calliditas
THERAPEUTICS

ANNUAL REPORT
2020

Contents

The Annual Report of Calliditas Therapeutics AB (publ), 556659-9766, is comprised of directors report, the Group's and the Parent Company's financial statements with notes and audit report (pages 32-81).

About Calliditas

Calliditas Therapeutics is a bio-pharmaceutical 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 candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. Calliditas has read out topline data from a global Phase 3 study within IgAN and has filed an NDA with the FDA. If approved, Calliditas aims to commercialize Nefecon in the United States on its own, whilst partnering ex-US. Calliditas is also exploring several pipeline indications including PBC, AIH and head and neck cancer.

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

Visit *www.calliditas.com* for further information.

2020 IN BRIEF

Business highlights

- In April, Calliditas appointed Dr. Richard Philipson as Chief Medical Officer.
- On June 5th, Calliditas completed an initial public offering on The Nasdaq Global Select Market in the United States for gross proceeds of approximately USD 90 million, or approximately SEK 828 million (before deduction of issuance costs and exercise of the green shoe.)
- The Annual General Meeting was held in June and the AGM, among other things, resolved on the election of Molly Henderson to the Board of Directors.
- In August, Calliditas announced that it had reached an agreement to acquire a controlling interest in Genkyotex SA, a leader in NOX inhibition therapies. On November 3rd, Calliditas closed this transaction, acquiring 62.7% of Genkyotex.
- On November 8th, Calliditas read out positive topline results from the pivotal Phase 3 NefIgArd trial.
- In November, Calliditas submitted a simplified public mandatory offer to the shareholders of Genkyotex. In December, by the end of the acceptance period, Calliditas controlled 86.2 percent of the shares in Genkyotex.

Significant events after the reporting period, in summary

- In January, Genkyotex read out positive Phase 1 data, demonstrating a favorable safety and pharmacokinetic profile of high-dose setanaxib.
- On January 21st, Calliditas announced full recruitment of all 360 patients for the post-approval confirmatory part of the global Phase 3 clinical trial NefIgArd.
- On March 15th, Calliditas announced the submission of its regulatory file to the FDA for accelerated approval of Nefecon.
- On April 23rd, Calliditas announced that Nefecon has been granted accelerated assessment procedure by the European Medicine Agency's (EMA) for the treatment of primary IgA Nephropathy (IgAN).

Financial summary for the Group

	2020	2019	2018	2017	2016
Net sales (SEK in thousands)	874	184,829	-	-	-
Loss before income tax (SEK in thousands)	(436,151)	(32,501)	(132,049)	(86,794)	(56,912)
Cash (SEK in thousands)	996,304	753,540	646,175	57,352	24,241
Total assets (SEK in thousands)	1,506,450	845,200	648,417	62,288	27,298
Equity ratio at the end of the year (%)	80%	93%	95%	53%	Neg.
Average number of employees	23	14	10	10	9

High competence in product development

Calliditas' vision

To leverage its 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.

As it has done with Nefecon, Calliditas focuses on projects that fulfil the criteria of addressing niche indications while also having a time and cost-effective path to market, including through reformulation and repurposing of existing compounds, and/or those that address orphan population needs.

Calliditas' strategy

To progress Nefecon through Phase 3 clinical development and towards regulatory approval and subsequent commercialization. Upon market approval, Calliditas intends to commercialize Nefecon for IgA nephropathy (IgAN) on a standalone basis in the US market and through partnerships in other regions. Calliditas will also selectively explore line extensions for Nefecon in other diseases where there is a strong scientific and clinical rationale and attractive commercial opportunity, such as in certain liver diseases.

Calliditas may also selectively consider leveraging the company's capabilities through acquiring additional product candidates with a strong strategic and commercial fit and with existing competences and assets, such as our acquisition of setanaxib, which we plan to investigate further in Primary Biliary Cholangitis (PBC) and oncology.

» 2020 has been a hugely exciting and significant year, in which we have as a company achieved some of our most important milestones to date.«

NefIgArd topline readout crowns a successful year.

On November 8, 2020, we announced positive topline readout of our Phase 3 pivotal trial, NefIgArd. This global trial evaluated patients across 19 countries from over 145 centres and was fully recruited in a year, in line with our original projections.

The 200 patient trial met both the primary and key secondary endpoint and demonstrated that Nefecon was well-tolerated. The readout confirmed the results seen in the Phase 2b trial, including eGFR stabilization in the treatment arm, reflecting a kidney protective effect during treatment.

These types of large and complex programs are usually conducted by pharma companies who are significantly larger and have access to vast resources. We are therefore exceedingly proud that a small Swedish company successfully managed to not only deliver this data readout but also to do so on time and on budget. The results were statistically significant and clinically relevant: proteinuria showed a 31% reduction versus baseline, a stronger effect than what was seen in the Phase 2b (27%), which is generally not the case when moving from Phase 2 to Phase 3. In addition, eGFR was stabilised in the treated patient population, which in the end is the true treatment goal, to protect the kidney from further deterioration.

We achieved this data readout despite the raging storm of the COVID-19 pandemic all around us in 2020. The well-established relationships with national co-ordinators and our CRO, in combination with the skill and dedication of our clinical team, were critical pieces of this endeavour, but we are most grateful for the commitment of all the patients and investigators who ultimately made this possible.

The Phase 2b and Phase 3 trials with Nefecon are the only randomized, double-blind placebo-controlled trials in IgA Nephropathy (IgAN) which have met both the primary and key secondary endpoint, as well as having a potential disease modifying effect. This is extremely exciting, and we are now well positioned to be the first approved treatment for IgAN, providing hope for patients that there will indeed be a medication available which holds the promise of delaying the decline of their kidney function and thereby hopefully helping to keep them out of dialysis and transplantation. I am immensely proud of every member of the Calliditas team, who all rose to the occasion under challenging circumstances and made possible the positive readout of this robust trial. The post-approval confirmatory part of the trial continues on a blinded basis and is fully recruited with a total of 360 patients included. The trial will report out the full data set in early 2023.

As of March 2021, we have filed our New Drug Application for accelerated approval of Nefecon with the FDA. We are looking forward to our further interactions with regulators and expect to also file with the EMA on time

in Q2. The submission to the FDA was a result of the expertise, dedication, and teamwork of everybody at the company. The effort involved in compiling all of the data and materials collected over years of clinical trials and CMC development was an enormous undertaking, with tens of thousands of pages and thousands of documents needing to be diligently reviewed and perfected, and we are excited to have reached this significant milestone. We have requested priority review and accelerated assessment from the respective agencies and, should we be granted priority review by the FDA, it would enable us to, subject to approval, start commercialization in the US in Q4, 2021. A standard review timeframe would result in a potential approval and US commercialization in Q1, 2022.

In June 2020, we successfully closed a $90m U.S. IPO on NASDAQ. The roadshow was launched on Monday June 1st and over a couple of days resulted in a significantly over subscribed offering and an upsizing of the transaction from $75m to $90m, which, including the greenshoe that was exercised, resulted in gross proceeds of $97m. This successful and pioneering transaction, which was the first time a Swedish life science company raised capital on NASDAQ Global Select in an IPO, secured the funding we believe will be necessary to fully complete our Phase 3 study and, if approved, commercially launch Nefecon in the United States. The U.S. IPO also gave us the added flexibility to pursue additional development initiatives related either to our existing pipeline or potential external additions.

In the fourth quarter of 2020, we concluded the purchase of a controlling block in Genkyotex. This is a company we had followed for quite a long time, and where we found the clinical data intriguing and their approach clearly differentiated. Even though their Phase 2 trial in primary biliary cholangitis (PBC) did not meet its primary endpoint, there was a clear impact on fibrosis across various metrics and some very interesting quality of life data, including a statistically significant effect on fatigue, the most common symptom of patients suffering from PBC. As we know, there are several reasons why earlier clinical trials fail to meet their endpoint; it is not always a question of whether the drug is active or efficacious or not, but may depend on the trial design, choice of endpoint or dosing levels. Genkyotex had positive interactions with the FDA in 2020, which resulted in plans for an adaptive pivotal Phase 2/3 design in PBC. In parallel, there was a Phase 1 PK study carried out looking into higher dosing, which read out positively in early 2021. In addition to the data in PBC, comprehensive and compelling preclinical data indicate that setanaxib, the lead compound, may have an important role to play in oncology, more precisely in solid tumours where today's immunotherapy has limited reach. Finally, we can also see applications for setanaxib in the kidney area, which we are continuing to explore.

We believe that the NOX inhibitor platform offers intriguing opportunities for further development in the orphan space. On November 3, 2020, we hence closed a transaction that resulted in Calliditas taking a controlling stake in Genkyotex of 62.7% of the shares. We subsequently launched a simplified mandatory tender offer which closed on December 16, resulting in a holding of 86.2%. Calliditas will continue to pursue a strategy to expand ownership of Genkyotex during 2021. We are excited about taking on a pioneering role in the NOX inhibitor space and are looking forward to sharing future clinical results with you. The second half of 2021 will see us start two late stage programs with setanaxib, a Phase 2/3 pivotal trial with an adaptive design in PBC and a Phase 2 proof of concept study in head and neck cancer. We will also conduct at least one earlier study in the kidney area.

There is a fairly recent publication by the Biotechnology innovation organization Amplion and Biomedtracker, claiming to be the largest study of clinical drug development success rates to date. Covering 2006-2015, a total of 9,985 clinical and regulatory phase transitions, from 7,455 development programs across 1,103 companies, were recorded and analyzed. By calculating the number of programs progressing to the next phase versus the total number of progressing and suspended programs, there was an assessment of the success rate at each of the four phases of development: Phase I, II, III, and regulatory filing. It revealed that only 9.6% of drug development programs from start to finish successfully make it to market. At Calliditas we are now at the very last stage of this chain as we seek drug approval, which is clearly a very significant achievement and hugely exciting, more so because this journey has truly been one of perseverance and a pioneering spirit. We are looking forward to 2021 and the excitement of completing our regulatory filings, as well as a potential approval in the US, which would make it possible for us to start commercialisation of Nefecon in the US in Q4 2021 and enable us to offer the promise of the first ever approved medication for IgAN for patients with this disease.

In summary, 2020 has been a hugely exciting and significant year, in which we have as a company achieved some of our most important milestones to date. I look forward to continuing to grow and build on the platform that we have created and expanded on this year, and I hope that you will all join us on the continued journey in 2021, which will see us explore trials with setanaxib, interact with the FDA and EMA and even potentially see Nefecon become an approved product by the end of the year.

Renée Aguiar-Lucander, CEO

IGA NEPHROPATHY

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

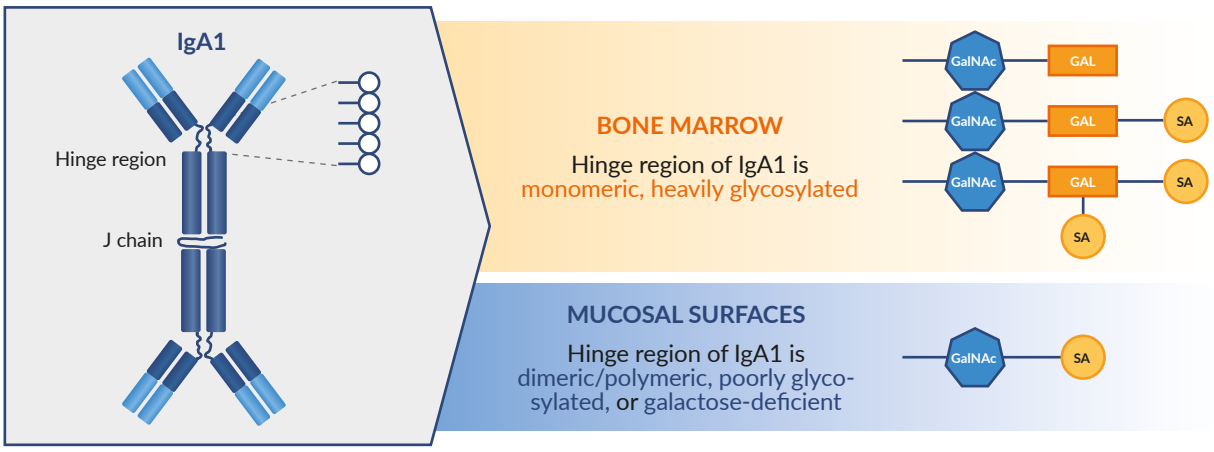
IgAN is a serious progressive autoimmune disease of the kidney, in which up to 50% of patients end up at risk of developing end-stage renal disease (ESRD) within ten to twenty years. The standard of care for ESRD is dialysis or kidney transplant, which represents a significant health economic burden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

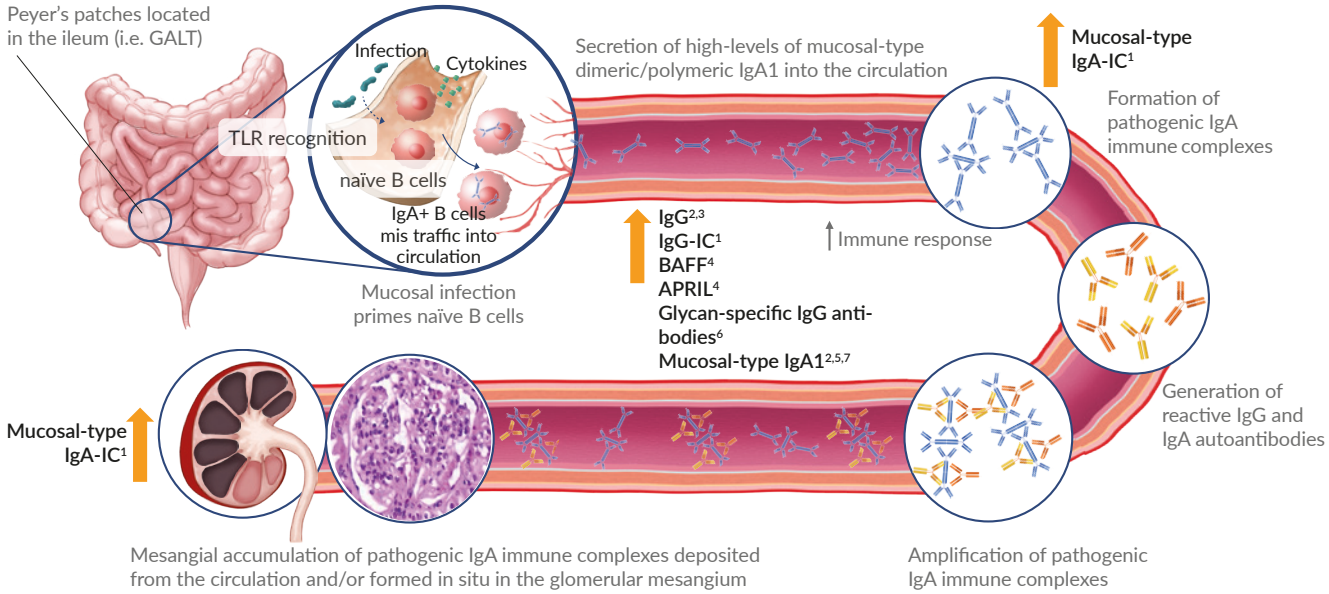
IgAN Pathophysiology

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.



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



In IgAN patients, a combination of a genetic predisposition and of environmental, bacterial and dietary factors is presumed to lead to an increased production of these galactose-deficient IgA 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

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.

Over time, some physicians attempt 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 has shown that the use of systemic steroids in this indication does not change the rate of decrease in estimated glomerular filtration rate (eGFR, a measure of kidney function,) and in addition comes at the cost of serious adverse effects. 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.

NEFECON

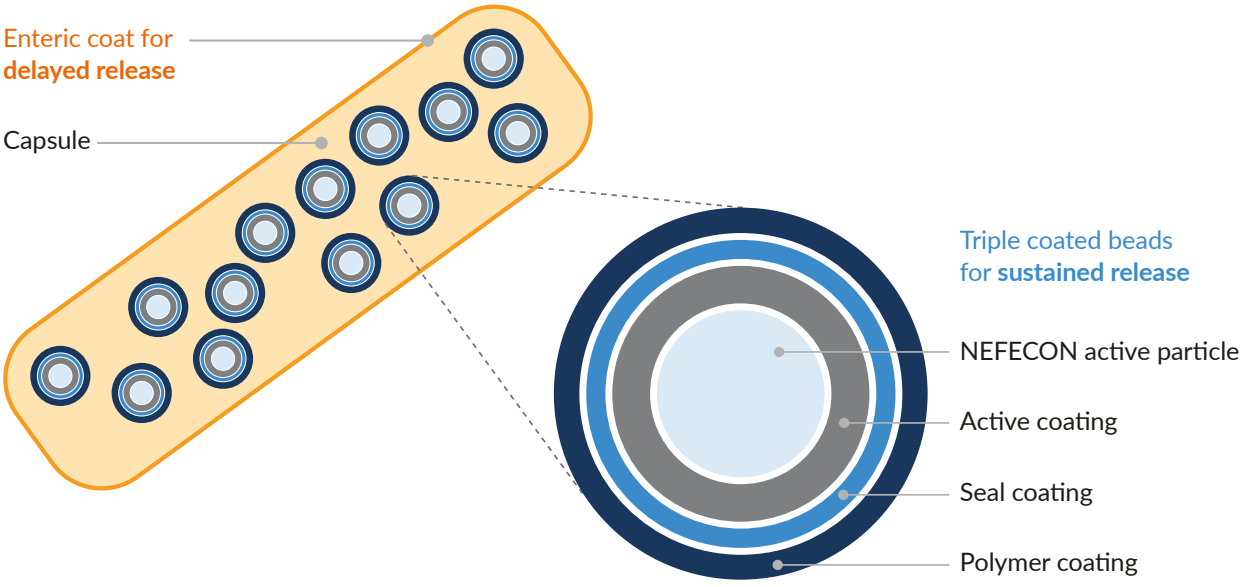
Overview of Calliditas' lead product candidate

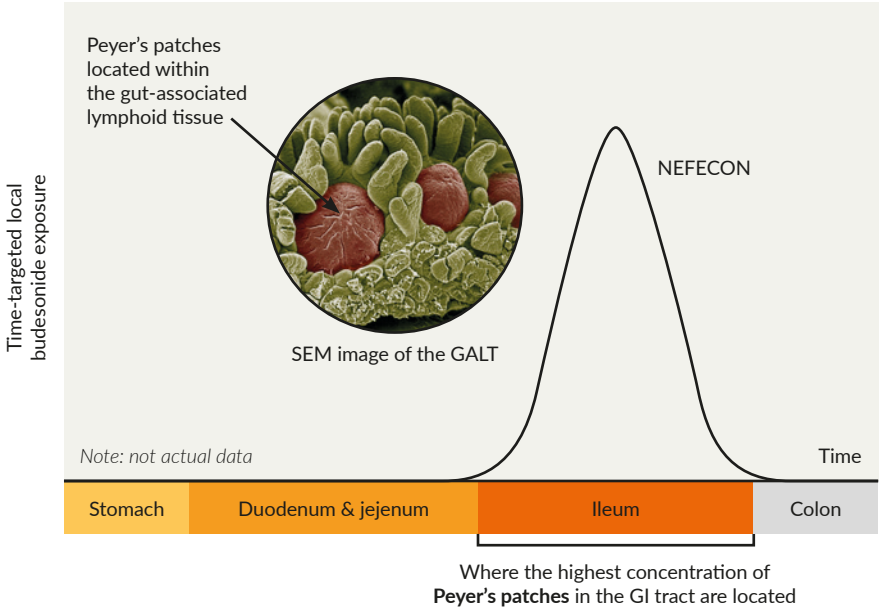
Nefecon is a proprietary, novel treatment for IgA nephropathy that focuses on disease modification by targeting the presumed origin of the disease. Nefecon is the most advanced product candidate globally and is positioned to become the first approved drug for IgAN. Calliditas submitted a New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) for Nefecon on March 15th 2021, and will file a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) in Q2 of 2021.

