>	<b>1,506,450</b>	<b>(42,542)</b>	<b>1,463,908</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<b>Total equity</b>	<b>1,256,300</b>	<b>-</b>	<b>1,256,300</b>
<b>Non-current liabilities</b>			
Other non-current Liabilities	55,361	-	55,361
Pensions Liabilities	8,296	-	8,296
Deferred tax liabilities	79,996	(42,542)	37,454
Lease liabilities	878	-	878
<b>Total non-current liabilities</b>	<b>144,531</b>	<b>(42,542)</b>	<b>101,989</b>
<b>Currents liabilities</b>			
<b>Total current liabilities</b>	<b>105,619</b>	<b>-</b>	<b>105,619</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1,506,450</b>	<b>(42,542)</b>	<b>1,463,908</b>



# GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

## Note 16 Intangible Assets and Impairment Testing

	December 31,	
	2021	2020
<b>Licenses and similar rights</b>		
Cost at opening balance	380,836	16,066
Business combinations	-	377,017
Acquisition for the year	16,066	-
Exchange differences on translation	(6,736)	(12,247)
<b>Cost at closing balance</b>	<b>390,166</b>	<b>380,836</b>
<b>Impairment</b>		
Cost at opening balance	-	-
Impairment	(27,975)	-
<b>Cost at closing balance</b>	<b>(27,975)</b>	<b>-</b>
<b>Goodwill</b>		
Cost at opening balance	37,989	-
Business combinations	-	39,265
Exchange differences on translation	(762)	(1,276)
<b>Cost at closing balance</b>	<b>37,227</b>	<b>37,989</b>
<b>Net book value</b>	<b>399,418</b>	<b>418,825</b>

Intangible assets consist of licenses and similar rights of SEK 362,191 and goodwill of SEK 37,227.

### Business combinations:

The acquisition of Genkyotex SA resulted in the Group acquiring the rights to the NOX platform and vaccine platform (SIIL agreement), as well as goodwill.

The net book value of the NOX platform amounts to SEK 330,059 as of December 31, 2021. 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.

The net book value of the vaccine platform (SIIL agreement), which is an out-license agreement with Serum Institute of India (SIIL) for the use of a vaccine technology, amounts to SEK 27,957 as of December 31, 2020 and written off as per December 31, 2021 since the project is not expected to generate future cash flows.

Goodwill amounts to SEK 37,227 as of December 31, 2021 and for further information please see Note 15 Business Combinations.

## 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, 2021, the Group's goodwill amounted to SEK 37,227. There is no impairment for the year ended December 31, 2021.

The following table shows the discount rate used before tax:

Parameter, %	Year Ended December 31,	
	2021	2020
Discount rate	11.0	10.5

### 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,	
	2021	2020
Discount rate NOX platform	17.7	18.8
Discount rate Vaccine platform	-	17.0
Discount rate Budenofalk 3 mg oral capsule	12.4	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 requirement.

## Note 17 Equipment

	December 31,		
	2021	2020	2019
Cost at opening balance	214	118	813
Acquisition for the year	6,588	-	118
Disposal for the year	(118)	-	(813)
Exchange differences	389	(4)	-
Additional, through business combinations	-	100	-
<b>Cost at closing balance</b>	<b>7,073</b>	<b>214</b>	<b>118</b>
Depreciation at opening balance	(51)	(14)	(706)
Deprecation for the year	(465)	(37)	(44)
Disposal for the year	51	-	736
Exchange differences	(299)	-	-
<b>Depreciation at closing balance</b>	<b>(764)</b>	<b>(51)</b>	<b>(14)</b>
<b>Net book value</b>	<b>6,309</b>	<b>163</b>	<b>104</b>

Depreciation on equipment are included in the consolidated statement of income under Research and development expenses amounted to SEK 59 and Administrative and selling expenses amounted to SEK 406 ( SEK 37 and SEK 44) for the year ended December 31, 2021, 2020 and 2019, respectively.

## Note 18 Non-Current Financial Assets

	December 31,		
	2021	2020	2019
Cost at opening balance	2,225	1,939	341
Bank guarantees granted	1,686	-	1,888
Reimbursement security deposit	-	-	(290)
Exchange differences	4	-	-
Acquisition through business combinations	-	286	-
<b>Net book value</b>	<b>3,915</b>	<b>2,225</b>	<b>1,939</b>

Non-current financial assets comprise of bank guarantees/deposits amounted to SEK 3,915 (SEK 2,225, SEK 1,939) as of December 31, 2021, 2020 and 2019, respectively.

## » GROUP - NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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### Note 19 Deferred Tax Assets and Deferred Tax Liabilities

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>

Deferred tax assets and liabilities as of December 31, 2020

	Deferred Tax Assets	Deferred Tax Liabilities	Net
Intangible assets	–	(47,120)	(47,120)
Personnel-related items	596	–	596
Tax loss carried forward	9,666	–	9,666
Other items	4	–	4
<b>Total</b>	<b>10,266</b>	<b>(47,120)</b>	<b>(36,854)</b>
Offsetting	(9,666)	9,666	–
<b>Tax assets/liabilities, net</b>	<b>600</b>	<b>(37,454)</b>	<b>(36,854)</b>

Tax losses carried forward of SEK 9,666 have been recognized as deferred tax assets in the statement of financial position as of December 31, 2020 due to future temporary differences that such asset can be used to offset.

#### Change in deferred tax, 2020

	Cost at Opening Balance	Recognized in Profit or Loss	Increase through Business Combinations	Cost at Closing Balance
Intangible assets	–	–	(47,120)	(47,120)
Personnel-related items	–	596	–	596
Tax loss carried forward	–	–	9,666	9,666
Other items	–	4	–	4
<b>Total</b>	<b>–</b>	<b>600</b>	<b>(37,454)</b>	<b>(36,854)</b>

No deferred tax assets and deferred tax liabilities occurred for the financial year 2019.

