
calliditas
THERAPEUTICS
ANNUAL REPORT
2019

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 26-69).

Calliditas Therapeutics is a clinical-stage biopharmaceutical company based in Stockholm, Sweden. It is 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, in which the company can partially or completely participate in the commercialization efforts. The company is focused on the development and commercialization of the product candidate Nefecon, a novel oral formulation optimized to combine a time lag effect with a concentrated release of the active substance budesonide, within a designated target area. This patented, locally acting formulation is intended for treatment of patients with the inflammatory renal disease IgA nephropathy (IgAN). Calliditas Therapeutics is running a global Phase 3 study within IgAN and aims to commercialize Nefecon, if approved, independently in the US and through partnerships in EU and Asia.

The company is listed on Nasdaq Stockholm (ticker: CALTX).
Visit www.calliditas.com for further information.

FOTO: SHUTTERSTOCK

2019 in brief

Business highlights

- In February, Calliditas was granted orphan drug designation (ODD) for the treatment of Autoimmune hepatitis (AIH) and Primary biliary cholangitis (PBC) by the US Food and Drug Administration (FDA).
- The Annual General Meeting of Calliditas was held in May, and the AGM resolved, among other things, on the election of Elmar Schnee (Chairman) and Diane Parks to the Board.
- In June, Calliditas and Everest Medicines entered into a license agreement, in which Everest Medicines will develop and commercialize Calliditas' leading drug candidate Nefecon for IgA Nephropathy (IgAN) in Greater China and Singapore. The total value of the agreement, including potential future milestone payments amount to USD 121 million (approximately SEK 1.1 billion) plus royalty income, of which USD 15 million (SEK 138.2 million) was recognized as revenue during the second quarter of 2019.
- In July, Calliditas completed a directed new share issue of 3.5 million shares, thereby raising SEK 210.3 million with the aim of expanding ongoing research programs and accelerating activities to further develop the project portfolio. As part of the capital raise BVF Partners became holders of Calliditas shares.
- In August, Calliditas entered into an exclusive in-licensing agreement of Budenofalk 3mg oral capsule for the US market with Dr Falk Pharma. This positions Calliditas potentialy to accelerate its development of the pipeline portfolio related to orphan liver disease, such as AIH.
- In September, Calliditas obtained positive feedback from the FDA that will have a significant impact on the ongoing pivotal Phase 3 study NefIgArd. The acceptance of a two-year eGFR based end point for Part B has resulted in a reduced length and size of the study, with significant positive impact on overall costs and recruitment time.
- In October, Calliditas obtained positive guidance from the European Medicines Agency (EMA) related to a conditional marketing authorization (CMA) of Nefecon.
- In December, Calliditas announced that a USD 5 million (SEK 46.6 million) milestone payment from Everest Medicines was triggered as per the licensing agreement under which Everest Medicines is to develop and commercialize Nefecon in Greater China and Singapore.
- In December, Calliditas announced the full recruitment of all 200 patients required for Part A of the NefIgArd study. Top line readout of Part A of the study is expected in Q4 2020.

Significant events after the reporting period

- In January, the Board of Directors determined to investigate whether there are conditions to support a potential offering of the company's securities in the US and announced that it had confidentially submitted a draft registration statement on Form F-1 to the US Securities and Exchange Commission relating to a potential initial public offering of American Depositary Shares in the US.
- In March 2020, Calliditas held an Extra General Meeting where authorization to issue new shares, adoption of new articles of association and adoption of a new incentive program was approved.

Financial summary for the Group

	2019	2018	2017	2016	2015
Net sales (SEK in thousands)	184,829	-	-	-	-
Loss before income tax (SEK in thousands)	(32,501)	(132,049)	(86,794)	(56,912)	(51,014)
Cash (SEK in thousands)	753,540	646,175	57,352	24,241	25,162
Total assets (SEK in thousands)	845,200	648,417	62,288	27,298	28,128
Equity ratio at the end of the year (%)	93%	95%	53%	Neg.	64%
Average number of employees	14	10	10	9	6

Our vision and strategy

High competence in product development

CALLIDITAS' VISION is 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.

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

CALLIDITAS' STRATEGY is 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 opportunities, 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 with existing competences and assets.