Nefecon is a patented, novel oral formulation of budesonide, an established and highly potent locally acting immunosuppressant, designed to deliver a targeted release directly to the Peyer's patches. Nefecon's optimized dose and release profile is intended to have a local effect and minimize systemic side effects. The active ingredient has a very low bioavailability, with around 90% of the budesonide being inactivated in the liver before it reaches the systemic circulation. This means that a high concentration of the active ingredient can be applied locally with limited systemic exposure and side effects. (An example of this type of mechanism in clinical practice is Pulmicort, which successfully treats the mucosa of the lungs.)

Nefecon utilizes a unique two-step enteric technology, which allows the drug to pass through the stomach and intestine without being broken down or absorbed and therefore to specifically target the location of the disease origin. The enteric-coated capsules are designed not to dissolve until they reach the ileum, where chemical and physical changes such as decreased acidity trigger the disintegration of the capsules and the release of their contents: beads triple coated with a variety of polymers that contain the active ingredient.

These triple coated beads are designed to provide a targeted, sustained dose of budesonide focused on the Peyer's patches, locally suppressing mucosal-type IgA1 antibody production and thereby decreasing the appearance of pathogenic immune complexes in the blood. This disrupts and interrupts the very initiation of the disease process related to IgAN, and hence holds the promise of disease modification. Due to the high first pass metabolism of budesonide in the liver, there is minimum subsequent systemic exposure of the drug. In this way, Nefecon combines maximum local efficiency with minimized systemic side effects.





Key highlights

- Targeted local delivery of budesonide
- 90% first-pass elimination
- Advanced biopharmaceutical technology to optimize release
- Designed to halt disease progression at the source

Biomarker analysis further validates Nefecon's ability to target the origin of this disease, demonstrating that Nefecon reduces the level of IgA1 galactose-deficient antibodies as well as circulating IgA immune complexes in the systemic circulation. At the 15th International Symposium on IgA Nephropathy (IIgANN 2018) in Buenos Aires, Professor Barratt from the Mayer IgA Nephropathy Laboratories at the University of Leicester published a poster demonstrating that Nefecon "Modifies Circulating IgA-IgG Immune Complex Levels and Levels of Poorly O-Galactosylated IgA in IgAN." His colleague at the Mayer Laboratory, Dr Karen Molyneux, presented at the American Society of Nephrology (ASN) Digital Kidney Week 2020 and showed that Nefecon had a demonstrated impact on circulating pathogenic biomarkers (BAFF, soluble BCMA, and TACI) in IgAN. These biomarker data support the pathophysiology of the disease and substantiate Nefecon's targeted effect on IgA antibody formation and on the presence of IgA immune complexes in the bloodstream. By targeting the origin of the disease and preventing the formation of immune complexes that would otherwise become trapped in the glomeruli, Nefecon aims to have a disease-modifying effect and thereby preserve kidney function and improve longer term outcomes.

Nefecon has been granted orphan drug designation in the United States and the European Union, which will provide marketing exclusivity for seven and ten years subject to approval, respectively. In addition, Calliditas has an approved formulation patent in the major geographic regions. We also believe that our precise delivery of the drug to the target area constitutes a soft barrier to entry that would require significant time, focus and investment for a competitor to achieve. In December 2019, Calliditas received a positive opinion from EMA's Paediatric Committee on the Paediatric Investigation Plan (PIP) for Nefecon for the treatment of IgAN. If the PIP is successfully completed then Nefecon, if approved, may be eligible for an additional two years of marketing exclusivity in the EU, on top of the ten years of market exclusivity provided by orphan drug designation in the EU at approval.

NEFECON IN CLINICAL TRIALS

Successful Readout in Pivotal Phase 3 Trial NefIgArd

Phase 3 Study NefIgArd

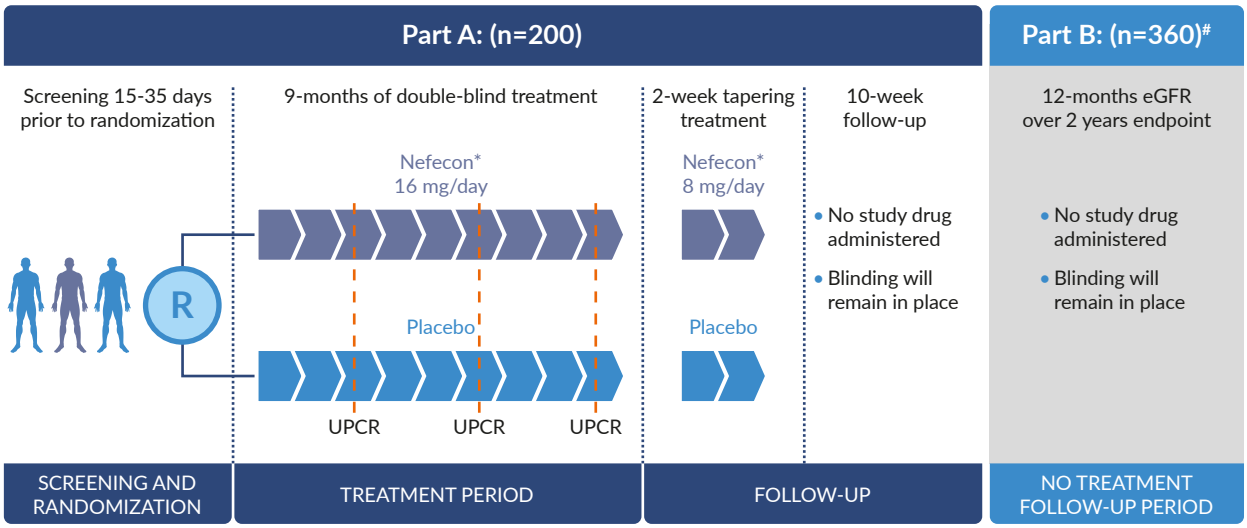
In November 2020, Calliditas read out topline data from the global pivotal Phase 3 clinical trial NefIgArd. The trial met the primary objective of demonstrating a statistically significant and clinically meaningful reduction in proteinuria. It also met the key secondary endpoint of showing a stabilisation of eGFR versus placebo, reflecting a stabilization of kidney function in the treatment arm during the treatment period, versus a continued decline in kidney function in the placebo arm. It was also demonstrated that Nefecon was well-tolerated. Collectively, the efficacy data indicated a significant and beneficial effect on key factors correlated to the delay of progression to ESRD for IgAN patients.

NefIgArd is a randomized, double-blind, placebo-controlled study evaluating reduction of the surrogate marker proteinuria as a primary endpoint. It is a global trial with recruitment across 19 countries at approximately 146 sites, including in North America, South America, Europe, Australia, and Asia. Patients enrolled in the trial have biopsy-confirmed IgAN and are on optimized and stable RAS blockade throughout.

The NefIgArd study consists of two parts, Part A and Part B. Part A with 200 patients compares nine months of 16mg Nefecon dosing data versus placebo, followed by a 3 month follow up period. For Part B an additional 160 patients are enrolled, resulting in a total of 360 patients. Part B is designed as a post approval confirmatory study looking at long term renal benefit and includes an observational 12 month period post completion of Part A. NefIgArd is the only successful randomized, double-blind, placebo-controlled Phase 3 clinical trial carried out in IgAN to date.

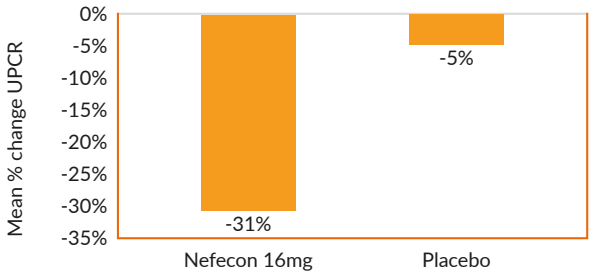
Part A

The first part of the NefIgArd study is a pivotal efficacy and safety trial, which forms the basis for the submission of an NDA for accelerated approval to the FDA and an MAA for conditional approval to the EMA. The primary endpoint of Part A is the reduction of proteinuria (measured by urine protein creatinine ratio, UPCR) in the first 200 randomized and dosed patients, after 9 months of treatment with either 16mg Nefecon or placebo. A key secondary endpoint is the difference in kidney function between treated and placebo patients as measured by estimated glomerular filtration rate (eGFR.)

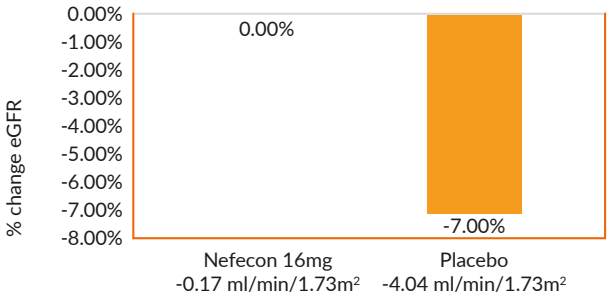


Phase 3 Trial Design

Primary endpoint: Reduction in proteinuria



Secondary endpoint: Stabilization of eGFR



The Phase 3 trial read out in November 2020 and demonstrated a statistically significant and clinically meaningful UPCR reduction of 27% compared to placebo, with the Nefecon arm reporting a 31% reduction in proteinuria versus baseline compared to a 5% reduction in the placebo arm. There was also a significant continued decline in proteinuria observed for those patients who had reached the 12 month mark, i.e. after 3 months off-drug. There was also stabilization of the kidney function in the treatment arm versus placebo. Statistically significant eGFR stabilization saw patients treated with Nefecon having a decrease in eGFR of only 0.17ml/min/1.73m^2 compared to the 4.04 ml/min/1.73m^2 decrease experienced by patients in the placebo arm.

Furthermore, Nefecon was shown to be generally well-tolerated. There were no severe infections, a common and troublesome side effect of many corticosteroids, and there was a significantly lower withdrawal rate compared to the Phase 2b NEFIGAN trial: only 19 patients (9.5% of those randomized) discontinued study treatment, with 10 of those being due to adverse effects (AEs.) The most common AEs were similar to those observed in the Phase 2b trial, and there was a lower frequency in reporting of some AEs in the Phase 3, likely due to the NEFIGAN trial's solicitation of GCS-related and GI-related AEs which the NefIgArd study did not replicate. There were no adverse clinical effects on body weight, systolic or diastolic blood pressure, or HbA1c.

Unlike the Phase 2b study, the NefIgArd trial permitted patients with Type 1 and Type 2 diabetes mellitus to take part, provided it was adequately controlled (defined as HbA1c ≤8% [64 mmol/mol].) Patients without a diagnosis of diabetes mellitus showed a pattern of HbA1c results similar to that seen in Phase 2b study, while some patients with diabetes mellitus showed clinically manageable increases in HbA1c during treatment, resolving on treatment discontinuation.

The findings from Part A of the trial support Nefecon's ability to reduce protein leakage in urine and to counteract a decline in kidney function. The clinical effects of Nefecon support the thesis that the drug has a disease-modifying effect, which would result in a delay of the onset of dialysis.

Part B

The second part of the NefIgArd study is a post-approval confirmatory trial, designed to show long term renal benefit. Following the completion of enrollment in Part A, which took place in December of 2019, Calliditas continued to recruit an additional 160 patients during 2020 and January of 2021 in order to meet the enrollment target for Part B. Enrollment was completed on January 21st 2021. Everest Medicines, Calliditas' partner in China, contributed to the enrollment for Part B, randomizing the first patient in China on September 8th 2020.

The aim of Part B is to assess the difference in kidney function between treated and placebo patients, as measured by eGFR over a two-year period from the start of dosing of each patient. Calliditas expects to report out data from Part B in early 2023.

NEFECON IN CLINICAL TRIALS

» To date, the NEFIGAN study remains the only successful randomized placebo-controlled Phase 2b study ever conducted in IgAN.«

NefIgArd Open Label Extension Study

In November 2020, Calliditas initiated an open-label extension trial for patients who have completed both Part A and Part B of NefIgArd. This study will dose all eligible patients with Nefecon, both those who previously received Nefecon in the NefIgArd trial and those who previously received placebo and thus will be treatment naïve to Nefecon. All of the patients will continue on a stable dose of RAS inhibitor therapy, and both patients and investigators will remain blinded to the treatment given in the NefIgArd trial. Patients will receive Nefecon for a 9-month period, after which the two primary endpoints – change in UPCR and change in eGFR – will be evaluated. After a further three months off-drug, all patients will come for a follow-up visit. This trial aims to read out data in 2024.

Earlier Studies

Phase 2a

Efficacy in IgAN patients was initially assessed in a multi-center 16-patient, open-label, Phase 2a (NCT00767221) study, in which patients received 8 mg Nefecon for six months before a three-month follow-up. Patients in this study had a mean reduction in proteinuria of 23% at end of treatment, with a further reduction to 40% below the base level two months after the end of treatment; an increase in eGFR of 8% as a result of the treatment was also observed.

Phase 2b

The effect of Nefecon was subsequently investigated in a 150 patient, multi-center Phase 2b (NEFIGAN, NCT01738035) study that involved leading clinicians at 62 sites across ten countries in Europe. Prior to the NefIgArd trial, this study was the largest double-blind trial ever conducted with an investigational candidate in IgAN patients, and it still remains the only successful randomized, placebo-controlled Phase 2b study to date. The study had three treatment arms: 8mg Nefecon, 16mg Nefecon and placebo.

At the end of nine months' treatment of either Nefecon or placebo, patients treated with 8mg and 16mg Nefecon showed an improvement in UPCR, while the placebo treated patients had an increase in UPCR. Statistically significant differences in eGFR between the Nefecon and placebo treated groups were also observed, with the Nefecon-treated patients in both dosing arms experiencing a stabilization of eGFR while the placebo arm experienced deterioration. In addition, Nefecon was well-tolerated, with no severe infections or clinically relevant impact on the metabolic system (blood pressure, weight gain, diabetes, etc.).

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

2013

- Investinor joins the existing investors to finance the completion of the Phase 2b study

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 NefIgArd
- Poster from Professor Barratt at IIgANN 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 NefIgArd study

2019

- All 200 patients are enrolled in Part A (required for market approval) of the NefIgArd study
- After positive interaction with the FDA, the design of Part B of the NefIgArd 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 NefIgArd Trial, which confirmed the results of the Phase 2b study, providing a basis for regulatory filing for accelerated approval and conditional approval by the FDA and EMA, respectively. NefIgArd is the only successful randomized, double-blind, placebo-controlled Phase 3 clinical trial carried out in IgAN to date
- 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 NefIgArd
- Full recruitment of 360 patients for the post-approval confirmatory part of the NefIgArd study
- NDA filing with FDA for accelerated approval in IgAN

COMMERCIALIZATION PLAN

An Exciting Market Opportunity

» Calliditas estimates the US target market opportunity for Nefecon to be approximately USD 4.5 billion to USD 5.0 billion annually.«

Calliditas retains global rights to Nefecon, other than in Greater China and Singapore. In 2019, Calliditas entered into an agreement with Everest Medicines Ltd (Ticker: HKEX 1952.HK) pursuant to which Calliditas granted Everest Medicines an exclusive license to develop and commercialize Nefecon for IgAN in Greater China and Singapore. Everest Medicines may exercise its option to develop Nefecon in additional indications subject to additional payment by Everest. If approved, Calliditas intends to commercialize Nefecon in the US independently, and through a commercial partnership in Europe.

The US Market

Calliditas estimates the US target market opportunity for Nefecon to be approximately USD 4.5 billion to USD 5.0 billion annually, based on our estimate of the prevalence of the disease in the US and on market landscape research conducted by IQVIA.
Calliditas intends to commercialize Nefecon in the U.S. with a targeted commercial infrastructure and with a primary focus on the specialist physicians treating IgAN patients at risk of progressing to ESRD.

Calliditas is currently focused on disease education, patient advocacy and market access, with the goal of facilitating access to Nefecon, if approved and commercialized, to the patients for which Nefecon can fulfil an unmet medical need. Calliditas believes this market can be addressed by a small and dedicated number of marketing and medical sales specialists, initially approximately 40, to efficiently cover the estimated 3,700 nephrologists focused on our target patient population in the U.S.

We estimate the prevalence of IgAN in the USA to be between 130,000 – 150,000 and that, importantly, up to 50% of IgAN patients progress and end up at risk of developing end stage renal disease (ESRD.) The primary market research conducted by IQVIA prior to our positive Phase 3 data readout provided an estimated price range of an initial course of treatment of Nefecon of USD 55,000 to USD 85,000 per patient.

In 2019, Calliditas conducted a U.S. market landscape research project with IQVIA, a leading global provider of advanced analytics, technology solutions and contract research services to the life sciences industry. The research included qualitative interviews with payors and 12 Key Opinion Leader (KOL) nephrologists, as well as a quantitative survey of 102 nephrologists that treat on average 14 IgAN patients per month.

The objectives of the study were to explore the current IgAN landscape, evaluate the rare disease pricing and reimbursement dynamics, and ascertain nephrologist and payor perceptions of a Nefecon product profile based on our Phase 2b trial results. The study findings provided helpful insights into how both nephrologists and payors see this indication and Nefecon's potential role in the IgAN space.

Patients are first officially diagnosed following a kidney biopsy, which is the only way to confirm an IgAN diagnosis. By that point, most are in varying stages of chronic kidney disease (CKD), with the vast majority being in the first three stages and the largest portion being in CKD stage 3.

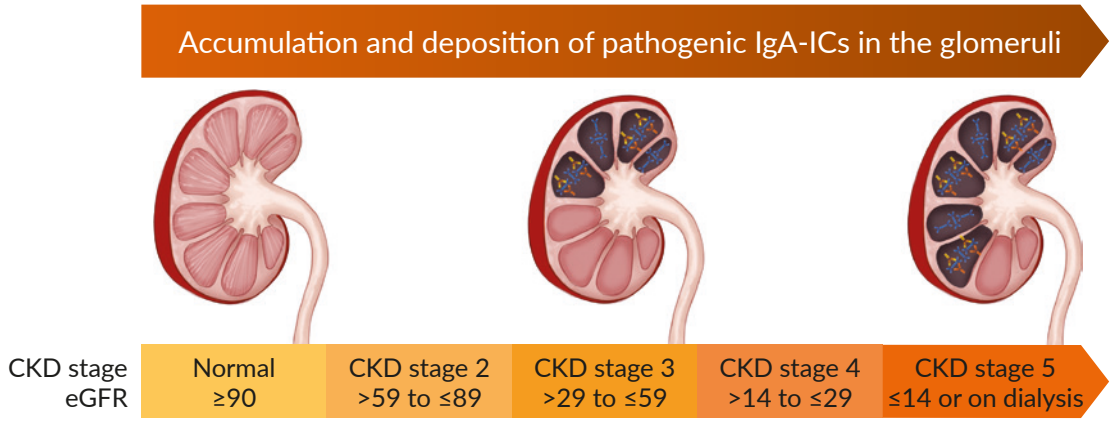
When asked, nephrologists felt that Nefecon would be appropriate for patients at all stages of CKD, and specifically that it would be appropriate for almost 50% of their CKD 3 patients. 68% of the nephrologists interviewed also said that they would prescribe Nefecon during its first year on the market. Furthermore, 90% of the nephrologists already familiar with budesonide had a neutral or more favourable opinion of Nefecon after they were informed of its active ingredient.