### Note 20 Financial and Non-Financial Assets and Liabilities

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>315,945</b>	<b>31,496</b>	<b>401,841</b>

Financial and non-financial assets and liabilities as of December 31, 2020

	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	–	2,225	–	2,225
Other current assets	–	112	22,689	22,801
Cash	–	996,304	–	996,304
	<b>–</b>	<b>998,641</b>	<b>22,689</b>	<b>1,021,330</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	48,969	–	–	48,969
Other non-current liabilities	–	878	–	878
Accounts payable	–	53,827	–	53,827
Other current liabilities	–	3,908	5,980	9,888
Accrued expenses and deferred revenue	–	24,890	16,496	41,386
	<b>48,969</b>	<b>83,503</b>	<b>22,476</b>	<b>154,948</b>

Financial assets valued at fair value through profit or loss consist of currency options. As of December 31, 2021 and 2020 respectively, there were no currency options outstanding since they had expired and as of December 31, 2019, currency options amounted to SEK 399. Currency options are valued at fair value based on calculation using the Black-Scholes option pricing model at Level 2 of the fair value hierarchy. Financial liabilities valued through profit or loss constitutes of contingent consideration in connection with the business combination of Genkyotex SA of SEK 54,399 (SEK 48,969) as of December 31, 2021 and 2020, 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.



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Note 21 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, liquidity risk and external risk. The Group's overall risk management focuses on the unpredictability of the financial markets and it endeavors to minimize potentially unfavorable effects on the Group's financial results.

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

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

Credit Risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument, leading to a financial loss for the Group. The Group's exposure to credit risk 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, and accordingly no provision for credit risk is recognized.

Credit risk accounts receivable

The payment terms amount to 20 business days depending on the counterparty.

Days past due, but not impaired, receivables on the closing day is given below. There is no reserve for bad debts and no recognized credit losses.

	December 31,		
	2021	2020	2019
Days past due account receivables	-	-	-
Not due account receivables	-	-	46,586
<b>Total</b>	<b>-</b>	<b>-</b>	<b>46,586</b>

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

Market Risks

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

Foreign Currency Risk

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

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 borrowings, the Group is exposed to interest rate risk. The Group does not currently have any variable interest rate.

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 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%

Currency Exposure 2019 (%)	Revenue	Operating Expenses
USD	100%	22%
EUR	-	54%
GBP	-	3%
SEK	-	21%

As presented in the table above, the Group's primary transaction exposure is 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 909 (SEK 10,247, SEK 10,246). A 10% stronger U.S. dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 22,402 (SEK 9,979, pos. SEK 14,359).

Translation Exposure

The 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 18,270 (SEK 1,256 as of December 31, 2021 and 2020. A 10% stronger Swedish Krona against the U.S. dollar would have a positive impact on equity of approximately SEK 1,827 (SEK 126). Translation against Euros amounted to SEK -93,814 (SEK 26,673) as of December 31, 2021 and 2020. A 10% stronger Swedish Krona against Euros would have a positive impact on equity of approximately SEK 9,381 (neg. SEK 2,667).

The Group also has a translation exposure arising from the translation of foreign trade debt to the Swedish Kronor. This exposure amounted to SEK 29,236 (SEK 15,811, SEK 5,866) at the closing date and in U.S. dollars SEK 10,707 (SEK 28,806, SEK 14,817) in Euros. A 10% stronger U.S. dollar against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 2,924 (SEK 1,581, SEK 587). A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 1,071 (SEK 2,881, SEK 1,482).

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 currently mainly financed by equity and thus is not exposed to large risk related to external loan financing. However, if the Group would increase the external loan financing, there would be a risk that the Group could not refinance these loans. Accordingly, the primary risks pertain to the risk of not securing additional contributions and investments from the share-holders.

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 day rate. Financial instruments with variable interest rates were measured at the rate on the closing date. Liabilities were included in the earliest period when repayment is required. For future lease payments see Note 8 Leases.

Maturity analysis

	December 31, 2021		
	<6 months	6-12 months	>12 months
Accounts payable	67,971	-	-
Other current liabilities	7,906	4,796	-
Accrued expenses	47,753	5,800	-
Contingent consideration	-	-	54,399

	December 31, 2020		
	<6 months	6-12 months	>12 months
Accounts payable	53,827	-	-
Other current liabilities	7,934	1,954	-
Accrued expenses	34,833	6,552	-
Contingent consideration	-	-	48,969

Non-current interest-bearing liabilities

	December 31,		
	2021	2020	2019
Opening balance	-	-	-
New borrowings	199,524	-	-
Transaction costs paid	(14,858)	-	-
Interest expense	2,145	-	-
Exchange difference on translation	2,353	-	-
<b>Closing balance</b>	<b>189,164</b>	<b>-</b>	<b>-</b>

In July 2021, Calliditas signed a loan agreement of up to the euroequivalent of 75 million dollar with Kreos Capital. The loan facility is divided into three tranches of 25 million dollar each. Drawdown of the first 25 million dollar tranche was made in September, 2021. Drawdown of the second tranche of 25 million dollar can be made until 30 June 2022. Drawdown of the third and final 25 million dollar tranche can be made until 31 December 2022 and will be available subject to certain revenue milestones and coverage metrics. The interest rate on the loan is 9 % per annum with a maturity to December 2025, which is recognized at Net financial income/(expenses). The loan has no financial covenants.

Note 22 Prepaid Expenses

	December 31,	
	2021	2020
Prepaid insurance premiums	10,813	10,743
Prepaid expenses for research and development	27,888	640
Other prepaid expenses	6,331	6,363
<b>Total</b>	<b>45,032</b>	<b>17,746</b>

Note 23 Cash

	December 31,		
	2021	2020	2019
Cash at Banks	955,507	996,304	753,540
<b>Total</b>	<b>955,507</b>	<b>996,304</b>	<b>753,540</b>

Cash and Banks balances are primarily in SEK and EUR.

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

	Year Ended December 31,		
	2021	2020	2019
Depreciation and Impairment	34,433	2,823	1,822
Change in Provisions	10,326	6,634	175
Share-based payments	21,960	6,012	249
Other items	(43)	(4)	62
<b>Total</b>	<b>66,676</b>	<b>15,465</b>	<b>2,308</b>

Reconciliation of liabilities from financing activities

	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>

	January 1, 2020	Cash-Flow	Non-Cash-Items	December 31, 2020
Lease liabilities	6,070	(3,972)	(2,688)	4,786
	<b>6,070</b>	<b>(3,972)</b>	<b>(2,688)</b>	<b>4,786</b>

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### Note 24 Group Companies

Company	Principal Activities	Country of Incorporation	% Equity Interest 2021	% Equity Interest 2020	% Equity Interest 2019
<b>Parent Company</b>					
Calliditas Therapeutics AB	Research and development of pharmaceuticals	Sweden	-	-	-
<b>Subsidiaries</b>					
Nefecon AB	Administration of incentive programs issued by the Parent Company	Sweden	100%	100%	100%
Calliditas NA Enterprises Inc.	Market access activities in the United States	United States	100%	100%	100%
Calliditas Therapeutics US Inc	Commercial activities in the United States	United States	100%	-	-
Calliditas Therapeutics France SAS	Research and development of pharmaceuticals	France	100%	86,2%	-
Calliditas Therapeutics Suisse SA	Research and development of pharmaceuticals	Switzerland	100%	86,2%	-

For further information on the business combination, see Note 15 Business Combinations.