Commercialization strategy for Nefecon

Rights	• Maintain all rights to Nefecon in the US in all indications	
Commercial strategy	**General commercial strategy**	**US commercialization strategy**
	• Focus on US commercialization • Assess partnerships in EU and RoW • Target IgAN patients at risk of progressing to ESRD (End-stage renal disease) (up to 50%) • Earlier stage treatment to prevent progression and preserve kidney function	• Focus on nephrologists who treat IgAN patients, many of whom perform a hub and spoke function of expertise to surrounding clinics • Calliditas can effectively target identified group of nephrologists with a relatively small sales and marketing organization
Rationale for US commercialization	• Significant unmet medical need • Orphan drug	• Desire for early stage and safer treatments • Specialist target market	• Sizeable socioeconomic benefits • Disease modifying potential

CEO Statement

Completion of recruitment to Part A of the NeflgArd study crowns a successful year

PHOTO: JANN LIPKA

»The completion of the recruitment to Part A of NeflgArd in time and on budget was a major milestone which we are very proud of.«

Renée Aguiar-Lucander, CEO

In the last quarter of 2019, we achieved a major milestone: the full recruitment of 200 patients for Part A of our pivotal Phase 3 study, NeflgArd. We continue to expect to read out top line data in Q4 2020 as projected at the start of the study, based on the 9 months treatment period. It is truly an amazing achievement, especially as we are dealing with an orphan disease. There is an old saying: "success has many fathers, whilst failure has none". That is obviously true here as well. Success in this case was due to a multitude of factors, including focus on planning and sizing the study adequately in the beginning, spending a lot of time assessing sites, doing feasibility studies and not underestimating the challenge of patient recruitment. It was also dependent on the CRO selection, collaboration and oversight, as well as the focus and incredibly hard work of the internal clinical team. Finally, however, recruitment is down to the local physicians and nurses who ultimately spend time trying to identify appropriate patients and enter them into a trial.

But beyond all of these technical, physical actions and facts, it is also a reflection of company culture and most importantly all of the people involved. I cannot tell you how proud I was of watching the entire company, irrespective of department and rank pulling together in the fourth quarter with a single-minded focus on patient recruitment. But it wasn't just the company, it was our CRO, our investigators, national coordinators and advisory board members cheering us on, joining us in our endeavors to reach our goal.

The 200th patient was randomized on December 22 in Argentina, and we had made it! We had completed recruitment in an orphan disease on budget and on time. No matter what might come in the future, this quarter was truly remarkable and something I will remember and keep forever. We should all allow ourselves to stop for a minute and savor our achievements, especially as drug development offers many setbacks and challenges.

Another key event during the quarter was the acceptance by the Chinese authorities NMPA of the IND filed in China by Everest Medicines, with whom we have a collaboration pursuant to which Everest will develop and commercialize Nefecon in the Chinese region and Singapore. We have worked intensely and seamlessly with Everest to bring this about, and we are very excited about the decision which will enable China to join the Phase 3 trial and hence accelerate the market launch of Nefecon into the Chinese market. The collaboration with Everest is proving to be as professional and fruitful as we had hoped when we were engaging in negations. The acceptance of the IND triggered one of several milestones under the agreement, resulting in a $5m (SEK 46.6m) payment to Calliditas in Q4, providing additional capital for clinical development programs. As I have previously noted, the Chinese market is very large and truly reflects the significant unmet medical need of this disease. We are very excited about continuing to deliver on the premise of being the first approved drug for IgAN in China, and we applaud Everest in driving this program forward so efficiently.

We also hosted our very first Capital Markets Day on November 4 in order to provide additional insights and information into the company's lead project as well as our pipeline indications. We were honored to host Professor Jonathan Barratt at the event, who is a leading KOL in the area of IgAN. We also had an opportunity to provide more information around our US pre-commercial activities and market research, provided by our VP Commercial North America. It was a well-attended event which we hope enabled investors there in person, as well as over the internet, to gain a better insight into our strategy and execution readiness.

Despite the enormous focus and importance of patient recruitment and our existing collaborations, we continued to create optionality for the business going forward. During the fourth quarter, we launched a process with US advisors to draft a prospectus, which was confidentially filed with the SEC, providing a potential path to a fund raising on NASDAQ in the US during 2020. This is dependent on completion of SEC and NASDAQ review, market conditions, investor demand and shareholder approval. We look forward to exploring this potential avenue further during 2020.

A year of focused value creation and growth

2019 in whole turned out to be an exceptional year for the company. Having randomized the first patient in the NeflgArd trial in November 2018, the focus in 2019 was firmly on achieving the target of completing recruitment before the end of the year. Multiple parallel strategies were initiated and pursued in order to ensure success. Engagement with patient organizations, development and launch of a website allowing patients to identify trial centers close to them, interactions with KOLs, establishment of national coordinators and continuous interaction with our CRO, were just a few of the initiatives successfully pursued during the year.