They envisioned prescribing Nefecon to their patients as the first agent after, or in conjunction with, blood pressure lowering medications (ACEIs/ARBs.) This is consistent with the design of our Phase 2b and Phase 3 trials, in which participants remained on optimised and stable RAS blockage throughout.

On the payor side, we discovered that there is a lack of experience and knowledge base surrounding IgAN, and that as a result there is a desire and request for education on the disease from KOLs and specialists. We were the first company to speak to payors about IgA nephropathy, given that we are the closest to having a drug on the market in this indication. The biggest takeaway was that payors see any treatments that could delay or help avoid dialysis and kidney transplant as providing high value, given the high cost and impact on quality of life for patients of these longer-term outcomes. Payors universally pointed to a delay of ESRD as a critical unmet need, as well as indicating that a targeted therapy and a disease modifying agent are also important unaddressed needs.

Pre-Commercial Activities: 2020

We have fully developed our launch plans and are implementing our pre-commercialisation activities, focusing on Medical Affairs, Market Access, and Marketing.



COMMERCIALIZATION PLAN

Medical Affairs

In 2020, we executed on our fully integrated publication plan, contributing abstracts, posters, and presentations at key nephrology meetings. Throughout the year, we also had a strong presence at all of the relevant conferences and congresses, including events such as the American Society of Nephrology's (ASN) Virtual Kidney Week. Due to the COVID-19 pandemic, like all companies, we had to navigate through the uncharted territory of creating virtual exhibits booths and having an online presence.

Our virtual booth at ASN Kidney Week 2020

Furthermore, in 2020 we established and held meetings with a US-based Academic Steering Committee consisting of KOLs from many centres of excellence spread across the United States, as reflected in the map below.

Calliditas grew its team of Medical Science Liaisons (MSLs) and initiated educational efforts to key nephrologists, as well as supporting IgAN specific advocacy programs. Despite the many restrictions on travel and face-to-face gatherings during the pandemic, the IgAN patient and advocacy community has grown significantly in 2020, and we are proud to have contributed to this growth.

We were the lead sponsor in the first annual patient forum, SPARK 2020, organised by the IgA Nephropathy Foundation of America.

IGA NEPHROPATHY FOUNDATION
Dedicated to finding a cure.

Calliditas was also the sole sponsor of a nationally televised segment on IgA nephropathy, with a feature on the 'Behind the Mystery' segment on The Balancing Act, LifeTime television's morning program.

Market Access

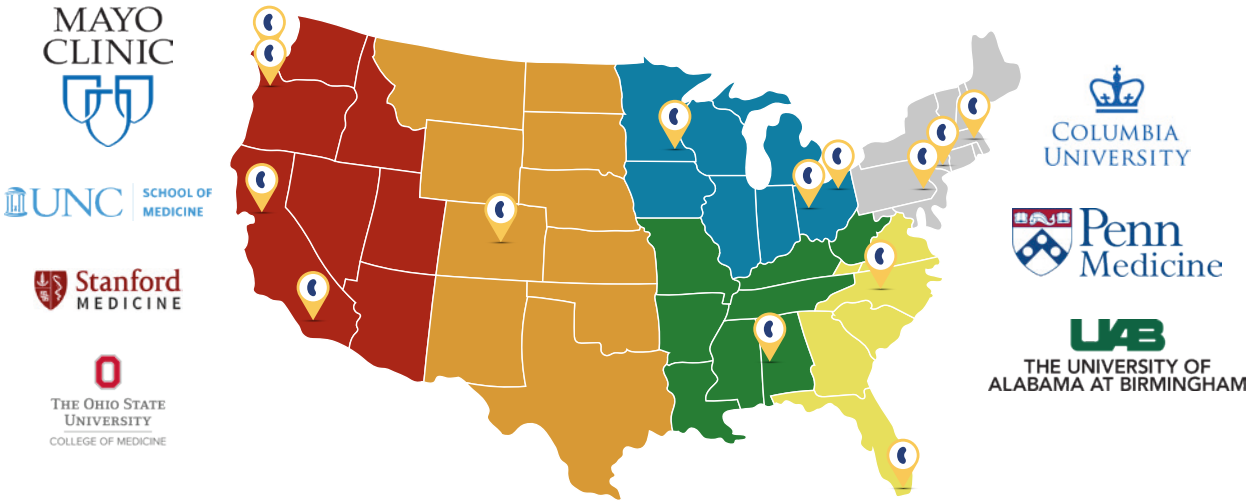
In 2020, we completed extensive benchmarking and primary research with stakeholders to finalize our channel and distribution strategy to support the launch of Nefecon. We also engaged a leading market access agency, Entrée Health, to develop pre-launch payor engagement collateral to support the managed markets activities which will commence in Q2 2021. Finally, we initiated final U.S. pricing research with ZS Associates to further assess launch price options as well as corresponding reimbursement with a large sample of U.S. payors and prescribers.

Marketing

Calliditas partnered with CDM, the Omnicom-award-winning creative agency based in New York City.

cdm. lifechanging

We also conducted several market research projects with our target audience in order to finalise product positioning. We know that in the minds of our audience, the consistency and strong topline results of the Phase 3 NefIgArd trial further support and enhance our unique position for Nefecon.



» We strive to protect the proprietary technologies that we believe are important to our business. «

Patents

Nefecon

Calliditas co-owns one patent family with Kyowa Kirin Services Ltd., f/k/a Archimedes Development Ltd., to which we have a sole and exclusive global license, even in relation to the other co-owner, in any field of use. This patent family protects a formulation for the oral delivery of budesonide and the medicinal use thereof. The patents in this patent family expire in 2029, and include a United States patent, a patent in each of China, Hong Kong and Japan, and a European patent that has been validated in 15 countries. The patents in this family are not eligible for extension in the United States because the active ingredient is used in existing approved drugs. In Europe, extension of the patents is not likely subject to the recent judgement of litigation in the European Union, CJEU C-443/17, related to the degree to which it is possible to obtain a Supplementary Protection Certificate for a previously authorized active ingredient.

Genkyotex's Patents

With regards to the NOX estate, there are three patent families covering various aspects of the setanaxib asset derived from three PCT applications. The composition of matter and certain methods of therapy are covered in two of these patent families, and the third covers the use of setanaxib in certain oncology indications. There are seven further patent families that cover other NOX inhibitors and their use. As these patents and applications cover new chemical entities, the territorial coverage is generally quite wide, and as the compounds do not yet form part of an approved drug product, patent life may potentially be extended in countries where legislation provides for patent term extension. The two families covering setanaxib's composition of matter have projected expiry dates in 2028 and 2029, excluding potential extensions.

The vaccine patent estate is a combination of licensed, wholly owned and jointly owned patent families. This estate stems from the French company Genticel S.A., or Genticel, into which Genkyotex merged in order to become listed on the Paris stock exchange. The vaccine technology is based on technologies from Institut Pasteur and Genticel. Later, Genticel entered into a partnership, also covering licenses to technology controlled by Genticel, with the Serum Institute of India, Pvt. Ltd. or SIIL. The partnership with the SIIL was continued and re-negotiated after the Genticel/Genkyotex merger. The vaccine technology covers certain immune-cell targeting and immune system stimulating methods and delivery of certain antigens to antigen presenting cells. The most recent patent family, co-owned by Genkyotex and SIIL, has a projected expiry date in 2035.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover the technologies incorporated into, or used to produce, our product candidates, including compositions of matter of our product candidates and their methods of use, as well as other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that we do not consider appropriate for patent protection, including certain aspects of our technology and drug product manufacturing.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, particularly our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

IgAN Patient Interview

John lives in Westbury, New York, with his wife of 20 years. He loves sports, and in particular has a passion for golf. He also has IgA nephropathy, and has been living with his diagnosis since 2005. A patient advocate who sits on the Board of Directors of the IgA Nephropathy Foundation of America, he chats with us about life with IgAN and the importance of finding an effective treatment for this disease.

How did you first find out you had IgAN?

Back in 2005 I went for a routine physical, and after I got home I received a call from my doctor saying that something was off in my urine and that I needed to be re-tested. She mentioned that she thought there was something wrong with my kidneys, so I had my follow up with a nephrologist. The nephrologist was the one who told me that I had IgA Nephropathy, but he didn't really say anything else at that appointment – there was no discussion about IgAN being a rare disease, or about me having to monitor anything or take any next steps. He just said, "I'll see you in 6 months," and that was that. I walked away from that appointment thinking that this diagnosis wasn't really anything to worry about, but also not understanding much about the disease. It was only later that year, when I tried to update my life insurance policy, that I realised how serious this diagnosis was – I was denied the coverage due to IgA nephropathy. Since my doctor had told me that IgAN was nothing to really worry about, this response from the life insurance company really shocked and alarmed me.

What were your symptoms like in the first few years? How did the disease progress?

Because IgA nephropathy is a rare disease, I really didn't know what to look for in terms of symptoms at the time. Looking back now, I can see what the signs really were: I was probably more tired than I should have been, and I did see some foam in my urine. I was stable for a few years, but after a while the protein in my urine started to increase. The physician who

I was seeing at the time explained that there was no treatment or cure, and that my only option was just to manage the symptoms. My doctor suggested a high dosage of prednisone as a way to try and manage the disease progression, so I started steroid treatment.

How did you fare with this course of treatment, and with dealing with the IgAN diagnosis?

I had many of the side effects of prednisone, including the irritability and the insomnia. The most significant side effect I experienced was the dramatic weight gain – I became almost unrecognizable to my friends and family.
These side-effects had a major impact on my life. I was no longer able to go out on weekends or evenings with my wife or friends; playing golf came to a screeching halt. Attempting to manage this disease had many add-on effects that were worse than anything I could have imagined.
The hardest part of all, however, is waiting for the lab results during each doctor visit, and trying to deal with the anxiety that comes with opening them. Each time, you have to face the truth of how badly you're doing and how much your kidney function has declined, all the while knowing that – with no cure or treatment available – even if the bloodwork IS bad there's nothing that you can really do. The uncertainty and powerlessness regarding my future is a major source of stress. This anxiety is even further amplified by the fact that everybody with this disease advances at a different rate, so even looking to how others with the same diagnosis have fared doesn't help you get a sense of what your life is going to be like in the next year or two. What will happen if I get to a point where I need dialysis? What if that means I can no longer work? These are the kinds of thoughts that keep me up at night, wondering what my future is going to hold. At a certain point, despite doing everything I could, my bloodwork showed that the prednisone was no longer working. I was referred to a different nephrologist, an IgAN specialist, who started me on a different management plan. This worked in the short term, but didn't last.

What next steps did you take after your management plans stopped working?

The IgA specialist I was seeing gave me two options: go back on prednisone or join a clinical trial for patients with IgA nephropathy. After my tough experience with steroid treatment, and after considering the different clinical trials that were available, I made the decision that I felt was best for me and enrolled in a clinical trial. My results from my most recent bloodwork have shown that my eGFR is stable and that the amount of protein in my urine has decreased dramatically – both really encouraging signs of progress that helped to relieve a lot of stress in my life.

What is your outlook like now?

A little while ago, after I was asked to sit on the board of directors for the IgA Foundation of America, and I was invited to take part in a panel where the speakers sought to address the FDA regarding the current research and clinical trials, and the need to bring a treatment to market as soon as possible. I left that panel that day very emotional, having listened to people who have terrible lives as a result of how their IgA nephropathy has progressed. It's difficult to express how lucky you feel to leave that gathering of people knowing that you're not at that stage yet. But, at the same time, you can't help but wonder what tomorrow brings if there is no true treatment or way to manage this disease.

» The most significant side effect I experienced was the dramatic weight gain – I became almost unrecognizable to my friends and family. «

ORPHAN LIVER INDICATIONS PIPELINE

Potential in selected autoimmune diseases

Calliditas believes that budesonide, Nefecon's active ingredient, also has potential in treating other select autoimmune diseases, like autoimmune hepatitis.

Autoimmune Hepatitis (AIH)

Budenofalk for AIH

Calliditas has exclusively in-licensed Budenofalk 3 mg oral capsules for the US market from Dr. Falk Pharma. Budenofalk is a formulation of budesonide originally developed to treat Crohn's disease. The licence covers all indications for the US market, excluding orphan indications outside of liver targets. Budenofalk has been tested in a large, randomized, controlled clinical trial in AIH patients and is approved for the treatment of AIH in several European countries, but there has been no clinical development or regulatory approval in the US. In addition, Budenofalk has been approved for the treatment of Crohn's disease and microscopic colitis in Europe. Calliditas believes Budenofalk has the potential to address AIH for patients in the US and has received orphan drug designation for the treatment of AIH by the FDA. We anticipate discussing our final development plans for AIH with the FDA in 2021.

AIH Disease Background

AIH is a rare disease associated with chronic inflammation of the liver. Based on current knowledge of AIH's pathophysiology, the origin of the autoimmune response is believed to be the production of cytotoxic T-cells and B-cell derived autoantibodies, which are directed towards liver cells or their components. This results in inflammation of the liver cells, which eventually destroys them and leads to fibrosis. AIH often presents as a slow progressing disease of the liver that leads at variable rates to cirrhosis, with complications such as liver failure and liver cancer. Typical symptoms are fatigue, abdominal discomfort, jaundice, enlarged liver, skin rashes, joint pains and, in women, loss of menstruation. Some patients have no obvious symptoms and are diagnosed based on liver problems identified during routine blood tests.

AIH Prevalence

AIH is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 50,000 to 80,000 patients in the US, where the annual incidence of AIH ranges from 0.1 to 1.9 cases per 100,000. The disease is at least three times as common in women as in men and can occur at any time during life.

» Calliditas believes Budenofalk has the potential to address AIH for patients in the US and have received orphan drug designation for the treatment of AIH by the FDA.«

Orphan drugs

To encourage the development of therapies for patients affected by orphan diseases with unmet medical needs, regulatory authorities worldwide introduced the 'orphan drug' designation.

The American Orphan Drug Act of 1983 introduced several incentives for drug companies to develop drugs for the purpose of preventing, diagnosing or treating orphan diseases that affect fewer than 200,000 individuals in the US.

In the US, these incentives consist of seven years of market exclusivity from the grant date of marketing approval, assistance in clinical research study designs, tax credits for the costs of clinical research, FDA fee waivers and eligibility for FDA grants.

The European Parliament adopted the Orphan Regulation on December 16, 1999, to establish the EU procedure for designation of orphan medicines and to stimulate the development of orphan medicinal products. In Europe, an orphan disease is defined as a disease or condition affecting no more than five in 10,000 individuals, with no satisfactory method of diagnosis, prevention or treatment.

The 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.

Current Treatments for AIH

There are currently no approved therapies for the treatment of AIH in the US. The standard of care includes immunosuppressive systemic corticosteroids, typically prednisone, alone or in combination with azathioprine. A common modality is to use a high-dose corticosteroid induction period followed by a lower-dose maintenance therapy. The clinical outcome target is to prevent development of cirrhosis or prevent progression if cirrhosis has already occurred. Many patients respond well to standard of care and achieve disease remission, in which case the prognosis is favorable.

However, up to 80% of treated patients report steroid related side effects after two years and 15% discontinue treatment due to drug-related adverse events. Between 50% and 90% of patients relapse if treatment is stopped. Furthermore, the high risk of adverse events in some patient groups (where systemic steroid treatment may be contraindicated) such as patients with osteoporosis, hypertension, diabetes or underlying mental illness, results in non-treatment, which leads to an increased risk of cirrhosis. Given the high rates of adverse events and the high rate of relapse among AIH patients, there is a significant unmet need.

A Nox Inhibitor Platform

On August 13, 2020, Calliditas announced that it had entered into an agreement to acquire 7,236,515 ordinary shares from Genkyotex's largest shareholders and management team, representing 62.7% of the share capital and voting rights.

After receiving clearance from the French Minister of Economy and Finance regarding foreign investments into France, on November 3 2020 Calliditas closed the off–market block trade for a total consideration of €19.8M in cash (€2.73 per ordinary share) plus contingent rights payable upon regulatory approvals of setanaxib, Genkyotex's lead asset. Calliditas then filed a simplified mandatory cash tender offer with the French Financial Market Authority (Autorité des Marchés Financiers – the "AMF") for the remaining Genkyotex shares at €2.80 per ordinary share plus contingent rights. The outcome of the tender offer resulted in Calliditas controlling a total of 10,121,676 shares in Genkyotex at the end of the year, which corresponds to 86.2 percent of the share capital and the total number of votes.

NOX Inhibitors

Genkyotex is a pioneer in NOX inhibitor therapies, and its lead candidate setanaxib is the first NOX inhibitor to reach the clinical trial stage. NOX enzyme inhibitors are a class of promising novel experimental drugs in redox pharmacology. In July 2019, the WHO approved a new stem, "naxib," which recognizes NOX inhibitors as a new therapeutic class.

Several other molecules are currently in use as experimental NOX inhibitors, most frequently diphenylene iodonium (DPI) and apocynin, but these molecules are not specific to NOX enzymes and have several off-target effects. Setanaxib is currently the only NOX inhibitor that specifically and exclusively acts on NOX enzymes, with no off-target effects.

Reactive Oxygen Species and NOX

Several human enzymes are capable of producing reactive oxygen species (ROS.) The only known enzymes that are solely dedicated to producing ROS as their primary function are nicotinamide adenine dinucleotide phosphate (NADPH) oxidases, otherwise known as NOX enzymes. 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, fibrosis and inflammation. However, the disruption of the redox homeostasis has been implicated in multiple disease pathways. Oxidative stress, which causes an excess of ROS, is a likely common underlying mechanism for cardiovascular diseases, neurodegenerative disorders, and cancer disease pathways.

NADPH oxidases 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 and modes of activation. NOX1, NOX2, NOX3, and NOX5 transfer electrons from NADPH to molecular oxygen, producing superoxide anion (O_2^{-}.) NOX4, DUOX1 and DUOX2, meanwhile, mainly produce hydrogen peroxide (H_2O_2.)

Setanaxib inhibits NOX1 and NOX4, enzymes which are implicated in inflammation and fibrosis pathways. While both types of enzymes are found all over the body, NOX1 is most highly expressed in the intestinal epithelium, while NOX4 is highly expressed in kidney cells.

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. 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 fibrosis. PBC can eventually lead to liver failure, necessitating the need for a liver transplant. 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.

Early symptoms of PBC include fatigue, itchy skin, dry eyes and mouth dryness. As the disease progresses, symptoms range from pain in the upper right abdomen and musculoskeletal pain to edema, 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.

GENKYOTEX ACQUISITION

Current Treatments for PBC

Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, marketed as Ocaliva by Intercept Pharmaceuticals, are the only FDA-approved treatments for PBC. Both of these agents are bile acid analogues whose mechanisms of action aim to protect the liver from damage caused by accumulation of endogenous bile acids and inhibition of bile acid synthesis. These drugs are primarily anticholestatic. Neither of these drugs specifically addresses the autoimmune response that is believed to drive PBC, the inflammatory consequences of the autoimmune response or the increased bile acid levels associated with PBC. Despite adequate dosing of UDCA, approximately one-third of PBC patients do not respond sufficiently and are at risk of requiring a liver transplant. Similarly, although Octaliva shows improvements in blood markers of liver function, it has not been proven in clinical testing to delay or avoid the need for liver transplant. Furthermore, while systemic corticosteroids have been shown to alleviate PBC symptoms, their adverse event profile limits their treatment potential.

Setanaxib in PBC

The effect of setanaxib in PBC was investigated in a Phase-II randomised double-blind placebo-controlled clinical trial. Reduction in serum gamma glutamyl transpeptidase (GGT) was the primary endpoint, and key secondary endpoints included reduction in the cholestatic marker alkaline phosphatase (ALP.) The patients were monitored with regular blood tests and transient elastography.