### Note 25 Equity

#### Share capital and other contributed capital

	Number of Shares	Share Capital	Additional Paid-in Capital
<b>As of January 1, 2019</b>	<b>35,202,347</b>	<b>1,408</b>	<b>1,072,319</b>
Premiums from warrants issuance	-	-	2,834
Share-based payment	-	-	249
New share issue	3,505,291	140	199,262
<b>As of December 31, 2019</b>	<b>38,707,638</b>	<b>1,548</b>	<b>1,274,664</b>
New share issue*	9,937,446	397	793,304
Exercise of warrants	1,296,500	52	59,199
Share-based payment	-	-	6,012
<b>As of December 31, 2020</b>	<b>49,941,584</b>	<b>1,998</b>	<b>2,133,179</b>
New share issue**	2,400,000	96	302,995
Share-based payment	-	-	23,567
<b>As of December 31, 2021</b>	<b>52,341,584</b>	<b>2,094</b>	<b>2,459,741</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

#### Share Capital

All shares have been fully paid and no shares are reserved for sale. All shares are common shares, confer the same entitlement to capital, and carry one vote. The quotient value is SEK 0.04 per share. No shares are held in treasury by the Parent Company or its subsidiaries.

#### Additional Paid-in Capital

Additional paid-in capital is comprised of capital contributed by the Parent Company's owners, in the event of share premiums arising on share subscription, warrants premiums and accounted capital from warrants, and other financing treated as equity.

#### 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,		
	2021	2020	2019
Opening balance	(6,090)	(45)	(34)
Change for the year ended	(20,889)	(6,045)	(11)
<b>Closing balance</b>	<b>(26,979)</b>	<b>(6,090)</b>	<b>(45)</b>

### Note 26 Provisions

#### 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
Additional provisions during 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>

#### Provisions as of December 31, 2020

	Social Security Costs on Share-Based Payment	Other Provisions	Provisions Net
Opening balance	175	-	175
Additional provisions during the year	4,797	1,443	6,240
Exchange differences	-	(24)	(24)
<b>Total</b>	<b>4,972</b>	<b>1,419</b>	<b>6,391</b>

#### Social Security Costs on Share-Based Payment

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

## Note 27 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 and selling expenses in the consolidated statements of income.

### Net obligation per country

	December 31,	
	2021	2020
Switzerland	(3,071)	(8,124)
France	(111)	(172)
<b>Total</b>	<b>(3,182)</b>	<b>(8,296)</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
January 1, 2021	(19,193)	(172)	11,069	(8,296)
Service cost	(2,165)	(13)	–	(2,178)
Interest expense	(17)	0	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
Experience effect	–	–	–	–
<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)	705	(286)
<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.

### Changes in the defined-benefit pension obligations

	December 31, 2020			
	Defined Benefit Plan Obligation (Switzerland)	Defined Benefit Plan Obligation (France)	Fair Value of Plan Assets (Switzerland)	Employee Benefit Obligations
January 1, 2020	–	–	–	–
Business combinations	(19,565)	(211)	10,673	(9,103)
Service costs	(567)	(6)	–	(573)
Interest expense	(10)	–	6	(4)
Curtailment	(20)	–	10	(10)
Employee contribution	–	–	45	45
<b>Subtotal included in the statement of consolidated operations</b>	<b>(597)</b>	<b>(6)</b>	<b>61</b>	<b>(542)</b>
Amounts paid/received	(410)	–	410	–
Return on assets (excluding interest expenses)	–	–	(5)	(5)
Actuarial gains/(losses) related to changes in demographic assumptions	1,858	45	–	1,903
Actuarial gains/(losses) related to changes in financial assumptions	(273)	–	–	(273)
Other actuarial gains/(losses)	(411)	–	–	(411)
<b>Subtotal included in other items of comprehensive income</b>	<b>1,174</b>	<b>45</b>	<b>(5)</b>	<b>1,214</b>
Employer contributions	–	–	47	47
Currency translation effect	205	–	(117)	88
<b>December 31, 2020</b>	<b>(19,193)</b>	<b>(172)</b>	<b>11,069</b>	<b>(8,296)</b>

### Distribution by plan assets (Switzerland)

	December 31,	
	2021	2020
Cash	205	244
Bonds	2,801	6,365
Mortgage loans	667	1,516
Shares	92	365
Real estate	760	1,638
Other investments	346	941
<b>Total</b>	<b>4,871</b>	<b>11,069</b>

Of the plan assets above, SEK 2,801 (SEK 6,365) 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 (fixedrate 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 balance sheet date

	December 31,	
	2021	2020
<b>Swiss pension plan</b>		
Discount rate	0.35 %	0.15 %
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	22,3 years	23,3 years
Retirement age	65 years	65 years



Sensitivity analysis

	December 31,	
	2021	2020
Pension commitments under current assumptions for Swiss pension plans	7,942	19,362
Discount rate , -0,5%	8,904	21,631
Discount rate , +0,5%	7,130	17,139
Retirement pension inflation rate, -0,5%	7,575	18,241
Retirement pension inflation rate, +0,5%	8,353	20,257
Salary revaluation rate, -0,5%	7,792	18,802
Salary revaluation rate, +0,5%	8,100	19,605

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.

For the 2021 financial year, contributions to plans for post-employment benefits are expected to be SEK 555 (SEK 805). The weighted average maturity of the obligation is an estimated 22.3 (23.3) years.

There are no defined benefit pension plans for the 2019 financial year.

Note 28 Accrued Expenses and Deferred Revenue

	December 31,	
	2021	2020
Vacation pay liabilities	6,107	4,921
Accrued salaries and Board fees	16,786	8,134
Social security costs	5,492	3,440
Deferred revenue	3,387	-
Accrued expenses for research and development	4,230	14,135
Accrued expenses for administrative and selling	17,551	10,756
<b>Total</b>	<b>53,553</b>	<b>41,386</b>

Note 29 Inventories

	December 31,		
	2021	2020	2019
Raw materials	889	-	-

The groups inventories are recognised after US Food and Drug Administration (FDA) has approved TARPEYO in the US under accelerated approval.