Before the Chinese authorities accepted the IND filing by Everest Medicines in the fourth quarter, our focus in 2019 was already very much on China, where a significant unmet medical need exists due to the high prevalence of the disease. We initiated a structured process to find a partner with strong local presence and deep understanding of the changing regulatory and clinical framework. In June 2019, we were able to announce the closing of an out-licensing deal with an initial upfront payment of USD 15.0 million and regulatory and commercial milestones of up to an additional USD 106.0 million with Everest Medicines, which would pave the way to an approval of Nefecon also in China. The fact that the NMPA accepted the IND related to the inclusion of China in the ongoing Phase 3 trial only six months later speaks directly to this strong local expertise and commitment, as well as both companies' ability to successfully manage a complex collaboration.

Another area of great strategic importance in the company is to review, and if possible, build on our regulatory interactions. This led us to engage in discussions both with the FDA and EMA in 2019, resulting in very positive outcomes in both instances. The FDA accepted a revision of our confirmatory Part B design of NeflgArd, which significantly reduced both the size of the study, as well as its duration. The agreed two-year eGFR-based endpoint for Part B has a strong relationship with the eGFR secondary endpoint which we expect to provide as part of our top line data readout in Q4 2020, providing additional predictability and comfort related to the eGFR endpoint expected to be available in 2022. Our interactions with EMA resulted in support from the agency related to the conditional approval pathway for Nefecon in Europe, which we are very excited about and which provides significant acceleration related to potential market access.

In the year, we also concluded an in-licensing transaction with Dr. Falk Pharma, adding a product to our roster which we believe has the potential to add value to a future US focused liver franchise. Finally, we continued to build out our resources and adding critical skills to the organization. The ability to deliver advances on all of these fronts in parallel, requires experienced, senior resources capable of executing against strategic initiatives and delivering results in a timely manner. To that end, we have added core resources in the areas of regulatory affairs, clinical trial management, medical affairs, QA and business development. We will continue to complement the organization as we grow, and 2020 will see a focused effort on building out our US footprint in expectation of a commercial launch.

In this first quarter of 2020, the world transformed in front of our eyes in light of a previously unknown virus, Covid-19. The initial reports from Wuhan, China reflected a highly contagious new corona virus which seemed to affect primarily the respiratory system of the infected patients. Quickly the virus spread across the western world in February and March and developed into the pandemic which now has engulfed the entire world. This has obviously had a significant impact on the entire healthcare system and there has been rapid and significant loss of life across all continents. Against this backdrop, the company has assessed the potential impact Covid-19 might have on the pivotal Phase 3 study presently ongoing. I am happy to report that due to the fact that the Part A of the study was fully recruited in December, that Nefecon is an oral formulation which patients are able to take at home and that the study has a fairly light touch with regards to healthcare system interaction, the impact to date has been very limited and our communicated timelines remain intact. We obviously will continue to assess the situation and put in place mitigating strategies where needed.

In summary, 2019 has been an exciting year and we have as a company achieved several important milestones. I look forward to continuing to grow and build on the platform we now have created, and I hope that you will all join us on the continued journey in 2020, which we expect will see the readout of our NeflgArd study in Q4.

Renée Aguiar-Lucander, CEO

IgA nephropathy

Overview of the disease

IgAN disease background

IgA nephropathy (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 to 150,000 people in the US and approximately 200,000 people in Europe.

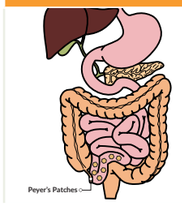
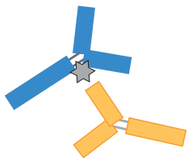
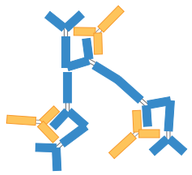
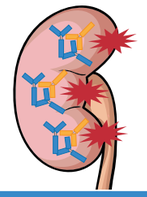
A significantly higher prevalence of IgAN has been observed in Asia, including in Greater China, where it has historically been a leading cause of ESRD. We estimate that IgAN affects approximately two million people in Greater China and 180,000 people in Japan. These estimates are based in part on the published prevalence of IgAN among patient populations in the US split across ethnicities, and in part on our own analyses of prevalence in Europe, and on published disease incidence rates for certain geographies and estimated for the populations of Greater China and Japan.

Although IgAN manifests in the kidney, the dominant pathogenesis thesis reflects that IgAN originates in the ileum, the distal part of the small intestine. The intestine contains the largest component of the immune system in the body, a site of continuous exposure to antigens and pathogens. Masses of lymphatic tissue, known as Peyer's patches, are predominantly found in the ileum where they produce secretory IgA antibodies. IgA antibodies play a key role in the immune system by protecting the body from foreign substances such as food-derived factors, bacteria and viruses. Patients with IgAN have elevated levels of a subclass of IgA antibodies originating in the gut that lack units of galactose, a type of sugar, at their hinge region. The hinge region is a flexible amino acid stretch in the central part of the heavy chains of the IgA antibody.