Phase 2b/3 Clinical Trial in PBC

Calliditas plans to initiate a pivotal Phase 2b/3 trial in early PBC, which we anticipate being a double-blind, randomized, placebo controlled study with an adaptive design. There will be a dose response component in the Phase 2b part of the trial, with patients being enrolled and randomised to one of two doses of setanaxib vs placebo. This will be followed by a futility analysis, and then one of the active doses will be taken into the Phase 3 component of the trial.

We anticipate that approximately 300 patients will be enrolled into the study, which will aim to begin recruitment in H2 2021, with the futility analysis likely taking place in H1 2023 and the full read-out expected in H2 2024 or H1 2025.

Key Highlights: Phase II Trial Results	
Setanaxib clearly demonstrated anti-fibrotic activity	In patients with an estimated liver fibrosis stage of F3 or higher, treatment with setanaxib resulted in a 22% reduction of liver stiffness (a reduction by 2.7 kPA,) compared to 4% increase (a mean absolute increase of 0.4 kPa) for the placebo arm.
Setanaxib met key secondary endpoints related to ALP and liver inflamation	Setanaxib achieved a reduction of 12% in ALP, the endpoint typically used in PBC trials. In the higher dose and higher liver stiffness subcategory of patients, this reduction was 24%.
Setanaxib significantly improved parameters important for the quality of life of patients	There was a statistically significant impact on fatigue, a very common and bothersome symptom of PBC, as well as demonstrated positive effects on emotional and social aspects.
Setanaxib showed a favourable safety profile throughout the treatment period	A Phase 1 clinical study with high-dose setanaxib in healthy subjects, which evaluated the drug at doses up to 1,600 mg/day, read out positive results in January 2021, providing support for the inclusion of higher doses of setanaxib in future clinical trials.

Setanaxib in Head and Neck Cancer

Immuno-oncology (IO) therapies are not as effective in highly fibrotic tumours, which introduces the potential for anti-fibrotic agents to be used to improve treatment.

NOX4 is highly over-expressed in cancer associated fibroblasts (CAFs) and drives myofibroblastic activation, where CAFs are enslaved by tumours and shield them from CD8+ (cytotoxic) T-cells. Targeting CAFs with setanaxib could improve patients' responses to immunotherapies, and function as an adjunct therapy to IO therapy.

A study investigating setanaxib in oncology is currently in the design phase, with the design and clinical trial protocol subject to finalization after interactions with regulatory authorities. The trial will be a proof-of-principle (POP) study in head and neck cancer, where the efficacy and safety of setanaxib will be explored when given with an immuno-oncology agent. The study will likely involve 30-40 patients and will start recruiting in H2 2021, with data readout expected in 2023.

Setanaxib in Other Fibrotic Kidney Diseases

NOX 1 and 4 enzymes have been demonstrated to be drivers of pathology in inflammatory and fibrotic diseases, and setanaxib demonstrated in the Phase II PBC trial that it has a clinically significant anti-fibrotic effect. It thus has the potential to be one of the first antifibrotic agents for a variety of kidney diseases. Calllidtas will carry out preclinical in vivo animal model work in 2021 to assist in exploring some selected kidney indications.

Investigator Led Studies

Idiopathic Pulmonary Fibrosis (IPF)

Setanaxib is currently being evaluated in IPF in an investigator-led study. Idiopathic Pulmonary Fibrosis is a lung disease in which lung tissue becomes damaged and scarred. This thickened, stiff tissue impairs lung function and, because the damage cannot be repaired, in some cases a lung transplant may become necessary. The scarring associated with pulmonary fibrosis can be caused by a multitude of factors, but in most cases, the cause is unknown.

The symptoms of IPF tend to develop gradually and get slowly worse over time, and can include shortness of breath, a persistent dry cough, tiredness, loss of appetite and weight loss. There is currently no cure for IPF, and the main aim of treatment is to relieve the symptoms as much as possible and slow down its progression. The medications commonly used include pirfenidone and nintedanib, both of which work to slow fibrosis by reducing the activity of the immune system.

A grant from the United States National Institutes of Health (NIH) was awarded to Professor Victor Thannickal at the University of Alabama at Birmingham to fund a multi-year research program evaluating the role of NOX enzymes in IPF. A Phase 2 double-blind, randomized placebo study started enrolment of 60 patients in September 2020. The primary outcome measure of this trial is a change in concentration of circulating o,o'-dityrosine, a surrogate biomarker of oxidative stress, following a 24 week treatment period. Secondary endpoints include changes in collagen degradation, measures of pulmonary function, and improved ambulatory ability.

Diabetic Kidney Disease

Setanaxib is also being evaluated in Type 1 diabetes in an investigator-led study funded by the Juvenile Diabetes Research Foundation. This investigator led study, conducted in Australia and New Zealand, is a double blind placebo controlled trial that will enroll approximately 100 patients; the primary endpoint is urine albumin to creatinine ratio (UACR) measured after 48 weeks of treatment.

Diabetic Kidney Disease develops in 20% to 40% of all patients with diabetes and is the leading cause of CKD worldwide. High blood glucose levels and high blood pressure, both common clinical features of diabetes, damage the blood vessels in the kidneys which causes a decline in kidney function and ultimately leads to ESRD, of which DKD is the leading cause. Symptoms of DKD include swollen extremities, hematuria, nausea, fatigue and shortness of breath. Current standard of care is to put patients on blood-pressure lowering agents such as ACE inhibitors or ARBs.

SUSTAINABILITY STRATEGY

Environmental, Social, and Corporate Governance

The foundation of our business is our drive to provide access to treatment for people with rare diseases with a high unmet medical need. We operate in a highly regulated industry, which requires the creation of and adherence to standard operating procedures related to many aspects of our daily work. Our sustainability strategy consists of three key commitments to help us strive towards increasing patient access to treatment:

1. Ensuring that in every area of our business, we act ethically and responsibly, with a commitment to the highest standards in clinical development and business ethics. We aim to create a sustainable organisation that serves the patient community and the broader global community.

2. Striving to conduct our business in a way that is conscious of safety issues and our environmental impact. We work towards this goal by strictly adhering to high quality and safety standards, and by undertaking initiatives to promote environmental responsibility.

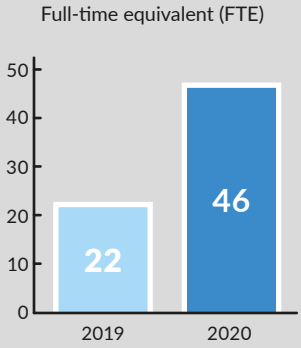
3. Supporting the rare disease community through our commitment to improving the lives of patients with orphan diseases, including working actively on clinical research and regulatory approval pathways to bring medication to patients where today there is a significant unmet medical need.

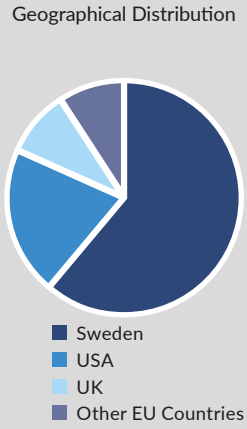
Ethical and Responsible Behaviour

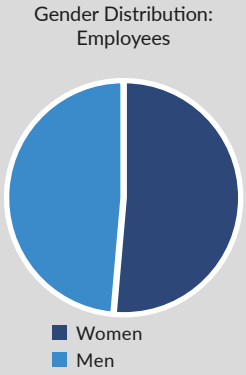
The success of Calliditas Therapeutics is determined by our ability to operate as a unified team as we work to earn the trust and respect of our co-workers, investors, and ultimately our patients. Our company is built on a foundation of creative, productive employees who are encouraged to share their expertise and provide solutions while thinking "outside the box." Calliditas is committed to ensuring equal opportunities for all employees to flourish. The dedicated hard work and commitment of every employee is critical for achieving our goals, and Calliditas strives to have every person in the company succeed in their job and actively contribute to our overall mission.

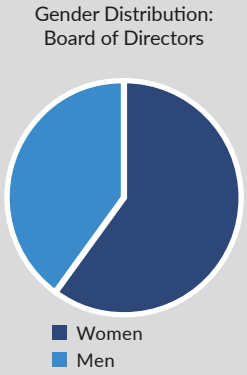
We always aim to act with integrity, and we hold our employees and ourselves to the highest ethical standards. 2020 was a year of tremendous growth, as the Calliditas team expanded more than two-fold. We continuously review and adapt our policies and quality control systems to ensure that we continue to maintain our high standards as we add more new hires, and our employees receive regular training on appropriate conduct. We look to promote ethical behaviour amongst our team through our company values and our employee code of conduct. Every employee is expected to act proactively by asking questions, seeking guidance and reporting suspected violations of this code and all other policies and procedures of the Company. We expressly forbid any retaliation against any employee who reports suspected misconduct, as we view our employees as essential to helping us maintain a work environment that meets a high ethical standard.

Creating and maintaining a good working environment is essential to Calliditas. It is our strong belief that both individual performance and the overall performance of the company is bolstered by a healthy work environment, which will also aid in recruitment and talent retention as we look to grow our team even more in 2021. As an employer, we continuously aim to better the Calliditas work environment and ensure that every employee feels valued, supported, and challenged to grow in their role. We strive to make sure that our work environment is as safe as possible, and that stress, interruptions of production and reduction in quality are avoided wherever possible. Being able to encourage an appropriate work-life balance is also of great importance to us, as we aim to maintain healthy employees and a healthy work environment. We are proud to offer a safe, healthy and inclusive 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 greenhouse gas emissions arise largely from energy consumption and business travel. With offices in Stockholm and New York City, and with employees based across Europe and the United States, business travel is important to our company. However, we are also conscious of reducing our greenhouse gas emissions in this area. In part due to necessity during the COVID-19 pandemic, we expanded on our use of videoconferencing and will aim to carry this forward when possible and appropriate into 2021 and beyond, even when travel resumes as normal. We believe that less travel will benefit not only the planet but also our employees, and we will ensure that travel is purposeful and occurs only when in-person interaction cannot be adequately replaced by remote working.

Calliditas is also committed to rigorous safety standards, both for ourselves and our partners. Calliditas does not own or manage any manufacturing or laboratory facilities, but in 2020, we began to establish our commercial supply chain via partnerships in preparation for having a product in the market by the end of the year or beginning of 2022 (subject to regulatory approval.) We adhere to the same high standards and processes when we select all our service providers and partners, be it in the clinical development area or in manufacturing. 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 so our supplier's overall management system has also been audited and the general site's standard has been reviewed through visual inspections, as far as was possible under restrictions due to the global pandemic. We have clearly outlined our expectations regarding these areas in our agreements with the suppliers, and will hold them to the same rigorous standards as we hold ourselves.

Commitment to Our Patients

Since our inception as a company, our mission and vision is to focus on unmet needs for orphan disease and bring to market treatments for those suffering from rare diseases. We have worked with the rare disease community as we strive to provide access to novel and innovative treatments, and see this cooperation as vital for our future development as a company, particularly as we file with regulators and prepare to potentially have a product on the market.

For IgA nephropathy, our lead indication, we have supported patient advocacy and disease state educational efforts. We are the only company to have carried out a successful randomized, placebo-controlled Phase 2b study to date in this disease, and the only company to have had a successful top-line data read-out of a Phase 3 study in IgAN. We have also pioneered the regulatory pathway in the nephrology space, having worked with therapeutic experts and regulators to create a path for medications to get marketing approval using proteinuria as a surrogate endpoint. Calliditas received the groundbreaking acceptance of this endpoint in an end of Phase 2b meeting in January 2017, and the design for the NefIgArd study was the first time the FDA granted approval for the use of proteinuria as surrogate endpoint for a Phase 3 nephrology study. We hope that our efforts will ease the path for patients to have access to safe and effective medications for IgAN, and look forward to bringing novel treatments to market for patients with other rare diseases as we expand on our pipeline in the future.

The Share

Share Performance

Nasdaq Stockholm

Calliditas was listed on Nasdaq Stockholm Mid-Cap, on June 29, 2018. As of December 30, 2020, the closing rate was SEK 139.6, yielding an increase of 84% in 2020. During the same period, the OMXSPI increased by 13%. The highest closing rate during the year was SEK 165.80 and the lowest SEK 55.20.

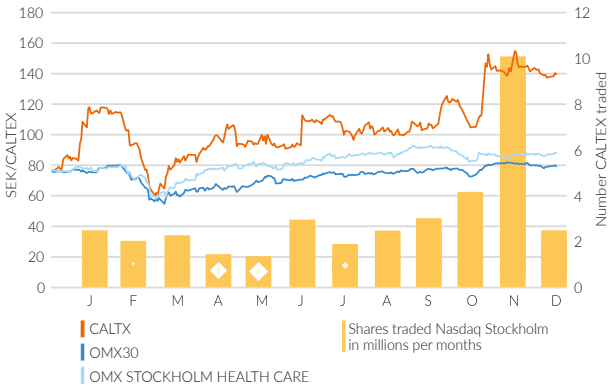
Nasdaq USA

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, 2020, the closing price was USD 33.6, which gave an increase of 71 percent during the period June-December 2020. Nasdaq Composite increased by 31 percent during the same period. The highest closing price during the year was USD 36.7 and the lowest was USD 19.2.

Turnover

Nasdaq Stockholm

A total of 29,416,340 shares were traded during the year, with a total value of SEK 3,539 million. On average, 116,732 shares were traded each day.



Nasdaq USA

During the period June-December 2020, a total of 6,046,217 ADS was traded for a total value of USD 166 million. On average, 42,579 ADS were traded per day.

Shareholders

As of December 31, 2020, Calliditas had 6,513 shareholders. The 15 largest shareholders controlled 66.0% of the capital and voting rights at year-end. The three largest shareholders were BVF Partners, Stiftelsen Industrifonden and Linc AB (Bengt Julander). Foreign shareholders accounted for 41.4% of voting rights and capital.

Share Capital

As of December 31, 2020, share capital in Calliditas amounted to SEK 1,998 thousand. The number of shares was 49,941,584 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 76% at year-end.

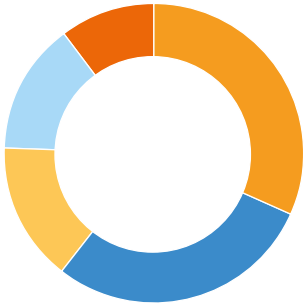
Investor Relations Work

Investor Relations work in 2020 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

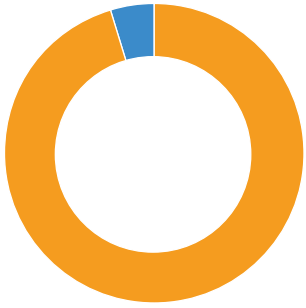
Calliditas is monitored by Carnegie, Stifel, Kempen, Citi, Jefferies, Life Sci Capital, HC Wainwright and Redeye.

Ownership per category, %



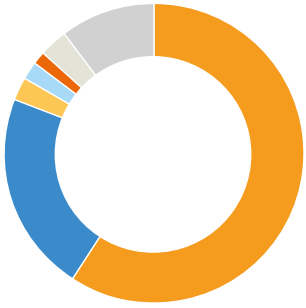
Swedish institutional owners	31.7%
Foreign institutional owners	29.0%
Other	14.8%
Swedish private persons	14.3%
Anonymous ownership	10.1%

Trading platforms, %



Nasdaq	95.29%
Cboe Global Markets	4.71%

Ownership per country, %



Sweden	59.2%
USA	21.7%
France	2.6%
Canada	1.8%
UK	1.3%
Other	3.2%
Anonymous ownership	10.1%

Source: Monitor by Modular Finance AB and Fidessa.

The 15 largest shareholders as of December 31, 2020

Shareholders	Total number of shares	Holding, %	Votes, %
BVF Partners LP	6,331,562	12.7%	12.7%
Stiftelsen Industrifonden	5,772,995	11.6%	11.6%
Linc AB (Bengt Julander)	4,836,108	9.7%	9.7%
Handelsbanken Fonder	2,634,684	5.3%	5.3%
Fjärde AP-fonden	2,230,773	4.5%	4.5%
Hillhouse Capital Advisors	2,095,374	4.2%	4.2%
Swedbank Robur Fonder	1,398,334	2.8%	2.8%
Gladiator	1,358,537	2.7%	2.7%
Sofinnova Partners	1,318,078	2.6%	2.6%
Unionen	1,199,899	2.4%	2.4%
Mikael Bender	1,177,317	2.4%	2.4%
AFA Försäkring	772,762	1.5%	1.5%
Vivo Capital	622,060	1.2%	1.2%
Avanza Pension	605,761	1.2%	1.2%
Logos Global Management LP	600,000	1.2%	1.2%
Total share of the 15 largest shareholders	**32,954,244**	**66.0%**	**66.0%**
Other shareholders	16,987,340	34.0%	34.0%
Total	**49,941,584**	**100.0%**	**100.0%**

CALTX share data 2020

Daily average turnover, SEK	14,043,342
Low, SEK	55.20
High, SEK	165.80
VWAP, SEK	120.30
Number of shares traded	29,416,340
Average number of shares traded per day	116,732
Average number of trades per day	613.1
Number of trades	154,496
Average value per trade, SEK	22,906
Daily turnover rel. Mcap, %	0.29%
Part Nasdaq (ordinary trade), %	89.3%
Part block transactions, %	7.3%
Part dark pools (Nasdaq), %	3.3%

Size classes as of December 31, 2020

Size classes	No. of known shareholders	No. of shares	Holding, %	Votes, %	Proportion of known shareholders
1 - 100	2,977	116,414	0.2%	0.2%	45.7%
101 - 200	783	129,315	0.3%	0.3%	12.0%
201 - 500	1,234	435,620	0.9%	0.9%	18.9%
501 - 1000	653	531,731	1.1%	1.1%	10.0%
1001 - 2000	364	576,492	1.2%	1.2%	5.6%
2001 - 5000	285	914,293	1.8%	1.8%	4.4%
5001 - 10000	95	712,306	1.4%	1.4%	1.5%
10001 - 20000	48	703,761	1.4%	1.4%	0.7%
20001 - 50000	26	904,856	1.8%	1.8%	0.4%
50001 - 100000	10	664,016	1.3%	1.3%	0.2%
100001 - 200000	10	1,454,588	3.0%	3.0%	0.2%
200001 - 500000	12	3,831,866	7.7%	7.7%	0.2%
500001 - 1000000	5	3,500,586	7.0%	7.0%	0.1%
1000001 - 4000000	8	13,412,996	26.9%	26.9%	0.1%
4000001 -	3	16,940,665	33.9%	33.9%	0.0%
Anonymous ownership		5,112,079	10.1%	10.1%	
TOTAL	**6,513**	**49,941,584**	**100.0%**	**100.0%**	**100.0%**

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 2020. All amounts are expressed in SEK millions unless otherwise stated.

Multi-Year Summary, Group

	2020	2019	2018	2017	2016
Net sales (SEK in thousands)	874	184,829	-	-	-
Loss before income tax (SEK in thousands)	(436,151)	(32,501)	(132,049)	(86,794)	(56,912)
Total assets (SEK in thousands)	1,506,450	845,200	648,417	62,288	27,298
Equity ratio at the end of the year (%)	80%	93%	95%	53%	Neg
Average number of employees	23	14	10	10	9

Multi-Year Summary, Parent Company

	2020	2019	2018	2017	2016
Net sales (SEK in thousands)	874	184,829	-	-	-
Loss before income tax (SEK in thousands)	(407,363)	(36,186)	(131,923)	(86,848)	(58,313)
Total assets (SEK in thousands)	1,318,525	838,249	651,633	65,366	30,325
Equity ratio at the end of the year (%)	94%	94%	95%	55%	Neg
Average number of employees	15	13	10	9	8

For definitions of key figures, see Note 32 Key Figure Definitions and Reconciliations of Alternative Performance Measures on page 67.