Not 30 Contingent Consideration

Contingent consideration as of December 31, 2021

Contingent consideration	
Opening balance	48,969
Change for the year	4,470
Exchange differences	960
<b>Total</b>	<b>54,399</b>

Contingent consideration as of December 31, 2020

Contingent consideration	
Opening balance	-
Business acquisition	50,614
Exchange differences	(1,645)
<b>Total</b>	<b>48,969</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 10.0 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.

Note 31 Related-Party Transactions

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

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

Note 32 Pledged Assets, Contingent Liabilities and Other Obligations

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

The Group has exclusive rights to use, develop and market the formulation under the license agreement with Archimedes, and Archimedes only has rights to royalties when the product is sold 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 3,915 (SEK 2,336) as of December 31, 2021 and 2020, 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 33 Events After the Reporting Period

In January 2022, Calliditas announced the commercial availability and first sale of TARPEYO.

In March 2022, all 856,586 warrants were subscribed for in the 2018/2022 warrant program, which entitled to purchase of a new share in the parent company at a subscription price of SEK 74.30

## PARENT COMPANY

## Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31,	
		2021	2020
Net sales	2	229,347	874
Research and development expenses	7	(275,950)	(227,027)
Administrative and selling expenses	5,6,7	(377,475)	(128,896)
Other operating income	3	70,234	2,482
Other operating expenses	4	(1,874)	-
<b>Operating loss</b>		<b>(355,717)</b>	<b>(352,567)</b>
<b>Profit/(loss) from financial income/(expenses)</b>			
Profit/loss from participations in Group companies	8	-	4
Other interest received and similar items	9	9,895	559
Interest expense and similar items	10	(8,583)	(55,359)
<b>Loss before income tax</b>		<b>(354,405)</b>	<b>(407,363)</b>
Income tax expense	11	-	-
<b>Loss for the year</b>		<b>(354,405)</b>	<b>(407,363)</b>

## Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31,	
		2021	2020
<b>Loss for the year</b>		<b>(354,405)</b>	<b>(407,363)</b>
Other comprehensive income/(loss) for the year		-	-
<b>Total comprehensive loss for the year</b>		<b>(354,405)</b>	<b>(407,363)</b>

## PARENT COMPANY

## Balance Sheet

(SEK in thousands)	Note	December 31,	
		2021	2020
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Intangible Assets</b>			
Licenses and similar rights	12	32,132	16,066
		<b>32,132</b>	<b>16,066</b>
<b>Tangible Assets</b>			
Equipment	13	514	80
		<b>514</b>	<b>80</b>
<b>Non-Current Financial Assets</b>			
Participations in Group companies	14	406,438	295,259
Receivables from Group companies	15	142,724	1,485
Other non-current financial assets	16	3,762	1,939
		<b>552,924</b>	<b>298,683</b>
<b>Total non-current assets</b>		<b>585,571</b>	<b>314,829</b>
<b>Current assets</b>			
Inventory		889	-
Other current assets		5,699	10,998
Prepaid expenses	17	41,825	14,490
		<b>48,413</b>	<b>25,488</b>
Cash	18	894,455	978,208
<b>Total current assets</b>		<b>942,868</b>	<b>1,003,696</b>
<b>TOTAL ASSETS</b>		<b>1,528,439</b>	<b>1,318,525</b>

## PARENT COMPANY Balance Sheet

		December 31,	
(SEK in thousands)	Note	2021	2020
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	19		
Restricted shareholders' equity			
Share capital		2,094	1,998
Statutory reserve		3,092	3,092
		5,186	5,090
Non-restricted shareholders' equity			
Share premium reserve		2,420,698	2,116,721
Retained earnings		(863,175)	(479,379)
Net loss for the year		(354,405)	(407,363)
		1,203,117	1,229,979
Total shareholders' equity		1,208,303	1,235,069
Non-current liabilities			
Provisions	20	9,075	4,972
Non-current interest-bearing liabilities	21	189,164	-
Liabilities to Group companies	23	105	105
Total non-current liabilities		198,344	5,077
Current liabilities			
Accounts payable		51,711	42,469
Liabilities to Group companies	24	31,121	4,003
Other current liabilities		2,345	1,120
Accrued expenses and deferred revenue	22	36,615	30,787
Total current liabilities		121,792	78,379
TOTAL SHAREHOLDERS EQUITY AND LIABILITIES		1,528,439	1,318,525

## PARENT COMPANY 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, 2020</b>	<b>1,548</b>	<b>3,092</b>	<b>1,268,334</b>	<b>(448,989)</b>	<b>(36,186)</b>	<b>787,799</b>
Transfer of previous year's loss	-	-	-	(36,186)	36,186	-
Loss for the year	-	-	-	-	(407,363)	(407,363)
Other comprehensive income/(loss) for the year	-	-	-	-	-	-
<b>Total comprehensive loss for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(407,363)</b>	<b>(407,363)</b>
<b>Transactions with owners:</b>						
New share issue	397	-	890,990	-	-	891,388
Costs attributable to new share issue	-	-	(97,686)	-	-	(97,686)
Exercise of warrants	52	-	55,083	(215)	-	54,920
Share-based payments	-	-	-	6,012	-	6,012
<b>Total transactions with owners</b>	<b>449</b>	<b>-</b>	<b>848,387</b>	<b>5,797</b>	<b>-</b>	<b>854,633</b>
<b>Closing equity December 31, 2020</b>	<b>1,998</b>	<b>3,092</b>	<b>2,116,721</b>	<b>(479,379)</b>	<b>(407,363)</b>	<b>1,235,069</b>
<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>