Operations

Calliditas Therapeutics is a bio-pharmaceutical 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 candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of adults with the autoimmune renal disease primary IgA nephropathy (IgAN), for which there is a high unmet medical need and there are no approved treatments. Calliditas has recently read out topline data from Part A of its global Phase 3 study in IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is also planning to start clinical trials with NOX inhibitors in primary biliary cholangitis and head and neck cancer in 2H 2021. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

Results from Part A of the Phase 3 clinical study have shown that Nefecon has the potential to preserve renal function in patients with IgA nephropathy by targeting the origin of the disease. The study showed a statistically significant and clinically relevant reduction in protein urine levels, ie the level of protein in the urine, and a stabilization of the glomerular filtration rate ("eGFR"), a measure of renal function. Proteinuria is an accepted marker for identifying and monitoring kidney disease. This marker indicates damage to the kidney's filtration function which results in protein leaking into the urine. Calliditas intends to commercialize Nefecon in the United States by itself and through partnerships in the rest of the world. In 2020, Calliditas focused mainly on the development of Nefecon and the ongoing pivotal Phase 3 study NefIgArd, and in November 2020, a positive reading of top line data from Part A of the NefIgArd study was announced. 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.

During the fourth quarter of 2020, Calliditas also completed the acquisition of a majority stake in the French listed company Genkyotex SA, which operates in NOX inhibitors.

The Group had limited revenues in 2020 of SEK 0.9 million and the Group is until Nefecon starts generating revenues depending on external financing to ensure continued operations. During the year, a listing was carried out with an associated new issue on Nasdaq Global Select Market in the U.S., which raised a total of SEK 891.4 million before issue costs.

The Group consists of the Parent Company Calliditas Therapeutics AB, the U.S. subsidiary Calliditas Therapeutics Inc, the French subsidiary Genkyotex SA and the Swedish subsidiary Nefecon, where there is no ongoing operations.

Significant Events During the Year

Positive opinion on the Paediatric Investigation Plan

In January 2020, EMA Paediatric Committee (PDCO) adopted a positive opinion on the Paediatric Investigation Plan (PIP) for Nefecon for the treatment of primary IgA nephropathy.

Extra General Meeting

In March 2020, Calliditas held an Extra General Meeting where authorization for the Board of Directors to issue up to 11 million new shares for a potential equity offering and listing in the United States was approved. At the meeting the adoption of new articles of association and the adoption of a new incentive program were also approved.

COVID-19 pandemic update

In April 2020, Calliditas anticipated that the COVID-19 pandemic would not significantly impact the ongoing clinical activities related to NefIgArd study. This was due to the facts that Part A of the study was fully recruited in December 2019, that Nefecon is an oral formulation which patients are able to take at home, and that the trial is global and requires limited interaction among participants and the healthcare system. The overall impact of the COVID-19 pandemic on the study has been limited.

Initial public offering on The Nasdaq Global Select Market in the U.S.

In June 2020, Calliditas completed an initial public offering on The Nasdaq Global Select Market in the United States, which was completed by the issuance of 9,230,770 new common shares for gross proceeds of approximately USD 90 million (approximately SEK 828 million) before deduction of issuance costs. Trading of the ADSs on The Nasdaq Global Select Market commenced on June 5, 2020, under the symbol "CALT". In July, 2020, the exercise of the partial over-allotment option from the IPO on The Nasdaq Global Select Market was completed. Calliditas was thereby provided with additional gross proceeds of approximately USD 6.9 million (approximately SEK 63 million), which means that Calliditas has been provided with in total approximately USD 96.9 million (approximately SEK 891 million) in gross proceeds from the U.S. IPO before deduction of issuance costs.

Positive topline results from Part A of the global Phase 3 clinical trial NefIgArd

In November 2020, Calliditas announced positive topline results from Part A of the global Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon versus placebo in patients with primary IgA nephropathy (IgAN).

The trial met its primary objective of demonstrating a statistically significant reduction in urine protein creatinine ratio, UPCR or proteinuria, after nine months of treatment with 16 mg of Nefecon compared to placebo, and also saw significant continued improvement at 12 months. The trial also met the key secondary endpoint showing a statistically significant difference in estimated glomerular filtration rate eGFR after nine months of treatment with Nefecon compared to placebo. Collectively the efficacy data from nine months of treatment with 16 mg of Nefecon indicated a significant and beneficial effect on key factors correlated to the progression to end stage renal disease (ESRD) for IgAN patients.

On the basis of these results, Calliditas submitted for accelerated approval with the US Food and Drug Administration (FDA) in March 2021 and plan for a submission for conditional approval with the European Medicines Agency in Q2 2021.

Acquisition of Genkyotex SA

In November 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 inflamma-tion. The purpose of the acquisition is it adds a late-stage orphan pipeline asset and platform in inflammation and fibrosis to Calliditas product portfolio in orphan diseases.

After the acquisition of the controlling interest, a mandatory simplified cash tender offer was launched and after the end of the acceptance period Calliditas controlled 86.2% of the shares in Genkyotex. The acquisition costs, excluding transaction costs, for the 86.2% amounted to EUR 27.8 million (SEK 287.0 million). In addition to this there are a potential future milestone payment relating to contingent rights amounting to a maximum of EUR 55 million, subject to future regulatory approvals of setanaxib.

Sales and Earnings

Sales amounted to SEK 0.9 million and SEK 184.8 million for the years ended December 31, 2020 and 2019, respectively. The sales derive in its entirety from the delivery of Nefecon to China as part of the license agreement with Everest Medicines from 2019.

Research and development expenses

Expenses for research and development amounted to SEK 241.4 million and SEK 149.8 million for the years ended December 31, 2020 and 2019, respectively. The increase is mainly explained by the increased activity in the NeflgArd studies and increased costs for Nefecon's product development compared with the previous year.

Administrative and selling expenses

Administrative and selling expenses amounted to SEK 141.7 million and SEK 62.9 million for the years ended December 31, 2020 and 2019, respectively. The increase compared with the previous year is mainly due to the commercial preparations for a potential future launch of Nefecon in the USA, and related personnel costs, as well as costs related to the parallel listing and the acquisition of Genkyotex SA.

Other operating income / expenses

Other operating income amounted to SEK 2.5 million and SEK 4.4 million for the years ended December 31, 2020 and 2019, respectively and mainly pertains to currency gains on operating receivables. No other operating expenses were recognized during the year (SEK 4.5) million.

Financial income / expenses

Financial income amounted to SEK 0.5 million and SEK 0.9 for the years ended December 31, 2020 and 2019, respectively and mainly pertains to interest income on financial assets. Financial expenses amounted to SEK 57.0 million and SEK 5.4 for the years ended December 31, 2020 and 2019, respectively and primarily derived by unrealized foreign currency transaction losses on cash accounts held in USD, due to a weakened USD against SEK.

Earnings

For the years ended December 31, 2020 and December 31, 2019, the Group had a net loss of SEK 436.5 million and SEK 32.6 million, respectively and the corresponding loss per share before and after dilution amounted to SEK 9.66 and SEK 0.88 for the years, respectively. The increase in the loss were primarily derived from revenues from the out-licensing of Nefecon for China as part of the license agreement with Everest Medicines, which occurred in 2019. Furthermore, the increase in the loss were derived from the increased activity in R&D, increased expenses from administration and pre-commercial activities and to the negative effect of the net financial income/(expenses).

Liquidity and Financial Position

Cash amounted to SEK 996.3 million and SEK 753.5 as of December 31, 2020 and 2019, respectively. In mid-2020, a new issue of 9.9 million shares was carried out in connection with the US listing. The total issue amount was SEK 795.5 million net after issue costs.

Equity attributable to equity holders of the Parent Company amounted to SEK 1,210.5 million and SEK 788.1 million as of December 31, 2020 and 2019, respectively.

Cash Flow

Net cash used for operating activities was SEK 309.2 million and SEK 71.0 million for the years ended December 31, 2020 and 2019, respectively. Cash flow used in investing activities was SEK 172.6 million and 18.1 million for the years ended December 31, 2020 and 2019, respectively and derives from the acquisition of Genkyotex SA.

Net cash provided by financing activities was SEK 768.6 million and SEK 198.8 million for the years ended December 31, 2020 and 2019, respectively, and arises mainly from the rights issue in connection with listing on Nasdaq in the USA and exercise of warrant program 2017/2020 reduced by the purchase of shares in Genkyotex SA.

Net increase in cash amounted to SEK 286.8 million and SEK 109.8 million for the years ended December 31, 2020 and 2019, respectively.

Personnel

The number of employees in the Group were 34 and 16 employees as of December 31, 2020 and 2019, respectively. The total number of full-time equivalent (FTE), including consultants, were 46 and 22 people as of December 31, 2020 and 2019, respectively.

The average number of employees were 23 and 14 for the year ended December 31, 2020 and 2019, respectively of which 43% are women and 57% are men.

Environment

Calliditas works proactively to reduce its adverse environmental impact and to evolve as a sustainable company. Since Calliditas has no sales, 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 has two warrant programs outstanding, issued in 2018 and 2019. The warrant program issued in 2018 was addressed to employees and consultants and expires 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, 2020, the total number of warrants outstanding, if fully subscribed, corresponded to 1,279,086 shares.

The Group also has an outstanding option program, ESOP 2020. The options have been 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 are eligible for exercise, 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. At the end of the year, 1,089,000 options were allocated.

Calliditas also has two long-term incentive programs for board members of Calliditas, LTIP 2019 and LTIP 2020. Participants in the programs will be allocated performance-based share awards free of charge. The share awards in LTIP 2019 are subject to performance-based earnings based on the development of Callidita's share price during the period from the date of the 2019 Annual General Meeting to June 1, 2022. The share awards in LTIP 2020 are subject to performance-based earnings based on the development of Callidita's share price during the period from Annual General Meeting 2020 through June 1, 2023.

In total, there were share awards outstanding corresponding to 82,770 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 2.0 million, divided into 49,941,584 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, Callidita's 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 Market in the U.S. At the end of 2020, Calliditas had 6,513 (2,835) shareholders and the ten largest shareholders owned 58.4 (73.0)% of all outstanding shares. On December 31, 2020, BVF Partners LP, Stiftelsen Industrifonden, and Linc AB (Bengt Julander) were the single largest shareholders in the company, with a total of 6,331,562, 5,772,995 and 4,836,108 shares, respectively, corresponding to 12.7%, 11.6% and 9,7%, respectively, of the votes and capital.

For further infomation regarding the share, please see pages 30-31.

Holdings of Treasury Shares and Warrants

No shares were held in treasury by Calliditas in 2020. The subsidiary Nefecon AB holds 1,610,000 warrants pending any distribution to future participants in the Board LTIP 2019 and 2020 programs and the ESOP 2020 program.

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 2021 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 2020, the board met 15 times. In addition to the board meetings, the chairman of the board and the CEO have a continuous dialogue about the company's management.

Guidelines for Executive Remuneration

The executive management for the Group falls within the provisions of these guidelines. Executive management refers to the CEO and other members of the executive management, as well as board members. The guidelines are forward-looking, i.e. they are applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the guidelines by the annual general meeting 2020. These guidelines do not apply to any remuneration decided or approved by the general meeting. 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. Upon potential accelerated approval, Calliditas intends to commercialize Nefecon for IgA nephropathy on a standalone basis in the United States market and through partnerships in other regions. Calliditas will also selectively explore line extensions for Nefecon, 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 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 twelve months upon notice by the company. Upon notice by the CEO, the notice period is six months. For other members of the executive management, notice periods of three to twelve 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 twelve months following termination of employment.

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 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 of pharmaceuticals, which is an area that is to a large extent both risky and capital-intensive. Calliditas has two product candidates in clinical development, Nefecon and setanaxib, for the treatment of IgA nephropathy and primary biliary cholangitis, 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 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.

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 conducted 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 future spread and mutation of the COVID-19 virus may impact Calliditas operations. The extent to which the coronavirus impacts Calliditas operations and the NefIgArd trial, or other trials, will depend on the type, degree and duration of the various restrictions put in place to contain the virus or treat those affected. The pandemic may negatively impact our trials as a result of disruptions, such as travel bans, quarantines, and inability of patients to access the trial sites and provide samples as well as interruptions in the supply chain, which could result in delays and impact on the data integrity of the trial. The continued spread of the coronavirus globally, may also negatively affect the operations of key governmental agencies, such as the FDA and EMA, which may delay the development and approvals of our product candidates, or could result in the inability of our suppliers to deliver components or raw materials on a timely basis, each of which in turn could have a negative impact on our business and results of operations.

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 2020, Calliditas has hedged currency risk with currency options in accordance with current financial policy and holds parts of the cash and cash equivalents in US dollars to reduce future currency exposure to 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, 2020 and December 31, 2019, the Parent Company had a net loss of SEK 407,4 million and SEK 36,2 million, respectively.

The Parent Company had cash of SEK 978,2 million and SEK 752,5 million as of December 31, 2020 and 2019, respectively.

Outlook

Callidita's drug candidate Nefecon has great market potential. Nefecon is currently in a Phase 3 clinical trial for IgA nephropathy which may be the basis for market approval. Positive top-line data were read out during the fourth quarter of 2020 from Part A of the registration-based Phase 3 study and after the end of the period in March 2021, an application was submitted for approval to the FDA in the USA. The business is capital intensive and until Nefecon will bring in steady income, external financing will be required. In 2020, a new share issue of a total of SEK 891.4 million was carried out before issue costs and the conditions are therefore good for Calliditas that Calliditas can carry out

a commercialization of Nefecon in the USA, subject to approval. The project thus requires a significant market value at present.

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	2,116,721
Retained earnings	(479,379)
Net loss for the year	**(407,363)**
	1,229,979

The Board of Directors proposes that SEK 1,229,979 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 commercial launch of Nefecon, 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 will be paid for the 2020 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, 2020	2019
Net sales	3	874	184,829
Research and development expenses	9,10	(241,371)	(149,826)
Administrative and selling expenses	6,8,9,10	(141,724)	(62,882)
Other operating income	4	2,501	4,385
Other operating expenses	5	-	(4,525)
Operating loss	7	**(379,720)**	**(28,019)**
Financial income	11	547	926
Financial expenses	12	(56,978)	(5,408)
Loss before income tax		**(436,151)**	**(32,501)**
Income tax expense	13	(360)	(77)
Loss for the year		**(436,511)**	**(32,578)**
Attributable to:			
Equity holders of the Parent Company		(433,494)	(32,578)
Non-controlling interests		(3,017)	-
		(436,511)	**(32,578)**
Loss per share			
Before and after dilution to ordinary equity holders of the Parent Company	14	(9.66)	(0.88)

GROUP

Consolidated Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31, 2020	2019
Loss for the year		**(436,511)**	**(32,578)**
Other comprehensive income			
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations	*21, 25*	(9,352)	(11)
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		**(9,352)**	**(11)**
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:			
Remeasurement gain on defined benefit plans	*27*	1,216	-
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods		**1,216**	**-**
Other comprehensive income/(loss) for the year		**(8,137)**	**(11)**
Total comprehensive loss for the year		**(444,648)**	**(32,589)**
Attributable to:			
Equity holders of the Parent Company		(438,343)	(32,589)
Non-controlling interests		(6,305)	-
		(444,648)	**(32,589)**

GROUP

Consolidated Statements of Financial Position

(SEK in thousands)	Note	December 31, 2020	2019
ASSETS			
Non-current assets			
Intangible assets	*15,16*	461,367	16,066
Equipment	*17*	163	104
Right-of-use assets	*8*	5,244	5,959
Non-current financial assets	*18,20, 30*	2,225	1,939
Deferred tax assets	*19*	600	-
Total non-current assets		**469,599**	**24,068**
Current assets			
Accounts receivables	*21*	-	46,586
Other current assets	*20*	22,801	2,719
Prepaid expenses	*22*	17,746	18,287
Cash	*23*	996,304	753,540
Total current assets		**1,036,851**	**821,132**
TOTAL ASSETS		**1,506,450**	**845,200**
EQUITY AND LIABILITIES			
Equity	*25*		
Share capital		1,998	1,548
Additional paid-in capital		2,133,179	1,274,664
Reserves		(6,090)	(45)
Retained earnings including net loss for the year		(918,596)	(488,096)
Equity attributable to equity holders of the Parent Company		**1,210,491**	**788,071**
Non-controlling interests		45,809	-
Total equity		**1,256,300**	**788,071**
Non-current liabilities			
Provisions	*15,26*	55,361	175
Pension liabilities	*27*	8,296	-
Deferred tax liabilities	*15,19*	79,996	-
Other non-current liabilities	*8,20*	878	3,584
Total non-current liabilities		**144,531**	**3,759**
Current liabilities			
Accounts payable	*20,21*	53,827	24,384
Current tax liabilities		518	77
Other current liabilities	*8,20*	9,888	3,394
Accrued expenses and deferred revenue	*28*	41,386	25,515
Total current liabilities		**105,619**	**53,370**
TOTAL EQUITY AND LIABILITIES		**1,506,450**	**845,200**

GROUP

Consolidated Statements of Changes in Equity

		Attributable to the Equity Holders of the Parent Company						
(SEK in thousands)	Note	Share Capital	Additional Paid-in Capital	Trans-lation Reserve	Retained Earnings incl. Net Loss for the Year	Total	Non-Con-trolling Interests	Total Equity
Opening equity January 1, 2019		**1,408**	**1,072,319**	**(34)**	**(455,518)**	**618,175**	**-**	**618,175**
Loss for the year		-	-	-	(32,578)	(32,578)	-	(32,578)
Other comprehensive income/(loss) for the year		-	-	(11)	-	(11)	-	(11)
Total comprehensive loss for the year		**-**	**-**	**(11)**	**(32,578)**	**(32,589)**	**-**	**(32,589)**
Transactions with owners:								
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
Total transactions with owners		**140**	**202,345**	**-**	**-**	**202,485**	**-**	**202,485**
Closing equity December 31, 2019		**1,548**	**1,274,664**	**(45)**	**(488,096)**	**788,071**	**-**	**788,071**
Opening equity January 1, 2020		**1,548**	**1,274,664**	**(45)**	**(488,096)**	**788,071**	**-**	**788,071**
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)
Total comprehensive loss for the year		**-**	**-**	**(6,045)**	**(432,298)**	**(438,343)**	**(6,305)**	**(444,648)**
Transactions with owners:								
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)
Total transactions with owners		**449**	**858,515**	**-**	**1,798**	**860,763**	**52,114**	**912,877**
Closing equity December 31, 2020	*10,15,25*	**1,998**	**2,133,179**	**(6,090)**	**(918,596)**	**1,210,491**	**45,809**	**1,256,300**

GROUP

Consolidated Statements of Cash Flows

		Year Ended December 31,	
(SEK in thousands)	Note	2020	2019
Operating activities			
Operating loss		(379,720)	(28,019)
Adjustments for non-cash items	23	15,465	2,308
Interest received		1,912	926
Interest paid		(393)	(325)
Income taxes paid		(528)	-
Cash flow from operating activities before changes in working capital		**(363,264)**	**(25,110)**
Cash flow from changes in working capital			
Changes in operating receivables		8,033	(53,546)
Changes in operating liabilities		46,050	7,645
Cash flow from operating activities		**(309,181)**	**(71,011)**
Investing activities			
Acquisition of a subsidiary, net of cash acquired	15	(172,602)	-
Purchase of equipment	17	-	(118)
Investments in non-current financial assets	18	(5)	(1,888)
Purchase of intangible assets	16	-	(16,066)
Cash flow from investing activities		**(172,607)**	**(18,072)**
Financing activities			
New share issue		891,388	210,317
Costs attributable to new share issue		(95,937)	(10,915)
Transaction costs, paid		-	(1,748)
Exercise of warrants		59,251	-
Premiums from warrants issuance		-	2,834
Purchase of non-controlling interests		(82,172)	-
Repayment of loans		(3,972)	(1,652)
Cash flow from financing activities		**768,558**	**198,835**
Net increase/(decrease) in cash		**286,770**	**109,752**
Cash at beginning of the year		**753,540**	**646,175**
Exchange-rate difference in cash		(44,006)	(2,387)
Cash at the end of the year	23	**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 activities in pharmaceuticals. These consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the year ended December 31, 2020 and December 31, 2019. 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, C8, 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, 2020, Calliditas is the Parent Company of three subsidiaries located in Sweden, France and in the United States. The Swedish subsidiary is Nefecon AB which is conducting no operating activities. The subsidiary in the United States is Calliditas Therapeutics Inc which is conducting pre-commercialization activities in the United States. In November 2020, Calliditas acquired a controlling interest in Genkyotex SA located in France. For the year ended December 31, 2020, Pharmalink Oncology AS ceased through voluntary liquidation, as no operations were conducted.