## PARENT COMPANY

# Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31,	
		2021	2020
<b>Operating activities</b>			
Operating loss		(355,717)	(352,567)
Adjustments for non-cash items	18	19,805	10,832
Interest received		103	1,912
Interest paid		(4,837)	(3)
<b>Cash flow from operating activities before changes in working capital</b>		<b>(340,647)</b>	<b>(339,826)</b>
<b>Cash flow from changes in working capital</b>			
Changes in inventory	25	(949)	-
Changes in operating receivables		(91,350)	13,884
Changes in operating liabilities		40,076	40,024
<b>Cash flow from operating activities</b>		<b>(392,811)</b>	<b>(285,918)</b>
<b>Investing activities</b>			
Acquisition of participations in Group companies	14	(100,091)	(294,059)
Purchase of equipment	13	(526)	-
Investments in non-current financial assets	16	(70,966)	(1,683)
Disposal of non-current financial assets		-	4
Purchase of intangible assets	12	(16,066)	-
<b>Cash flow from investing activities</b>		<b>(187,648)</b>	<b>(295,738)</b>
<b>Financing activities</b>			
New share issue		324,000	891,388
Costs attributable to new share issue		(19,927)	(95,938)
Transaction costs, paid		-	54,920
New borrowings	21	199,524	-
Costs attributable to new loans		(14,857)	-
<b>Cash flow from financing activities</b>		<b>488,739</b>	<b>850,370</b>
<b>Net increase/(decrease) in cash</b>		<b>(91,720)</b>	<b>268,714</b>
Cash at beginning of the year		978,208	752,448
Exchange-rate difference in cash		7,967	(42,954)
<b>Cash at the end of the year</b>	<b>18</b>	<b>894,455</b>	<b>978,208</b>

## PARENT COMPANY

# 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,	
	2021	2020
<b>Type of goods or service</b>		
Out-licensing	225,252	-
Performance of certain regulatory services	4,095	-
Provision of drugs	-	874
<b>Total</b>	<b>229,347</b>	<b>874</b>
<b>Geographical markets</b>		
Europe	201,878	-
China, Hong Kong, Macau, Taiwan and Singapore	27,469	874
<b>Total</b>	<b>229,347</b>	<b>874</b>

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

## Note 3 Other Operating Income

	Year Ended December 31,	
	2021	2020
Re-invoicing of costs	70,218	-
Exchange rate differences	16	2,482
<b>Total</b>	<b>70,234</b>	<b>2,482</b>

## Note 4 Other Operating Expense

	Year Ended December 31,	
	2021	2020
Exchange rate differences	1,807	-
Net loss on disposal of equipment	67	-
<b>Total</b>	<b>1,874</b>	<b>-</b>

## Note 5 Auditors' Fee

	Year Ended December 31,	
	2021	2020
<b>EY</b>		
Audit services	6,235	4,449
Other audit activities	2,105	3,774
Tax advice	73	-
Other services	-	-
<b>Total</b>	<b>8,413</b>	<b>8,223</b>

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

Other auditing activities are those services in accordance with a special agreement on financial statements. Other services include advice on accounting issues and advice on processes and internal control.

## Note 6 Leases

Leasing expenses for the year in respect to operating leases amounted to SEK 3,565 and SEK 3,326 for the year ended December 31, 2021 and 2020, respectively. Future payment commitments for operating leases are specified as follows:

	Year Ended December 31,	
	2021	2020
<b>Future minimum lease payments</b>		
Within 1 year	6,540	2,835
Between 1 and 5 years	12,295	1,087
More than 5 years	-	-
<b>Total</b>	<b>18,835</b>	<b>3,922</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 warrants 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 Profit/Loss from Participations  
in Group Companies

	Year Ended December 31,	
	2021	2020
Profit on liquidation of subsidiaries	-	4
<b>Total</b>	<b>-</b>	<b>4</b>

The former subsidiary Pharmedlink Oncology AS ceased through voluntary liquidation, as no operations were conducted for the year ended December 31, 2020.

Note 9 Other Interest Received and Similar Items

	Year Ended December 31,	
	2021	2020
Interest income from Group companies	886	11
Other interest income	102	548
Exchange rate differences	8,907	-
<b>Total</b>	<b>9,895</b>	<b>559</b>

Note 10 Interest Expense and Similar Items

	Year Ended December 31,	
	2021	2020
Interest expense	(6,438)	(4)
Exchange rate differences	-	(52,037)
Changes in FX options measured at fair value	-	(3,318)
Other financial expenses	(2,145)	-
<b>Total</b>	<b>(8,583)</b>	<b>(55,359)</b>

Note 11 Income Tax Expense

	Year Ended December 31,	
	2021	2020
Current tax taxes	-	-
<b>Income tax expense recognized in the statements of income</b>	<b>-</b>	<b>-</b>
<i>Reconciliation of effective tax rate</i>		
Accounting loss before tax	(354,405)	(407,363)
Tax in accordance with applicable tax rate for the Parent Company 20,6% (21,4%)	73,007	87,176
<i>Tax effect of:</i>		
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(69,425)	(87,084)
Non-deductible expenses	(3,582)	(93)
Non-taxable income	-	1
<b>Income tax expense recognized in the statements of income</b>	<b>-</b>	<b>-</b>
<b>At the effective income tax rate</b>	<b>0%</b>	<b>0%</b>

The Parent Company has costs attributable to new share issue amounted to SEK 19,927 and SEK 97,686 for the year ended December 31, 2021 and 2020, respectively, which are recognized directly against equity. These costs are deductible for tax purposes.

The Parent Company has SEK 1,432,462 and SEK 1,081,734 of tax losses carried forward for which deferred tax assets have not been recognized in the statements of financial position as of December 31, 2021 and 2020, 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 12 Intangible Assets

	December 31,	
	2021	2020
<i>Licenses and similar rights</i>		
Cost at opening balance	16,066	16,066
Acquisition for the year	16,066	-
<b>Cost at closing balance</b>	<b>32,132</b>	<b>16,066</b>
<b>Net book value</b>	<b>32,132</b>	<b>16,066</b>

For additional information on intangible assets in the Parent Company, see Note 16 Intangible Assets and Impairment Testing in the Group.

Note 13 Equipment

	December 31,	
	2021	2020
Cost at opening balance	118	118
Acquisition for the year	526	-
Disposal for the year	(118)	-
<b>Cost at closing balance</b>	<b>526</b>	<b>118</b>
Depreciation at opening balance	(38)	(14)
Depreciation for the year	(25)	(24)
Disposal for the year	51	-
<b>Depreciation at closing balance</b>	<b>(12)</b>	<b>(38)</b>
<b>Net book value</b>	<b>514</b>	<b>80</b>

Note 14 Participations in Group Companies

	December 31,	
	2021	2020
Cost at opening balance	298,998	5 371
Acquisition for the year	98,993	295,158
Shareholders' contributions	12,187	-
Liquidation	-	(1,531)
<b>Cost at closing balance</b>	<b>410,177</b>	<b>298,998</b>
Impairment at opening balance	(3,739)	(5,270)
Reversal of write-downs	-	1,531
<b>Impairment at closing balance</b>	<b>(3,739)</b>	<b>(3,739)</b>
<b>Net book value</b>	<b>406,438</b>	<b>295,259</b>

Paid additions correspond to share-based remuneration recognized in the subsidiaries.

Company / Corporate Registration Number / Registered office	December 31,	
	2021	2020
<i>Nefecon AB, 556604-9069, Stockholm</i>		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	1,000	1,000
<b>Net book value</b>	<b>100</b>	<b>100</b>
<i>Calliditas NA Enterprises Inc, 83-4094951, USA</i>		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	1,000	1,000
<b>Net book value</b>	<b>11 356</b>	<b>1</b>
<i>Calliditas Therapeutics US Inc., 86-3169403 USA</i>		
Share of equity	100%	-
Share of voting power	100%	-
Number of participation rights	1 000	-
<b>Net book value</b>	<b>707</b>	<b>-</b>
<i>Calliditas Therapeutics France SAS, 439 489 022, France</i>		
Share of equity	100%	86%
Share of voting power	100%	86%
Number of participation rights	14,074,165	10,121,676
<b>Net book value</b>	<b>394,275</b>	<b>295,158</b>

Note 15 Receivables from Group Companies

	December 31,	
	2021	2020
Opening balance	1,485	-
Additional receivables	140,682	1,694
Exchange differences	557	(209)
<b>Net book value</b>	<b>142,724</b>	<b>1,485</b>

Note 16 Other Non-Current Financial Assets

	December 31,	
	2021	2020
Opening balance	1,939	1,939
Bank guarantees granted	1,823	-
<b>Net book value</b>	<b>3,762</b>	<b>1,939</b>

Note 17 Prepaid Expenses

	December 31,	
	2021	2020
Prepaid rental charges	1,179	792
Prepaid insurance premiums	10,246	10,186
Prepaid expenses for research and development	27,465	224
Other prepaid expenses	2,935	3,288
<b>Total</b>	<b>41 825</b>	<b>14 490</b>

Note 18 Cash

	December 31,	
	2021	2020
Cash at Banks	894 455	978 208
<b>Total</b>	<b>894 455</b>	<b>978 208</b>

Adjustments for non-cash items

	Year Ended December 31,	
	2021	2020
Depreciation	25	24
Change in Provisions	5,454	4,797
Share-based payments	14,259	6,011
Other	67	-
<b>Total</b>	<b>19,805</b>	<b>10,832</b>

Reconciliation of liabilities from financing activities

	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>

No liabilities from financing activities for the year ended December 31, 2020.

» **PARENT COMPANY - NOTES TO FINANCIAL STATEMENTS**  
(SEK in thousands, except per share amounts or as otherwise indicated)

### Note 19 Shareholders' Equity

#### As of December 31, 2021

Share capital consists of 52,341,584 and 49,941,584 shares with a quotient value of SEK 0.04 as of December 31, 2021 and 2020, respectively. All shares hold has the same entitlement 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,	
	2021	2020
Share premium reserve	2,420,698	2,116,721
Retained earnings	(863,175)	(479,379)
Net loss for the year	(354,405)	(407,363)
	<b>1,203,117</b>	<b>1,229,979</b>
To be distributed as follows:		
<b>To be carried forward</b>	<b>1,203,117</b>	<b>1,229,979</b>

### Note 20 Provisions

	December 31,	
	2021	2020
Opening balance	4,972	175
Provisions for the year	4,103	4,797
<b>Total</b>	<b>9,075</b>	<b>4,972</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,	
	2021	2020
<i>Due for payment between 1 and 5 years</i>		
Non-current interest-bearing liabilities	189,164	-

For additional information, see Note 21 Financial Risks in the Group.

### Note 22 Accrued Expenses and Deferred Revenue

	December 31,	
	2021	2020
Accrued salaries and Board fees	9,586	5,925
Vacation pay liability	4,155	2,603
Social security costs	2,769	3,441
Deferred revenue	3,387	-
Accrued expenses for research and development	2,049	13,072
Accrued expenses for administrative and selling expenses	14,670	5,746
<b>Total</b>	<b>36,615</b>	<b>30,787</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 30 Assets Pledged, Contingent Liabilities and Other Obligations. In the Parent Company restricted bank accounts amounts to SEK 3,762 and SEK 1,938 as of December 31, 2021 and 2020, 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>					
Year Ended December 31, 2021	70,218	91,786	-	142,724	31,226
Year Ended December 31, 2020	-	19,648	-	1,485	4,108

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

### Note 25 Inventories

	December 31,		
	2021	2020	2019
Raw materials	889	-	-

inventories are recognised after US Food and Drug Administration (FDA) has approved TARPEYO in the US under accelerated approval.

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, 2022

Elmar Schnee  
Board Chairman

Renée Aguiar-Lucander  
CEO

Diane Parks  
Board member

Hilde Furberg  
Board member

Molly Henderson  
Board member

Lennart Hansson  
Board member

Our audit report was submitted in April 27, 2022

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 2021. The annual accounts and consolidated accounts of the company are included on pages 28-77 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 2021 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 2021 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

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

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

### Basis for Opinions

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

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

### Key Audit Matters

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

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

## Revenue recognition

### Description

For the year ended December 31, 2021, the Group's and Parent Company's revenues were SEK 229,347 thousand. As explained in Note 1 and Note 3 of the consolidated financial statements, revenues are generated from contracts for transferring the commercial rights to the Nefecon product for specific regions to partner companies. These revenue contracts consist of multiple performance obligations, which are the outlicensing of commercial rights and the performance of certain regulatory services.

The allocation of the transaction price between these performance obligations is based on the standalone selling price of each performance obligation. Since revenues for outlicensing the commercial rights are recognized at the time control of the intellectual property passes to the customer and revenues for the provision of regulatory services are recognized over time as the services are performed, the allocation of the transaction price to the different performance obligations materially impacts the timing of the related revenue recognition.

We determined revenue recognition to be a key audit matter, as auditing the allocation of the transaction price between the performance obligations and the related revenue to recognize was complex, because of the significant judgments made by management in determining the stand-alone selling price for the provision of regulatory services, which includes estimates of the expected cost to fulfil the performance obligation and the appropriate profit margin to recognize in relation thereto.