The Board of Directors (the "Board") approved, and authorized for issuance, these consolidated financial statements on April 27, 2021, which will be presented for adoption at the Annual General Meeting on May 27, 2021.

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, 2020. Control is achieved when the Parent Company has power over the investee, the Parent Company is exposed to or has rights to variable returns from its involvement in the investee, and the Parent Company has the ability to use its power over the investee to affect the amount of the investor's returns, which normally means that the Parent Company owns more than half of the number of votes for all of the shares and participations.

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

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

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

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

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

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

New and Amended Standards and Interpretations
Updated standards and interpretations from IASB and IFRIC interpretations that came into effect for the year ended December 31, 2020 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 recognizes revenue as the identified performance obligations are performed. The Group's revenue for the year ended December 31, 2020 consisted of revenues for the delivery of trial-related drugs within the framework of the out-licensing of Nefecon in connection with the agreement with Everest Medicines to Greater China and Singapore. Revenue for the provision of drugs for conducting clinical trials was recognized at a point in time, which occurred when control over the drug was transferred to Everest Medicines. Calliditas has completed all performance obligations within the agreement as of the delivery of study-related drugs to Everest Medicines for the year ended December 31, 2020. Variable remuneration (for example, attributable to future regulatory milestones) is not included in the transaction price while there is significant uncertainty as to whether these will occur. Revenue is recognized when these milestones occur. Compensation attributable to sales-based milestones or royalties are not recognized until the sale that results in the right to milestones or royalties arises.

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 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
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 other non-current 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 and the vaccine platform (SIIL agreement), 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. The vaccine platform (SIIL agreement) is an out-license agreement with Serum Institute of India (SIIL) for the use of a vaccine technology.

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. 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

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

Impairment of Non-Financial Assets
Goodwill and intangible assets not yet available for use, are not amortized but the Group assesses for impairment at each reporting date, 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, derivatives, other current receivables and cash, all of which, except derivatives, are classified at amortized cost. Derivatives are classified at fair value through profit or loss.

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 are 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.

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).

Intangible Assets
The Group's intangible assets are essentially attributable to the Group acquiring the rights to the NOX platform and the vaccine platform (SIIL agreement), 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, 2020, the Group's goodwill amounted to SEK 47,252 and other intangible assets amounted to SEK 414,115. The impairment testing showed no impairment.

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 was not deemed to meet the capitalization criteria for the year ended December 31, 2020 and was thus expensed. Capitalization of expenditures for the development of pharmaceuticals typically takes place late in Phase 3 (the final stage of clinical trials where the product is given to large groups of people to confirm effectiveness) and subsequent to market approval, or alternatively in conjunction with the initiation of pivotal studies, 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. Market approval have not yet been obtained for any products and, accordingly, the conditions for capitalizing development expenditures are not met.

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, 2020, 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 year ended December 31, 2020 consisted of revenues for the delivery of study-related drugs within the framework of the out-licensing of Nefecon in connection with the agreement with Everest Medicines to Greater China and Singapore. Revenue for the provision of drug for conducting clinical trials was recognized at a point in time, which occurred when control over the drug was transferred to Everest Medicines and has been measured by the acquisition price based on the cost of the goods, plus a fair market margin.

The Group has identified two performance obligations within the agreement:
1) Out-licensing of the product candidate Nefecon in existing condition at the signing of the agreement, and
2) Provision of drugs for conducting clinical trials.

The Group has completed all performance obligations within the agreement as of the delivery of study-related drugs to Everest Medicines for the year ended December 31, 2020.

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

	Year Ended December 31,	
	2020	2019
Type of goods or service		
Out-licensing	-	184,829
Provision of drugs	874	-
Total	**874**	**184,829**
Geographical markets		
China, Hong Kong, Macau, Taiwan and Singapore	874	184,829
Total	**874**	**184,829**

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

Note 4 Other Operating Income

	Year Ended December 31,	
	2020	2019
Exchange rate differences	2,501	4,385
Total	**2,501**	**4,385**

Note 5 Other Operating Expenses

	Year Ended December 31,	
	2020	2019
Exchange rate differences	–	4,464
Net loss on disposal of equipment	–	61
Total	**–**	**4,525**

Note 6 Auditors' Fee

	Year Ended December 31,	
	2020	2019
Ernst & Young AB		
Audit services	4,449	645
Other audit activities	3,774	3,343
Other services	-	98
Total	**8,223**	**4,086**
KPMG		
Audit services	102	–
Other audit activities	2,552	–
Total	**2,654**	**–**
Other auditors		
Audit services	102	–
Total	**102**	**–**
Total audit fee	**10,979**	**4,086**

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,	
	2020	2019
Other external expenses	311,329	176,729
Personnel costs	68,943	34,157
Depreciation on equipment's and right-of-use assets	2,823	1,822
Other operating expenses	-	4,525
Total	**383,095**	**217,233**

Note 8 Leases

Right-of-use assets

	December 31,	
	2020	2019
Opening balance	7,527	1,819
Additional agreements	98	7,527
Termination of agreement	–	(1,819)
Exchange differences	(8)	–
Additional agreements, through acquisition	1,978	–
Closing balance	**9,595**	**7,527**
Depreciation		
Opening balance	(1,568)	–
Depreciation	(2,786)	(1,778)
Termination of agreement	–	210
Exchange differences	3	–
Closing balance	**(4,351)**	**(1,568)**
Net book value	**5,244**	**5,959**

Depreciation on right-of-use assets are included in the consolidated statements of income under Research and development expenses amounted to SEK 165 and SEK 0 for the year ended December 31, 2020 and 2019, respectively, and Administrative and selling expenses amounted to SEK 2,621 and SEK 1,778 for the year ended December 31, 2020 and 2019, respectively.

Lease liabilities

	December 31,	
	2020	2019
Non-current lease liabilities	878	3,584
Current lease liabilities	3,908	2,486
Total	**4,786**	**6,070**

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,	
	2020	2019
<12 months	4,521	3,816
1-2 years	1,105	2,306
>2 years	–	533
	5,626	**6,655**

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 2021, 2022 and 2023 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,	
	2020	2019
Interest expenses attributable to lease liabilities	388	307
Expenses attributable to short-term lease	731	265
Expenses attributable to leasing agreements with low value	103	96
Expenses attributable to variable lease payments that are not included in lease liabilities	344	187
This year's lease payments in the Group	4,930	2,343

Note 9 Employees and Personnel Costs

Average Number of Employees

	Year Ended December 31,			
	2020		2019	
	Number of Employees	Percentage of Male Employees	Number of Employees	Percentage of Male Employees
Parent Company				
Sweden	16	44%	13	38%
	16	**44%**	**13**	**38%**
Subsidiaries				
Switzerland	2	50%	–	–
United States	5	100%	1	100%
	7	**86%**	**1**	**100%**
Total for the Group	**23**	**57%**	**14**	**43%**

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

Wages and Salaries

	Year Ended December 31,	
	2020	2019
Parent Company		
Board and executive management[1)]	19,211	13,109
Other employees	15,598	6,091
Subsidiaries		
Board and executive management	3,184	2,973
Other employees	11,615	–
Total	**49,608**	**22,173**

[1)] *Executive management includes CEO and other executive management.*

Social Security Costs and Pension Costs

	Year Ended December 31,	
	2020	2019
Parent Company		
Pension costs for the Board and executive management	1,748	1,644
Pension costs to other employees	1,666	1,180
Social security costs	12,330	3,008
Subsidiaries		
Pension costs for the Board and executive management	129	–
Pension costs to other employees	506	–
Social security costs	225	299
Total	**16,604**	**6,131**

Gender Distribution Among the Board and Executive Management

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

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

Disclosures Regarding Total Remuneration of the Board and Executive Management

	Year Ended December 31, 2020					
	Base Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-Based Payments	Total
Chairman of the Board						
Elmar Schnee	834	-	-	-	310	1,144
Board members						
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
Executive management						
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*
Total	**15,459**	**1,876**	**3,117**	**472**	**3,820**	**24,744**

	Year Ended December 31, 2019					
	Basic Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-based Payments	Total
Chairman of the Board						
Elmar Schnee	402	-	-	-	101	503
Board members						
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
Executive management						
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*
Total	**12,886**	**1,644**	**2,947**	**4,701**	**249**	**22,427**

Other Remuneration
Other remuneration comprises of fees for services rendered to the Parent Company. Management services purchased from Cordcom Consultants KB amounted to SEK 472 and SEK 853 for the year ended December 31, 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, 2020, 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, Head of North America, Commercial 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 2020 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. 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. A discount was offered in all programs since the warrants are not listed. 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**

The allocated weighted-average exercise price for warrants that are outstanding amounts to SEK 74 and SEK 58 as of December 31, 2020 and 2019, respectively. During 2020, 5,186 warrants were exerciseed 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.

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

	Warrants Outstanding as of		Inputs used for the Black & Scholes valuation					
Outstanding Warrants per Year	**December 31, 2019**	**December 31, 2020**	**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	74.30	3.29	46.50	(0.28%)	33%	2022-03-31
Warrant program 2019/2022	422,500	422,500	74.50	6,69*	54,39*	(0,55%)*	36%*	2022-12-31
Total	**2,575,586**	**1,279,086**						

** Average value*

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

		Warrants Outstanding as of			
Holder	**January 1, 2019**	**Change**	**December 31, 2019**	**Change**	**December 31, 2020**
CEO Renée Lucander	719,500	195,000	914,500	(369,500)	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
Other employees, consultants and external parties	930,750	(245,000)	685,750	(389,164)	296,586
Total	**2,518,086**	**57,500**	**2,575,586**	**(1,296,500)**	**1,279,086**

Option Program

ESOP 2020
In 2020, Calliditas implemented an option program 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 employess and consultants on the opening and closing balance are presented below:

		Options Outstanding as of			
Holder	**January 1, 2019**	**Change**	**December 31, 2019**	**Change**	**December 31, 2020**
Renée Aguiar-Lucander, CEO	-	-	-	225,000	225,000
Other executive management	-	-	-	415,000	415,000
Other employees and consultants	-	-	-	449,000	449,000
Total	**-**	**-**	**-**	**1,089,000**	**1,089,000**

Calculation of fair value of option program (ESOP 2020)
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%	974,000
ESOP 2020:2	September 17, 2020	September 17, 2023	22.50	116.78	41.6%	115,000
						1,089,000

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 1,500,000 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,	
	2020	2019
Share-based payments	5,304	-
Provisions attributable to social security costs (Share-based payments)	3,164	-
Total	**8,468**	**-**

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:

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

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,	
	2020	2019
Share-based payments	440	249
Provisions attributable to social security costs (Share-based payments)	1,426	175
Total	**1,866**	**424**

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

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:

	Share Awards Outstanding as of				
Holder	**January 1, 2019**	**Change**	**December 31, 2019**	**Change**	**December 31, 2020**
Elmar Schnee, Chairman of the Board	-	-	-	14,063	14,063
Hilde Furberg, Board member	-	-	-	4,327	4,327
Lennart Hansson, Board member	-	-	-	4,327	4,327
Diane Parks, Board member	-	-	-	4,327	4,327
Molly Hendersson, Board member	-	-	-	4,327	4,327
Total	**-**	**-**	**-**	**31,371**	**31,371**

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,	
	2020	**2019**
Share-based payments	267	-
Provisions attributable to social security costs (Share-based payments)	207	-
Total	**474**	**-**

Note 11 Financial Income

	Year Ended December 31,	
	2020	**2019**
Interest income	547	926
Total	**547**	**926**

Note 12 Financial Expenses

	Year Ended December 31,	
	2020	**2019**
Interest on lease liabilities	(388)	(307)
Other interest expenses	(5)	(18)
Exchange rate differences	(53,267)	(2,383)
Changes in FX options measured at fair value	(3,318)	(2,700)
Total	**(56,978)**	**(5,408)**

Note 13 Income Tax Expense

	Year Ended December 31,	
	2020	2019
Current income taxes	(1,035)	(77)
Deferred tax	675	–
Income tax expense recognized in the consolidated statements of income	**(360)**	**(77)**

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

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

The Group has SEK 2,704,803 and 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, 2020, and 2019, respectively, except for such circumstances where there are future temporary differences that such losses can be used to offset. The tax losses carried forward are allocated between Sweden of SEK 1,085,430, France of SEK 995,093 and Switzerland of SEK 624,280, where the tax losses carried forward in Sweden and France may be carried forward indefinitely, but in Switzerland there is a time limit of seven years. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized, or to the extent that there are temporary differences which these can be utilized to offset.

Note 14 Earnings per Share

	Year Ended December 31,	
	2020	2019
Loss per share before and after dilution		
Net loss for the year attributable to equity holders of the Parent Company	(433,494)	(32,578)
Weighted-average number of common shares outstanding	44,873,448	36,940,587
Loss per share before and after dilution	**(9.66)**	**(0.88)**

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 – 2020. 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 2,368,086 shares, since the Group is in a loss position for the year ended December 31, 2020 and December 31, 2019, respectively. Further, there is no dilution effect for issued share awards with entitlement to receive 82,770 shares, due to performance-based vesting.

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

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

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.

Calliditas acquired 7,236,515 ordinary shares of Genkyotex from Genkyotex's largest shareholders and management team (the "Block Sellers"), representing 62.7 percent of the share capital and voting rights for SEK 204,867 (EUR 19,747) in cash at EUR 2.73 per share. The acquisition date was November 3, 2020, when Calliditas acquired a controlling interest over Genkyotex. The acquisition resulted in recognition of goodwill for SEK 48,839 (EUR 4,708). Goodwill is mainly justified by access to new attractive clinical areas. No recorded goodwill is expected to be tax deductible.

After the acquisition of the controlling interest, a mandatory simplified cash tender offer was launched of EUR 2.80 and non-transferable contingent rights, per share to the remaining shareholders in Genkyotex. In the final outcome after the acceptance period, 2,885,161 shares have been tendered into the offer, for which an acquisition price of SEK 82,172 (EUR 8,078). As a result Calliditas controls a total of 10,121,676 shares in Genkyotex, which corresponds to 86.2 percent of the share capital and the total number of votes in Genkyotex as of December 31, 2020. Purchase of non-controlling interests after the business combination have been recognized under financing activities in the consolidated statements of cash flows.

In addition to this there are potential future milestone payments relating to contingent consideration amounting to a maximum of EUR 55 000, subject to future regulatory approvals of setanaxib. 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. See Note 26 Provisions.

Acquisition costs during the financial year amounted to SEK 8,118, which are recognized under administrative and selling expenses in the consolidated statements of income and under operating activities in the consolidated statements of cash flows. Acquisition costs are expensed in the consolidated statements of income when they occur.

There was no business combination for the year ended December 31, 2019.

Company	Operation	Acquisition Date	Acquired Ownership Share as of December 31, 2020	Sales during the Holding Period	Operating Loss during the Holding Period	Sales for the Year Ended December 31, 2020	Operating Loss for the Year Ended December 31, 2020
Genkyotex SA	Biopharmaceutical company specializing in NOX therapies	November 2020	86.2%	-	(20,698)	-	(143,447)

Purchase price	
Cash	204,867
Contingent consideration	50,614
Total	**255,481**

Fair value of the 7,236,515 ordinary shares purchased as part of the purchase price for Genkyotex S.A. (SEK 204,867) was based on the agreed share price of EUR 2.73 per share. Non-controlling interests are based on fair value utilizing the listed share price of the share in the acquired company at the acquisition date, which was EUR 3.02. For the year ended December 31, 2020, acquisition costs amount to SEK 8,118, of which SEK 7,020 is attributable to the acquisition of the controlling interest. All costs are directly attributable to the acquisition of Genkyotex SA.

	Fair Value
The assets and liabilities recognized in conjunction with the acquisition are as follows:	
Intangible assets: NOX Platform	382,521
Intangible assets: Other licenses	28,893
Non-current assets	2,438
Other current assets	10,022
Cash	32,265
Pension liabilities	(9,410)
Deferred tax liabilities	(82,683)
Other non-current liabilities	(643)
Other current liabilities	(20,677)
Acquired identified assets	**342,726**
Non-controlling interests	(136,084)
Goodwill	48,839
Acquired net assets	**255,481**

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

Analysis of Cash Flow	
Purchase price paid in cash (included in the Cash flow used in investing activities)	(204,867)
Cash equivalents in the acquired company (included in the Cash flow used in investing activities)	32,265
Acquisition costs attributable to the acquisition of subsidiaries (included in the Cash flow used in operating activities)	(7,020)

Note 16 Intangible Assets and Impairment Testing

	December 31, 2020	2019
Licenses and similar rights		
Cost at opening balance	16,066	–
Business combinations	411,414	–
Acquisition for the year	–	16,066
Exchange differences on translation	(13,365)	–
Cost at closing balance	**414,115**	**16,066**
Goodwill		
Cost at opening balance	-	-
Business combinations	48,839	-
Exchange differences on translation	(1,587)	-
Cost at closing balance	**47,252**	**-**
Net book value	**461,367**	**16,066**

Intangible assets consist of licenses and similar rights of SEK 414,115 and goodwill of SEK 47,252.

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 370,092 as of December 31, 2020. 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. The estimated fair value of the vaccine platform (SIIL agreement) and extensions was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence.

Goodwill amounts to SEK 47,252 as of December 31, 2020 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, 2020, the Group's goodwill amounted to SEK 47,252. There is no impairment for the year ended December 31, 2020.

The following table shows the discount rate used:

	Year Ended December 31,	
	2020	2019
Parameter, %		
Discount rate	10.50	-

Intangible assets, not yet available for use
These significantly consist of the NOX platform, the vaccine platform (SIIL-agreement) 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:

	Year Ended December 31,	
	2020	2019
Parameter, %		
Discount rate NOX platform	18.8	-
Discount rate Vaccine platform	17.0	-
Discount rate Budenofalk 3 mg oral capsule	12.4	11.6

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,	
	2020	2019
Cost at opening balance	118	813
Acquisition for the year	–	118
Disposal for the year	–	(813)
Exchange differences	(4)	–
Additional, through business combinations	100	–
Cost at closing balance	**214**	**118**
Depreciation at opening balance	(14)	(706)
Deprecation for the year	(37)	(44)
Disposal for the year	–	736
Depreciation at closing balance	**(51)**	**(14)**
Net book value	**163**	**104**

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

Note 18 Non-Current Financial Assets

	December 31,	
	2020	2019
Cost at opening balance	1,939	341
Bank guarantees granted	–	1,888
Reimbursement security deposit	–	(290)
Acquisition through business combinations	286	–
Net book value	**2,225**	**1,939**

Non-current financial assets comprise of bank guarantees/deposits amounted to SEK 2,224 and SEK 1,938 as of December 31, 2020 and 2019, respectively.