### How our audit addressed this key audit matter

We performed audit procedures to test the allocation of the transaction price, which included, among others, evaluating the Company's revenue recognition policies, understanding the methodologies utilized and reading customer contracts to understand the terms that constitute promises to provide goods or services after the initial transfer of intellectual property, as these could constitute performance obligations.

We evaluated management's estimates of expected costs to fulfil the performance obligation for regulatory services by comparing expected internal resources and external expenses to actual costs incurred subsequently and compared the profit margins utilized to determine the standalone selling price to those of comparable companies.

## Valuation of intangible assets

### Description

Intangible assets for the Group and Parent Company amount to SEK 399,418 thousand and SEK 32,132 thousand, respectively, as of December 31, 2021. As explained in Note 1 and Note 16 of the consolidated financial statements, the Company performs an impairment assessment of goodwill and intangible assets not yet available for use, 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 to take into account the development risk. Changes in assumptions used by management could have a significant impact on either the recoverable amount, the amount of any impairment charge, or both.

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, understanding management's methodology for estimating the recoverable value and evaluating the appropriateness of the discounted cash flow model utilized. In addition, we tested the inputs and assumptions utilized by management regarding potential commercialization, expected market size and the probability of the products reaching the market by comparing these to statistical data for the clinical indications targeted and for other development projects within the industry.

We also performed a sensitivity analysis of the Company's discounted cash flow models. With the assistance of our valuation specialists, we evaluated the discount rates used by comparing these to rates used by peers, and tested the mathematical accuracy of calculations within the impairment models.

### 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 1-27 and 86-99. 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 2021 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 year 2021.

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

In our opinion, the ESEF report #[341fcbcf-069d68ea293374251f9d32f9ea6474f-e708099e134a59430804f09d0] 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 technical validation of the Esef report, i.e. if the file containing the Esef report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 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 Esef report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, financial position, changes in equity and cash flow.

Ernst & Young AB, Hamngatan 26, 111 47 Stockholm, was appointed auditor of Calliditas Therapeutics AB by the general meeting of the shareholders on the 27 May 2021 and has been the company's auditor since the 15 April 2004.

Stockholm, April 27, 2022  
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 2021 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 2021, the total number of shares and voting rights amounted to 52,341,584, distributed between 19,972 shareholders. The ten largest shareholders held 59.07% of shares outstanding and other shareholders 40.93%. As of December 31, 2021, three shareholders owned shares that each represented 10% or more of the total number of shares and voting rights in the company: BVF Partners LP 12.7%, Stiftelsen Industrifonden, 11.0% and Linc AB 10.5%.

## 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 2022

Calliditas' 2022 AGM will be held on Thursday, May 19, 2022. With reference to the Swedish Act (2022:121) on temporary exceptions to facilitate the execution of general meetings in companies and other associations, the Board of Directors has decided that the annual general meeting will be conducted by advance voting only, without physical presence of shareholders, proxies and third parties.

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

## Participation at the Annual General Meeting

Shareholders who wish to participate, through advance voting, in the meeting must:

- be recorded in the share register maintained by Euroclear Sweden AB relating to the circumstances on Wednesday 11 May 2022, and
- give notice of participation by casting their advance votes in accordance with the instructions under the heading "Advance voting" below, so that the advance voting form is received by Euroclear Sweden AB no later than on Wednesday 18 May 2022.

Shareholders whose shares are registered in the name of a nominee through a bank or a securities institution must temporarily register their shares in their own names to be entitled to participate in the meeting. Such registration, which may be temporary (so-called voting rights registration), must be duly effected in the share register maintained by Euroclear Sweden AB on Friday 13 May 2022, and the shareholders must therefore advise their nominees well in advance of this date.

## 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

in 2022 consists of:

- Patrik Swobocki, appointed by Stiftelsen Industrifonden
- Per Sjögemark, appointed by Handelsbanken Fonder
- Karl Tobieson, appointed by Linc AB (Chairman)
- 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 2022 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 2021 AGM elected the registered firm of accountants Ernst & Young AB as auditor, up to the 2022 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 2021, 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 Asso-

ciation, 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 five 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 on page XX presents the independence of members at the date on which this report was published.

### Work of the Board in 2021

During 2021, the Board of Directors held a total of 16

meetings, of which 6 were ordinary and 10 extraordinary meetings. Calliditas' CEO participates in Board meetings, as does the company's CFO and General Counsel, who was secretary at the meetings. Other employees from Calliditas have reported on particular issues at the meetings. The extraordinary meetings were a result of the company's work with acquisition and capital raise.

### Board Remuneration

Fees to members elected by the Annual General Meeting are decided by the Annual General Meeting. The Annual General Meeting on May 27, 2021 resolved that fees to the Board for the period up to the end of the next Annual General Meeting shall be as follows: Board fees shall be SEK 850,000 to the Chairman of the Board and SEK 300,000 to each of the other members not employed in the Group, SEK 150,000 SEK 50,000 to the Chairman of the Audit Committee and SEK 75,000 to other members of the Audit Committee who are not employees of the Group, and SEK 50,000 to the Chairman of the Remuneration Committee and SEK 25,000 to other members of the Remuneration Committee who are not employees of the Group. In addition to the fee proposed above for ordinary board work, it is proposed that a board member who is resident in the USA shall receive an extra fee of SEK 140,000 and that a board member who is resident in Europe but outside the Nordic region shall receive an extra fee 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: Molly Henderson (Chairman), Lennart Hansson 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 five meetings in 2021. 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.

#### Remuneration Committee

Calliditas has a Remuneration Committee consisting

of three members: Elmar Schnee (Chairman), Lennart Hansson 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 three meetings in 2021. 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 27, 2021.

### Remuneration of the CEO and Executive Management 2021

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 per cent 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

### Board members' independence, attendance and remuneration in 2021

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	16/16	-	3/3	1,363
Lennart Hansson	Board Member	2009	Yes	Yes	15/16	5/5	3/3	522
Hilde Furberg	Board Member	2014	Yes	Yes	15/16	5/5	-	499
Diane Parks	Board Member	2019	Yes	Yes	16/16	-	3/3	584
Molly Henderson	Board Member	2020	Yes	Yes	14/16	5/5	-	664



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 six individuals and includes, in addition to the CEO, the Chief Financial Officer, Chief Medical Officer, Vice President Operations, Vice President Regulatory Affairs, and President North America. For information about current senior executives at Calliditas, when these assumed their positions, and date of birth, education, experience, shareholding in the company and current and previous assignments, refer to pages 94-95 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 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 has also in 2021 initiated an implementation of an inter-control structure according to the Sarbanes-Oxley Act to meet the requirements for companies listed in the USA. In addition to the abovementioned internal control, there is also internal, business-specific control of data as regards research and development, as well as quality control including systematic surveillance and evaluation of the company's development and manufacturing operations.