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

Note 19 Deferred Tax Assets and Deferred Tax Liabilities

Deferred tax assets and liabilities as of December 31, 2020

	Deferred Tax Assets	Deferred Tax Liabilities	Net
Intangible assets	–	(92,523)	(92,523)
Personnel-related items	596	–	596
Tax loss carried forward	12,527	–	12,527
Other items	4	–	4
Total	**13,127**	**(92,523)**	**(79,396)**
Offsetting	(12,527)	12,527	–
Tax assets/liabilities, net	**600**	**(79,996)**	**(79,396)**

Tax losses carried forward of SEK 12,527 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 losses 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	–	–	(92,523)	(92,523)
Personnel-related items	–	596	–	596
Tax loss carried forward	–	–	12,527	12,527
Other items	–	4	–	4
Total	**–**	**600**	**(79,996)**	**(79,396)**

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, 2020

	Financial Assets Measured at Fair Value through Profit or Loss	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Assets				
Non-current financial assets	–	2,225	–	2,225
Other current assets	–	112	22,689	22,801
Cash	–	996,304	–	996,304
	–	**998,641**	**22,689**	**1,021,330**

	Financial Liabilities Measured at Fair Value through Profit or Loss	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
Liabilities				
Provisions	48,969	–	6,392	55,361
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
	48,969	**83,503**	**28,868**	**161,340**

Financial and non-financial assets and liabilities as of December 31, 2019

	Financial Assets Measured at Fair Value through Profit or Loss	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Assets				
Non-current financial assets	–	1,939	-	1,939
Account receivables	–	46,586	-	46,586
Other current assets	399	-	2,320	2,719
Cash	–	753,540	-	753,540
	399	**802,065**	**2,320**	**804,784**

	Financial Liabilities Measured at Fair Value through Profit or Loss	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
Liabilities				
Other non-current liabilities	–	3,584	–	3,584
Accounts payable	–	24,384	–	24,384
Other current liabilities	–	2,486	908	3,394
Accrued expenses and deferred revenue	–	14,837	10,678	25,515
	-	**45,291**	**11,586**	**56,877**

Financial assets valued at fair value through profit or loss consist of currency options. As of December 31, 2020, 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 Genkytex SA of SEK 48,969 as of December 31, 2020. 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.

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

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

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

Credit Risk

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument, leading to a financial loss for the Group. The Group's exposure to credit risk 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, 2020	2019
Days past due account receivables	–	–
Not due account receivables	–	46,586
Total	**–**	**46,586**

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.

Foregin Currency Risk

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

Transaction Exposure

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

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

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

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 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 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 9,979 (pos. SEK 14,359).

Translation Exposure
The Group also has translation exposure that arises on the translation of earnings and net assets of foreign subsidiaries to the Swedish Kronor. Translation against U.S. dollar amounted to SEK 1,256 as of December 31, 2020. A 10% stronger Swedish Krona against the U.S. dollar would have a positive impact on equity of approximately SEK 126. Translation against Euros amounted to SEK 26,673 as of December 31, 2020. A 10% stronger Swedish Krona against Euros would have a positive impact on equity of approximately 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 15,811 (SEK 5,866) at the closing date in U.S. dollars and 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 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 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 financed by equity and thus is not exposed to risks related to external loan financing. Accordingly, the primary risks pertain to the risk of not securing additional contributions and investments from the owners.

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, 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	–

	December 31, 2019		
	<6 months	6-12 months	>12 months
Accounts payable	24,384	-	-
Other current liabilities	2,151	1,243	-
Accrued expenses	21,982	2,659	-

Note 22 Prepaid Expenses

	December 31,	
	2020	2019
Prepaid rental charges	–	771
Prepaid insurance premiums	10,743	–
Prepaid expenses for research and development	640	2,854
Prepaid transaction costs	–	14,662
Other prepaid expenses	6,363	–
Total	**17,746**	**18,287**

Note 23 Cash

	December 31,	
	2020	2019
Available balances	996,304	753,540
Total	**996,304**	**753,540**

Cash refer to cash at banks and are primarily in Swedish Kronor.

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

	Year Ended December 31,	
	2020	2019
Depreciation	2,823	1,822
Change in Provisions	6,634	175
Share-based payments	6,012	249
Other items	(4)	62
Total	**15,465**	**2,308**

Reconciliation of liabilities from financing activities

			Non-Cash-Items			
	January 1, 2020	Cash-Flow	Additional Agreement	Business Combinations	Exchange Differences	December 31, 2020
Lease liabilities	6,070	(3,972)	98	2,677	(87)	4,786
	6,070	**(3,972)**	**98**	**2,677**	**(87)**	**4,786**

			Non-Cash-Items			
	January 1, 2019	Cash-Flow	Additional Agreement	Termination of Agreement	Exchange Differences	December 31, 2019
Lease liabilities	1,819	(1,652)	7,527	(1,624)	-	6,070
	1,819	**(1,652)**	**7,527**	**(1,624)**	**-**	**6,070**

Note 24 Group Companies

Company	Principal Activities	Country of Incorporation	% Equity Interest 2020	% Equity Interest 2019
Parent Company				
Calliditas Therapeutics AB	Research and development of pharmaceuticals	Sweden	-	-
Subsidiaries				
Nefecon AB	Administration of incentive programs issued by the Parent Company	Sweden	100%	100%
Calliditas Therapeutics Inc	Pre-commercialization activities in the United States	United States	100%	100%
Genkyotex SA	Research and development of pharmaceuticals	France	86,2%	-
Genkyotex Suisse SA	Research and development of pharmaceuticals	Switzerland	-	-

The former subsidiary Pharmalink Oncology AS ceased through voluntary liquidation, as no operations were conducted for the year ended December 31, 2020. For further information on the business combination of Genkyotex SA, see Note 15 Business Combinations.

Note 25 Equity

Share capital and other contributed capital

	Number of Shares	Share Capital	Additional Paid-in Capital
As of January 1, 2019	**35,202,347**	**1,408**	**1,072,319**
Premiums from warrants issuance	-	-	2,834
Share-based payment	-	-	249
New share issue	3,505,291	140	199,262
As of December 31, 2019	**38,707,638**	**1,548**	**1,274,664**
New share issue*	9,937,446	397	793,304
Exercise of warrants	1,296,500	52	59,199
Share-based payment	–	–	6,012
As of December 31, 2020	**49,941,584**	**1,998**	**2,133,179**

** 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.*

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,	
	2020	2019
Opening balance	(45)	(34)
Change for the year ended	(6,045)	(11)
Closing balance	**(6,090)**	**(45)**

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

Note 26 Provisions

Provisions as of December 31, 2020

	Social Security Costs on Share-Based Payment	Contingent Consideration	Other Provisions	Provisions Net
Opening balance	175	–	–	175
Provisions for the year	4,797	50,614	1,443	56,855
Exchange differences	–	(1,645)	(24)	(1,669)
Total	**4,972**	**48,969**	**1,419**	**55,361**

Provisions as of December 31, 2019

	Social Security Costs on Share-Based Payment	Contingent Consideration	Other Provisions	Provisions Net
Opening balance	–	-	-	–
Provisions for the year	175	-	-	175
Total	**175**	**-**	**-**	**175**

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.

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 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. 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, 2020
Switzerland	(8,124)
France	(172)
Total	**(8,296)**

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
Subtotal included in the statement of consolidated operations	***(597)***	***(6)***	***61***	***(542)***
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)
Subtotal included in other items of comprehensive income	***1,174***	***45***	***(5)***	***1,214***
Employer contributions	–	–	47	47
Currency translation effect	205	–	(117)	88
December 31, 2020	**(19,193)**	**(172)**	**11,069**	**(8,296)**

Distribution by plan assets (Switzerland)

	December 31,
	2020
Cash	244
Bonds	6,365
Mortgage loans	1,516
Shares	365
Real estate	1,638
Other investments	941
Total	**11,069**

Of the plan assets above, 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.

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

Actuarial assumptions on the balance sheet date

	December 31, 2020
Swiss pension plan	
Discount rate	0.15%
Mortality table	LPP 2020 generation
Salary revaluation rate	1.00%
Retirement pension inflation rate	0.50%
Deposit rate on savings accounts	1.00%
Turnover rate	10.00%
Remaining life expectancy after retirement	23,3 years
Retirement age	65 years

Sensitivity analysis

	December 31, 2020
Pension commitments under current assumptions for Swiss pension plans	19,365
Discount rate , -0,5%	21,631
Discount rate , +0,5%	17,139
Retirement pension inflation rate, -0,5%	18,241
Retirement pension inflation rate, +0,5%	20,257
Salary revaluation rate, -0,5%	18,802
Salary revaluation rate, +0,5%	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 805. The weighted average maturity of the obligation is an estimated 23.3 years.

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

Note 28 Accrued Expenses and Deferred Revenue

	December 31, 2020	2019
Accrued salaries and Board fees	8,134	4,726
Vacation pay liabilities	4,921	1,904
Social security costs	3,440	2,975
Accrued expenses for research and development	14,135	1,176
Deffered revenue	–	874
Accrued expenses for administrative and selling	10,756	4,144
Other accrued expenses	–	9,716
Total	**41,386**	**25,515**

Note 29 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 30 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, if approved, 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 2,336 and SEK 1,938 as of December 31, 2020 and 2019, respectively, which consist of restricted bank accounts and lease deposits. The assets are pledged for the benefit of certain leaseholders and other suppliers. The Group has no other obligations.

Note 31 Events After the Reporting Period

In January 2021, Calliditas shared the clinical development plan for seta-naxib and addition-al data from Part A of NefIgArd study at the R&D Day.

In March 2021, Calliditsa submitted an application to the US Food and Drug Administration (FDA) for approval of Nefecon for the treatment of IgA nephropathy.

In April 2021, Nefecon was granted accelerated assessment procedure by the European Medicine Agency's (EMA) for the treatment of IgA nephropathy.

Note 32 Key Figure Definitions and Reconciliations of Alternative Performance Measures

Equity ratio at the end of the year in %	The ratio at the end of respective period is calculated by dividing total equity attributable to equity holders of the Parent Company by total assets.	The equity ratio measures the proportion of the total assets that are financed by shareholders.
Research and development expenses/Total operating expenses in %	Research and development expenses, divided by total operating expenses, which is the sum of research and development expenses, administrative and selling expenses, other operating income and expenses.	The key performance indicator helps the reader of the interim financial statements to analyse the portion of the Groups expenses that are attributable to the Group's research and development activities.

	Year Ended December 31,	
	2020	2019
Expenses relating to research and development/ operating expenses, %		
Research and development expenses	(241,371)	(149,826)
Administarative and selling expenses	(141,724)	(62,882)
Other operating income/expenses	2,501	(140)
Total operating expenses	**(380,594)**	**(212,848)**
Expenses relating to research and development/operating expenses, %	**63%**	**70%**

	December 31,	
	2020	2019
Equity ratio at the end of the year %		
Equity attributable to equity holders of the Parent Company at the end of the year	1,210,491	788,071
Total assets at the end of the year	1,506,450	845,200
Equity ratio at the end of the year %	**80%**	**93%**

PARENT COMPANY

Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31, 2020	2019
Net sales	2	874	184,829
Research and development expenses	7	(227,027)	(149,826)
Administrative and selling expenses	5,6,7	(128,896)	(63,410)
Other operating income	3	2,482	4,385
Other operating expenses	4	-	(4,540)
Operating loss		**(352,567)**	**(28,562)**
Profit/(loss) from financial income/(expenses)			
Profit/loss from participations in Group companies	8	4	(3,439)
Other interest received and similar items	9	559	926
Interest expense and similar items	10	(55,359)	(5,111)
Loss before income tax		**(407,363)**	**(36,186)**
Income tax expense	11	-	-
Loss for the year		**(407,363)**	**(36,186)**

Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31, 2020	2019
Loss for the year		**(407,363)**	**(36,186)**
Other comprehensive income/(loss) for the year		-	-
Total comprehensive loss for the year		**(407,363)**	**(36,186)**

PARENT COMPANY

Balance Sheet

(SEK in thousands)	Note	December 31, 2020	2019
ASSETS			
Non-current assets			
Intangible Assets			
Licenses and similar rights	12	16,066	16,066
		16,066	**16,066**
Tangible Assets			
Equipment	13	80	104
		80	**104**
Non-Current Financial Assets			
Participations in Group companies	14	295,259	101
Receivables from Group companies	15	1,485	-
Other non-current financial assets	16	1,939	1,939
		298,683	**2,040**
Total non-current assets		**314,829**	**18,210**
Current assets			
Accounts receivables		-	46,586
Other current assets		10,998	2,718
Prepaid expenses	17	14,490	18,287
		25,488	**67,591**
Cash	18	978,208	752,448
Total current assets		**1,003,696**	**820,039**
TOTAL ASSETS		**1,318,525**	**838,249**

PARENT COMPANY

Balance Sheet

(SEK in thousands)	Note	December 31, 2020	2019
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	19		
Restricted shareholders' equity			
Share capital		1,998	1,548
Statutory reserve		3,092	3,092
		5,090	**4,640**
Non-restricted shareholders' equity			
Share premium reserve		2,116,721	1,268,334
Retained earnings		(479,379)	(448,989)
Net loss for the year		(407,363)	(36,186)
		1,229,979	**783,159**
Total shareholders' equity		**1,235,069**	**787,799**
Non-current liabilities			
Provisions	20	4,972	175
Liabilities to Group companies	23	105	50
Total non-current liabilities		**5,077**	**225**
Current liabilities			
Accounts payable		42,469	24,362
Liabilities to Group companies	23	4,003	425
Other current liabilities		1,120	907
Accrued expenses and deferred revenue	21	30,787	24,531
Total current liabilities		**78,379**	**50,225**
TOTAL SHAREHOLDERS EQUITY AND LIABILITIES		**1,318,525**	**838,249**

PARENT COMPANY

Statements of Changes in Shareholders' Equity

	Restricted Shareholders' Equity		Non-Restricted Shareholders' Equity			
(SEK in thousands)	Share Capital	Statutory Reserve	Share Premium Reserve	Retained Earnings	Net Loss For the Year	Total
Opening equity January 1, 2019	**1,408**	**3,092**	**1,069,072**	**(320,299)**	**(131,923)**	**621,350**
Transfer of previous year's loss	-	-	-	(131,923)	131,923	-
Loss for the year	-	-	-	-	(36,186)	(36,186)
Other comprehensive income/(loss) for the year	-	-	-	-	-	-
Total comprehensive loss for the year	**-**	**-**	**-**	**-**	**(36,186)**	**(36,186)**
Profit on merger of subsidiaries	-	-	-	150	-	150
Transactions with owners:						
New share issue	140	-	210,177	-	-	210,317
Costs attributable to new share issue	-	-	(10,915)	-	-	(10,915)
Premiums from warrants issuance	-	-	-	2,834	-	2,834
Share-based payments	-	-	-	249	-	249
Total transactions with owners	**140**	**-**	**199,262**	**3,083**	**-**	**202,485**
Closing equity December 31, 2019	**1,548**	**3,092**	**1,268,334**	**(448,989)**	**(36,186)**	**787,799**
Opening equity January 1, 2020	**1,548**	**3,092**	**1,268,334**	**(448,989)**	**(36,186)**	**787,799**
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	-	-	-	-	-	-
Total comprehensive loss for the year	**-**	**-**	**-**	**-**	**(407,363)**	**(407,363)**
Transactions with owners:						
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
Total transactions with owners	**449**	**-**	**848,387**	**5,797**	**-**	**854,633**
Closing equity December 31, 2020	**1,998**	**3,092**	**2,116,721**	**(479,379)**	**(407,363)**	**1,235,069**

PARENT COMPANY

Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31, 2020	2019
Operating activities			
Operating loss		(352,567)	(28,562)
Adjustments for non-cash items	18	10,832	546
Interest received		1,912	926
Interest paid		(3)	(18)
Cash flow from operating activities before changes in working capital		**(339,826)**	**(27,108)**
Cash flow from changes in working capital			
Changes in operating receivables		13,884	(53,546)
Changes in operating liabilities		40,024	7,105
Cash flow from operating activities		**(285,918)**	**(73,549)**
Investing activities			
Funds acquired from merger with Group companies		-	72
Acqusition of participations in Group companies	14	(294,059)	-
Purchase of equipment	13	-	(118)
Investments in non-current financial assets	16	(1,683)	(1,888)
Disposal of non-current financial assets		4	-
Purchase of intangible assets	12	-	(16,066)
Cash flow from investing activities		**(295,738)**	**(18,000)**
Financing activities			
New share issue		891,388	210,317
Costs attributable to new share issue		(95,938)	(10,915)
Transaction costs, paid		-	(1,748)
Exercise of warrants		54,920	-
Premiums from warrants issuance		-	2,834
Cash flow from financing activities		**850,370**	**200,488**
Net increase/(decrease) in cash		**268,714**	**108,939**
Cash at beginning of the year		**752,448**	**645,903**
Exchange-rate difference in cash		(42,954)	(2,394)
Cash at the end of the year	18	**978,208**	**752,448**

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,	
	2020	2019
Type of goods or service		
Out-licensing	–	184,829
Provision of drugs	874	–
Total	**874**	**184,829**
Geographical markets		
China, Hong Kong, Macau, Taiwan and Singapore	874	184,829
Total	**874**	**184,829**

Note 3 Other Operating Income

	Year Ended December 31,	
	2020	2019
Exchange rate differences	2,482	4,385
Total	**2,482**	**4,385**

Note 4 Other Operating Expense

	Year Ended December 31,	
	2020	2019
Exchange rate differences	–	4,464
Net loss on disposal of equipment	–	76
Total	**–**	**4,540**

Note 5 Auditors' Fee

	Year Ended December 31,	
	2020	2019
Ernst & Young AB		
Audit services	4,449	645
Other audit activities	3,774	3,343
Other services	–	98
Total	**8,223**	**4,086**

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 3,326 and SEK 2,508 for the year ended December 31, 2020 and 2019, respectively. Future payment commitments for operating leases are specified as follows:

	Year Ended December 31,	
	2020	2019
Future minimum lease payments		
Within 1 year	2,835	3,284
Between 1 and 5 years	1,087	3,808
More than 5 years	-	-
Total	**3,922**	**7,092**

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.

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

Note 8 Profit/Loss from Participations in Group Companies

	Year Ended December 31,	
	2020	2019
Profit on liquidation of subsidiaries	4	–
Impairment of participations in Group companies	–	(3,739)
Reversal of impairment of receivables within the Group companies	–	300
Total	**4**	**(3,439)**

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

For the year ended December 31, 2019, a write-down of participation in Group Companies in the subsidiary Nefecon AB of SEK 3,739 occured, due to the expiration of patents relating to methods and means for the treatment of glomerulonephritis.

Note 9 Other Interest Received and Similar Items

	Year Ended December 31,	
	2020	2019
Interest income	559	926
Total	**559**	**926**

Note 10 Interest Expense and Similar Items

	Year Ended December 31,	
	2020	2019
Interest expense	(4)	(18)
Exchange rate differences	(52,037)	(2,393)
Changes in FX options measured at fair value	(3,318)	(2,700)
Total	**(55,359)**	**(5,111)**

Note 11 Income Tax Expense

	Year Ended December 31,	
	2020	2019
Current tax taxes	-	-
Income tax expense recognized in the statements of income	**-**	**-**
Reconciliation of effective tax rate		
Accounting loss before tax	(407,363)	(36,186)
Tax in accordance with applicable tax rate for the Parent Company 21,4% (21,4%)	87,176	7,744
Tax effect of:		
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(87,084)	(6,290)
Non-deductible expenses	(93)	(1,518)
Non-taxable income	1	64
Income tax expense recognized in the statements of income	**-**	**-**
At the effective income tax rate	**0%**	**0%**

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

The Parent Company has SEK 1,081,734 and SEK 574,422 of tax losses carried forward for which deferred tax assets have not been recognized in the statements of financial position as of December 31, 2020 and 2019, 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,	
	2020	2019
Licenses and similar rights		
Cost at opening balance	16,066	–
Acquisition for the year	–	16,066
Cost at closing balance	**16,066**	**16,066**
Net book value	**16,066**	**16,066**

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,	
	2020	2019
Cost at opening balance	118	813
Acquisition for the year	–	118
Disposal for the year	–	(813)
Cost at closing balance	**118**	**118**
Depreciation at opening balance	(14)	(706)
Deprecation for the year	(24)	(44)
Disposal for the year	–	736
Depreciation at closing balance	**(38)**	**(14)**
Net book value	**80**	**104**

Note 14 Participations in Group Companies

	December 31,	
	2020	2019
Cost at opening balance	5,371	5,924
Acquisition for the year	295,158	1
Shareholders' contributions	–	350
Liquidation	(1,531)	–
Reclassification by merger	–	(904)
Cost at closing balance	**298,998**	**5,371**
Impairment at opening balance	(5,270)	(2,435)
Reversal of write-downs	1,531	–
Impairment for the year	–	(3,739)
Reclassification by merger	–	904
Impairment at closing balance	**(3,739)**	**(5,270)**
Net book value	**295,259**	**101**

Acquisition for the year
See Note 15 Business Combinations in the Group for further information on this year's acquisition, which refers to the business combination of Genkyotex SA.

	December 31,	
Company / Corporate Registration Number / Registered office	**2020**	**2019**
Nefecon AB, 556604-9069, Stockholm		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	1,000	1,000
Net book value	**100**	**100**
Calliditas Therapeutics Inc., 83-4094951, USA		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	1,000	1,000
Net book value	**1**	**1**
Genkyotex SA, 439 489 022, France		
Share of equity	86%	–
Share of voting power	86%	–
Number of participation rights	10,121,676	–
Net book value	**295,158**	**–**

For the year ended December 31, 2020, Pharmalink Oncology AS ceased through voluntary liquidation. Calliditas has also aquired a controlling interest in Genkyotex SA. For further information on the business combination, see Note 15 Business Combinations in the Group.

Note 15 Receivables from Group Companies

	December 31,	
	2020	2019
Opening balance	–	–
Additional receivables	1,694	–
Exchange differences	(209)	–
Net book value	**1,485**	**–**

Note 16 Other Non-Current Financial Assets

	December 31,	
	2020	2019
Opening balance	1,939	341
Bank guarantees granted	–	1,888
Reimbursement security deposit	–	(290)
Net book value	**1,939**	**1,939**

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

Note 17 Prepaid Expenses

	December 31,	
	2020	2019
Prepaid rental charges	792	771
Prepaid insurance premiums	10,186	–
Prepaid expenses for research and development	224	2,854
Prepaid transaction costs	–	14,662
Other prepaid expenses	3,288	–
Total	**14,490**	**18,287**

Note 18 Cash

	December 31,	
	2020	2019
Available balances	978,208	752,448
Total	**978,208**	**752,448**

Adjustments for non-cash items

	Year Ended December 31,	
	2020	2019
Depreciation	24	44
Chage in Provisions	4,797	175
Share-based payments	6,011	249
Other	–	78
Total	**10,832**	**546**

Reconciliation of liabilities from financing activities
No liabilities from financing activities for the year ended December 31, 2020 and 2019, respectively.

Note 19 Shareholders' Equity

As of December 31, 2020
Share capital consists of 49,941,584 and 38,707,638 shares with a quotient value of SEK 0.04 as of December 31, 2020 and 2019, 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,	
	2020	2019
Share premium reserve	2,116,721	1,268,334
Retained earnings	(479,379)	(448,989)
Net loss for the year	(407,363)	(36,186)
	1,229,979	**783,159**
To be distributed as follows:		
To be carried forward	**1,229,979**	**783,159**

Note 20 Provisions

	December 31,	
	2020	2019
Opening balance	175	–
Provisions for the year	4,797	175
Total	**4,972**	**175**

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

Note 21 Accrued Expenses and Deferred Revenue

	December 31,	
	2020	2019
Accrued salaries and Board fees	5,925	4,143
Vacation pay liability	2,603	1,502
Social security costs	3,441	2,975
Accrued expenses for research and development	13,072	1,177
Deffered revenue	–	874
Accrued expenses for administrative and selling expenses	5,746	4,144
Other accrued expenses	–	9,716
Total	**30,787**	**24,531**

Note 22 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 1,938 and SEK 1,938 as of December 31, 2020 and 2019, respectively.

Note 23 Related-Party Transactions

	Sales of Goods/ Services	Purchase of Goods/ Services	Other	Receivables on Closing Balance	Liabilities on Closing Balance
Subsidiaries					
Year Ended December 31, 2020	–	19,648	–	1,485	4,108
Year Ended December 31, 2019	–	4,086	–	–	475

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

The undersigned declare that the annual report has been prepared in accordance with generally accepted accounting principles in Sweden and these consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS), as adopted by the European Union (EU). The annual report and consolidated financial statements respectively provide fair and accurate impression of the financial position and earnings of the Group and the Parent Company.
The Report of the Board of Directors' for the Parent Company and Group gives a true and fair view of the performance of the Parent Company's and the Group's operations, position and results and describes the significant risks and uncertainties facing the Parent Company and the companies included in the Group.

Stockholm, April 27, 2021

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, 2021

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 2020. The annual accounts and consolidated accounts of the company are included on pages 32-77 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 2020 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 2020 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 income statement and balance sheet for the parent company, and the income statement 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 matter below, provide the basis for our audit opinion on the accompanying financial statements.

Business combinations

Description

As described in Note 15 of the consolidated financial statements, during the financial year the Group has acquired a controlling interest in Genkyotex SA.

The acquisition cost of the assets and liabilities included in the business combination is determined through a purchase price allocation in connection with the business combination, as described in Note 1 of the consolidated financial statements. Acquired identifiable assets and assumed liabilities are initially recognized at fair value at the time of acquisition, and the difference between the purchase price and the fair values of identifiable assets and assumed liabilities is recognized as goodwill.

As described in Note 2 and note 15, the accounting for business combinations requires management to make assessments and assumptions in order to estimate the fair value of acquired assets and assumed liabilities. Incorrect assumptions and calculations related to business combinations could have a material impact

on the valuation of acquired assets and liabilities. For this reason, we have determined that this is a key audit matter.

How our audit addressed this key audit matter
In our audit for the financial year, we have reviewed the acquisition agreement and evaluated management's process for the preparation of the purchase price allocation.

We have also evaluated management's assessments and valuation of identified assets and assumed liabilities, and performed reconciliations of purchase price allocations to the underlying accounting records. We have also, with the support of our valuation specialists, evaluated applied valuation methods and management's assumptions in relation to these.

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

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-31 and 82-95. The report on management remuneration for the financial year 2020 which will be issued after the date of this auditor's report is also considered other information. 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 the other information which we received up until the date of this auditor's report, 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.

If we, in connection with reading the management remuneration report, conclude that there is a material misstatement we are required to report this to the board of directors and request correction.

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.

AUDITOR'S REPORT

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, related safeguards.

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

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 2020 and the proposed appropriations of the company's profit or loss.

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

Basis for opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.
We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general. The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

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

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

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

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

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined the Board of Directors' reasoned statement and a selection of supporting evidence in order to be able to assess whether the proposal is in accordance with the Companies Act.
Ernst & Young AB, Hamngatan 26, 111 47, Stockholm, was appointed auditor of Calliditas Therapeutics AB by the general meeting of the shareholders on June 25, 2020 and has been the company's auditor since April 15, 2004.

Stockholm, April 27, 2021
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 Market in the U.S. and is traded under the ticker CALTX and CALT, respectively. This report pertains to the financial year of 2020 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, i.e. 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

Shareholders

Calliditas' shares were admitted to trading on Nasdaq Stockholm, Mid Cap, in June 2018 and on Nasdag Global Select Market in the U.S., in June 5, 2020. At the end of 2020, the total number of shares and voting rights amounted to 49,941,584, distributed between 6,513 shareholders. The ten largest shareholders held 58.4% of shares outstanding and other shareholders 41.6%. As of December 31, 2020, two 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% and Stiftelsen Industrifonden, 11.6%.

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 the company should prioritize progression of the development program, and until the future commercial launch of Nefecon, financial resources should mainly be used to finance the company's development programs. In view of Calliditas' 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 2021

Calliditas' 2021 AGM will be held on Thursday, May 27, 2021. In order to mitigate the spread of Covid-19, 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.

Participation at the Annual General Meeting

The shareholders may only exercise their voting rights at the annual general meeting by voting in advance, so-called postal voting in accordance with Section 22 of the Act (2020:198) on temporary exceptions to facilitate the execution of general meetings in companies and other associations. A special form shall be used for advance voting. The form will be available on Calliditas Therapeutics' website, www.calliditas.se. The advance voting form is considered as the notification of participation.

The completed voting form must be received by Euroclear Sweden AB no later than Wednesday 26 May 2021.

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

Nomination Committee

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

At the Extraordinary General Meeting held on September 14, 2017, it was resolved that the Nomination Committee shall be composed of the Chairman of the Board of Directors together with one representative of each of the three largest shareholders, based on ownership in Calliditas as of the end of the third quarter of the fiscal year. The Nomination Committee in 2021 consists of:

- Patrik Sobocki, appointed by Stiftelsen Industrifonden (Chairman)
- Sike Loy, appointed by BVF Partners LP
- Karl Tobieson, appointed by Linc AB
- Elmar Schnee, Chairman of the Board.

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

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

The Nomination Committee will be constituted and will meet in advance of the 2021 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, prior to the AGM.

Auditor

In accordance with the Articles of Association, Calliditas must appoint a registered firm of accountants as external auditor. The 2020 AGM elected the registered firm of accountants Ernst & Young AB as auditor, up to the 2021 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 report in 2020, which satisfies the requirements of the Code. For information about remuneration of the auditor, refer to Note 6 Auditors' Fee.

Board of Directors

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

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

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

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

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

Currently, the company's Board of Directors consists of 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 below presents the independence of members at the date on which this report was published.

Board members' independence, attendance and remuneration in 2019

			Independent in relation to		Attendance			
Name	Position	Board member since	The company and management	Major shareholders	Board meetings	Audit Committee meetings	Remuneration Committee meetings	Total remuneration, SEK in thousand
Elmar Schnee	Board Chairman	2019	Yes	Yes	15/15	-	4/4	1,144
Bengt Julander (until June 2020)	Board Member	2004	Yes	No	9/9	-	-	58
Lennart Hansson	Board Member	2009	Yes	Yes	15/15	2/2	2/2	387
Hilde Furberg	Board Member	2014	Yes	Yes	15/15	4/4	-	379
Thomas Eklund (until June 2020)	Board Member	2017	Yes	Yes	9/9	2/2	-	115
Diane Parks	Board Member	2019	Yes	Yes	15/15	-	4/4	485
Molly Henderson (from June 2020)	Board Member	2020	Yes	Yes	6/6	2/2	-	382

Work of the Board in 2020

During 2020, the Board of Directors held a total of 15 meetings, of which six were ordinary and nine 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 AGM are decided by the AGM. The AGM of June 25, 2020, decided that the fees payable to the Board for the period up to the end of the next AGM shall be as follows.

The directors' fees shall be paid with SEK 850,000 to the chairman of the board of directors and SEK 250,000 to each one of the other members who are not employed in the Group, SEK 150,000 to the chairman of the audit committee and SEK 75,000 to the other members of the audit committee who are not employed in the Group as well as SEK 50,000 to the chairman of the remuneration committee and SEK 25,000 to the other members of the remuneration committee who are not employed in the Group. In addition to the above proposed remuneration for ordinary board work, it is proposed that board members residing in the United States shall receive an additional amount of SEK 140,000 and that board members residing in Europe, but outside the Nordics, shall receive an additional amount of SEK 50,000.

For more information regarding remuneration of Board members, refer to Note 9 Employees and Personnel Costs, and the table on page 51.

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 four meetings in 2020. The company's auditors took part in three 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 four meetings in 2020. At these meetings, the Committee discussed the current compensation system in the company, including a proposal for remuneration of the CEO and executive management and the direction and terms of the incentive program that was approved for implementation by the Annual General Meeting on June 25, 2020.

Remuneration of the CEO and Executive Management 2020

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% of the fixed salary. Notwithstanding the above, the Board of Directors is entitled to offer other solutions which, in terms of cost, are equivalent to the above.

Evaluation of the Board and CEO

Every year, the Board Chairman initiates an evaluation of the Board's work. The evaluation aims to gain an opinion of the views of Board members on how the work of the Board is progressing and what measures can be implemented to enhance the efficiency of the Board. The aim is also to gain an opinion of the type of issues the Board believes should be offered more space and areas where further expertise may be needed on the Board. The Board of Directors continuously assesses the work of the CEO by monitoring the performance of the operations compared with established targets and makes a formal assessment each year.

CEO and Management Team

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

Calliditas' management consists of six individuals and includes, in addition to the CEO, the Chief Financial Officer, Chief Medical Officer, Vice President Operations, Vice President Regulatory Affairs, and Head of North America, Commercial. For information about current executive management at Calliditas, when these assumed their positions, and date of birth, education, experience, shareholding in the company and current and previous assignments, refer to page 90 and the company's website, www.calliditas.se.

Internal Control and Risk Management

The Board of Director's responsibility for the internal control is governed by the Swedish Companies Act, the Swedish Annual Reports Act – which requires that information about the main features of Calliditas' system for internal control and risk management related to financial reporting each year must be included in the corporate governance report – and the Code. The Board of Directors shall, among other tasks, ensure that Calliditas has sufficient internal control and formalized routines to ensure that established principles for financial reporting and internal control are adhered to and that there are effective systems to monitor and control the company's operations and the risks associated with the company and its operations. The overall purpose of the internal control is to ensure that the company's operating strategies and targets are monitored and that the owners' investments are protected, to a reasonable degree. Furthermore, the internal control shall ensure that the external financial reporting, with reasonable certainty, is reliable and prepared in accordance with generally accepted accounting practice, that applicable laws and regulations are followed, and that the requirements imposed on listed companies are complied with. The internal control primarily consists of the following five components.

Control environment

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

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

Risk assessment

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

Control activities

Control activities limit the identified risks and ensure accurate and reliable financial reporting. The Board of Directors is responsible for the internal control and monitoring of the company's management. This is done through both internal and external control activities, and through examination and monitoring of the company's guidelines related to risk management. The effectiveness of the control activities are assessed annually and the results from these assessments are reported to the Board of Directors and the Audit Committee. In agreements with essential subcontractors, the company has secured the right to audit each respective subcontractors' fulfillment of relevant services, including quality aspects.

Monitoring

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

Information and communication

The company has information and communication channels to promote the accuracy of the financial reporting and to facilitate reporting and feedback from operations to the Board of Directors and senior management, for example by making corporate governance documents such as internal policies, guidelines and instructions regarding the financial reporting available and known to the employees concerned. The Board of Directors has also adopted an information policy governing the company's disclosure of information.

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 2020 on pages 82-87 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, 2021
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 Lts, Noorik Biopharmaceuticals AG and Advanz Pharma as well a member of the board of directors of Jazz Pharmaceuticals, Kuste Biopharma and Damian Pharma AG.

Holdings in the Company: Elmar Schnee holds 23,236 share awards in board LTIP 2019 and 14,063 share awards in LTIP 2020. 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. Her experience is in various fields of rare diseases, which she gained working in small companies and large global corporations. Hilde has worked for companies such as Genzyme and Baxter, she was most recently SVP and General Manger/European Head of Rare Diseases at Sanofi Genzyme. In addition to working for Genzyme/Sanofi Genzyme, Hilde has since 2005 worked as non-executive director and Board member of Probi, Pronova, Clavis, Bergenbio and Algeta.

Other current assignments: She is currently an industrial advisor to Investinor and Board member of Tappin, 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 and 4,327 share awards in board LTIP 2020. 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 Committe.

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 and 4,327 share awards in board LTIP 2020. 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 and 4,327 share awards in board LTIP 2020. 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 and member of the Audit Committee.

Experience: Molly Henderson has served as the CFO of several listed life science companies for over 17 years. Currently, she is the CFO of UroGen Pharma, Inc. She was previously the CFO 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 UroGen Pharma, Inc.

Holdings in the Company: Molly Henderson holds 100 shares in the company and 4,327 share awards in board LTIP 2020. 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 412,000 shares in the Company, 545,000 warrants[1] and 296,000 options[2].

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 21,250 shares in the Company, 140,000 warrants[1] and 130,000 options[2].

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 12,500 warrants[1] and 45,000 options[2].

[1] Holding in Warrant program 2018/2022 and/or Warrant program 2019/2022. [2] Holding in ESOP 2020.

Andrew Udell

Head of North America Commercial

Born 1970.
Head of North America Commercial since 2019.

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

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

Holding in the Company: Andrew Udell holds 220,000 warrants[1] and 100,000 options[2].

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 65,000 warrants[1] and 45,000 options[2].

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 125,000 options[2].

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

Hérnan 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, 2021	May 18, 2021
Annual General Meeting 2021	May 27, 2021
Interim report for the period January 1–June 30, 2020	August 19, 2021
Interim report for the period January 1–September 30, 2020	November 18, 2021
Year-end report for the period January 1–December 31, 2020	February 24, 2022

Glossary

Adjunct Therapy: Also known as adjuvant care/therapy, adjunct therapy is therapy that is given in addition to the primary or initial therapy to maximize its effectiveness

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

AIH: Autoimmune hepatitis, a rare autoimmune inflammatory disease of the liver

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

Alport Syndrome: Alport syndrome is a genetic condition characterized by kidney disease, hearing loss, and eye abnormalities. People with Alport syndrome experience progressive loss of kidney function

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

CKD: Chronic kidney disease

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

FSGS: Focal segmental glomerulosclerosis (FSGS) is a disease in which scar tissue develops on the parts of the kidneys that filter waste from the blood (glomeruli.) FSGS can be caused by a variety of conditions

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'

Hematuria: blood in the urine, a sign of leakage in the kidneys

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

Medicare: A publicly funded health insurance system in the US for persons over the age of 65 or living with certain disabilities. It is different from Medicaid, which is a federal health insurance program in the US that supports people with limited income and their families

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' 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 Principle Trial: Proof of 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_2

Redox Homeostasis: Redox homeostasis is attained by the regulation of the formation and removal of reactive oxygen species (ROS) from the body system

Renal biopsy: a tissue sample from the kidney taken to ensure diagnosis

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

USRDS: US Renal Data System, a public database for kidney disease in the US

calliditas
THERAPEUTICS

Calliditas Therapeutics AB
Kungsbron 1, C8, SE-111 22 Stockholm, Sweden
Phone: +46 (0)8 411 3005
Mail: info@calliditas.com
Web: www.calliditas.com