#### Internal Audit

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

## Auditor's report on the corporate governance statement

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

### Engagement and responsibility

It is the Board of Directors who is responsible for the corporate governance statement for the year 2021 on pages 86-91 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 27, 2022  
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 previously held several senior global management positions with UCB and Sanofi.

**Other current assignments:** Chairman of the board of directors of Santhera Pharmaceutical, ProCom Rx SA, Moleac Pte Ltd and Noorik Biopharmaceuticals AG as well a member of the board of directors of Kuste Biopharma and Damian Pharma AG.

**Holdings in the Company:** Elmar Schnee holds 10,000 shares in the company, 23,236 share awards in board LTIP 2019, 14,063 share awards in LTIP 2020 and 10,624 share awards in LTIP 2021. 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 in leadership from her 35 years in sales, marketing, strategy and management in Pharma/Biotech. Hilde has worked for 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:** She is currently an industrial advisor to Investinor and Board member of PCI Biotech, OncoZenge, Herantis Pharma and Bio-Me.

**Holdings in the Company:** Hilde Furberg holds 44,750 shares in the company, 8,449 share awards in board LTIP 2019, 4,327 share awards in board LTIP 2020 and 4,086 share awards in LTIP 2021. Independent in relation to the Company and its management and in relation to major shareholders.



## Lennart Hansson

### Non-executive Director

Born 1956.  
Board member since 2009.

**Education:** PhD in Genetics from the University of Umeå.

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

**Experience:** Lennart Hansson has broad experience from leading positions within pharmaceutical development and business development in both biotech and pharma companies such as KabiGen AB, Symbicom AB, AstraZeneca, Biovitrum AB and as CEO of Arexis AB. Lennart was responsible for Industrifonden's life science operations between 2008– 2016. He has worked on more than 30 company boards and is also the co-founder of two pharmaceutical development companies.

**Other current assignments:** Chairman of the Board of Directors of Sixera Pharma AB, Ignitus AB and Cinclus Pharma Holding AB. Member of the Board of Directors of InDex Pharmaceuticals Holding AB (publ) and Medivir AB (publ).

**Holdings in the Company:** Lennart Hansson holds 12,000 shares in the company and 8,449 share awards in board LTIP 2019, 4,327 share awards in board LTIP 2020 and 4,086 share awards in LTIP 2021. Independent in relation to the Company and its management and in relation to major shareholders.



## Diane Parks

### Non-executive Director

Born 1952.  
Board member since 2019.

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

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

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

**Other current assignments:** Board member in Kura Oncology, Soligenix and TriSalus Life Sciences.

**Holdings in the Company:** Diane Parks holds 8,449 share awards in board LTIP 2019, 4,327 share awards in board LTIP 2020 and 4,086 share awards in LTIP 2021. 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:** Chairman 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 and 4,327 share awards in board LTIP 2020 and 4,086 share awards in LTIP 2021. Independent in relation to the Company and its management and in relation to major shareholders.

# Management team



**Renee Aguiar-Lucander**  
*Chief Executive Officer*

Born 1962.  
CEO since 2017.

**Education:** BA in Finance from Stockholm School of Economics. MBA from INSEAD.

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

**Other current assignments:** Chairman of the board of directors of Exenta Inc. Member of the board of directors of Medcap AB (publ) and RAL Capital Ltd.

**Holdings in the Company:** Renée Aguiar-Lucander holds 593,000 shares in the Company, 195,000 warrants<sup>1</sup> and 416,000 options<sup>2</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 37,750 shares in the Company, 50,000 warrants<sup>1</sup> and 180,000 options<sup>2</sup>.



**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 6,000 share in the Company, 7,500 warrants<sup>1</sup> and 45,000 options<sup>2</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 multi-functional team for a multi-billion pain medication franchise.

**Holding in the Company:** Andrew Udell holds 26,000 share in the company, 20,000 warrants<sup>1</sup> and 210,000 options<sup>2</sup>.



**Katayoun Welin-Berger**  
*Vice President Operations*

Born 1968.  
VP Operations since 2020.

**Education:** PhD in Pharmacy from Uppsala University, Sweden.

**Experience:** Katayoun Welin-Berger has more than 28 years of commercial experience in the pharmaceutical and biologics industry. Before joining Calliditas, Katayoun worked as Vice President of Operations at BioGaia. Katayoun began her career in the pharmaceutical industry at AstraZeneca and held several positions within both R&D and Operations.

**Holding in the Company:** Katayoun Welin-Berger holds 11,000 shares through a related party, 65,000 warrants<sup>1</sup> and 45,000 options<sup>2</sup>.



**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 biotechs. He has extensive experience in rare diseases, having brought several products from early development to the market. Prior to joining Calliditas, Richard worked as CMO with the UK-based biotech company Trizell where he led the Adstiladrin® phase 3 clinical program and Biologics License Application in non-muscle invasive bladder cancer, submitted to the FDA in September 2019. Before Trizell, he worked for Takeda as an Executive Medical Director and spent 16 years at GlaxoSmithKline, where he held a number of senior positions, including Disease Area Head and Acting Chief Medical Officer for the Rare Diseases Unit. Before joining the industry, Richard worked as a physician in several clinical positions with various patient populations, including patients with IgA nephropathy.

**Holding in the Company:** Richard Philipson holds 185,000 options<sup>2</sup>.

<sup>1</sup> Holding in Warrant program 2019/2022. <sup>2</sup> Holding in ESOP 2020. and/or ESOP 2021



# 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

**Daniel C. Cattran**

Professor of Medicine, University of Toronto; Senior Scientist, Toronto General Research Institute, 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, 2022	May 18, 2022
Annual General Meeting 2022	May 19, 2022
Interim report for the period January 1–June 30, 2022	August 19, 2022
interim report for the period January 1–September 30, 2022	November 18, 2022
Year-end report for the period January 1–December 31, 2022	February 24, 2023

# 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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