In IgAN patients, a combination of genetic predisposition, environmental, bacterial or dietary factors are presumed to lead to an increased production of these galactose-deficient IgA antibodies, potentially in combination with increased intestinal permeability, which leads to these antibodies appearing in the blood. The galactose-deficient IgA antibodies are immunogenic when found in the circulation, which triggers autoantibodies, or antibodies created by the body in response to a constituent of its own tissue.

This in turn leads to the formation of pathogenic immune complexes, or clusters of antibodies, which deposit in the membranes of the glomeruli, the kidney's filtration apparatus. These trapped immune complexes initiate an inflammatory cascade that damages the membranes, resulting in protein and blood leaking into the urine. Ultimately the glomeruli will be destroyed, reducing the kidney's ability to remove waste products from the blood. As the disease progresses, waste products that are normally removed from the blood will accumulate and will lead to potentially life-threatening complications that in many patients will lead to the need for dialysis or kidney transplant.

The graphic on page 8 shows the pathogenesis of IgAN. IgA production in the Peyer's patches in the ileum is believed to cause IgAN in the kidney.

Peyer's Patches	1. Galactose-deficient IgA	2. Immune recognition	3. IgA – dependent immune complex	4. IgA nephropathy (IgAN)
				
Follicles of lymphatic tissue, know as Peyer's patches, in the distal part of the small intestine (ileum) produce secretory IgA antibodies.	Patients with IgAN have an increased appearance in the blood of secretory IgA antibodies that lack galactose units (galactosedeficient IgA) in the hinge region, which makes the antibody immunogenic.	The galactose-deficient IgA antibodies trigger autoantibody production Autoantibodies bind to and form complexes with the galactose-deficient IgA autoantibodies.	These aggregates form pathogenic immune complexes that deposit in the glomeruli, which are the filtration apparatus of the kidney.	The deposits of immune complexes in the glomeruli cause an inflammatory cascade that destroys the glomeruli, reducing the kidney's ability to remove waste products from the blood and eventually may result in ESRD.

Source: Suzuki et al, J Am Soc Nephrol 2011;22(10):1795-803; Novak et al, Curr Opin Nephrol Hypertens 2013; 22(3):287-94; Novak et al, Kidney Dis (Basel). 2015; 1(1):8-18. Kruningenet al, Inflamm Bowel Diseases 2002; 8(3), 180-185.

Treatment landscape for IgAN patients

There are currently no approved treatment options for IgAN. KDIGO (Kidney Disease Improving Global Outcomes) recommends the use of blood pressure-lowering agents that inhibit or block the reninangiotensin system, or RAS, using either angiotensin converting enzyme, or ACE, inhibitors or angiotensin receptor blockers, or ARBs. RAS blockade reduces pressure in the kidney glomeruli, thereby lowering leakage and protein excretion in urine. Treatment via RAS inhibition is primarily symptomatic and does not address the underlying cause of IgAN. Over time, physicians attempt to control disease progression with a variety of off-label treatments, as a significant proportion of patients experience continued deterioration of kidney function, as no approved treatment options currently available.

For IgAN patients whose disease has progressed, clinicians may treat patients with systemic immunosuppressive agents, primarily consisting of high doses of systemic corticosteroids, such as prednisone, prednisolone and methylprednisolone. While some published reports indicate that these agents may reduce proteinuria, high dosing of systemic corticosteroids is also associated with a wide range of adverse events, including high blood pressure, weight gain, diabetes serious infections and osteoporosis.

The seriousness of these adverse events in patients with IgAN has been documented in two independent clinical trials investigating the safety and efficacy of systemic corticosteroids in IgAN. In the Therapeutic Evaluation of Steroids in IgA Nephropathy Global, or TESTING, clinical trial conducted by The George Institute for Global Health based in Sydney, Australia, 262 patients who had progressive IgAN despite treatment with RAS blockade agents were randomized to receive the systemic corticosteroid methylprednisolone or placebo. A significantly higher rate of serious infections and two infection-related deaths were observed in patients receiving methylprednisolone, leading to the suspension of the trial. While patients receiving methylprednisolone appeared to have improved outcomes compared to those receiving placebo, the early termination of the trial prevented a full efficacy analysis.

In the open-label Supportive Versus Immunosuppressive Therapy for the Treatment of Progressive IgA Nephropathy trial (STOP IgAN), conducted by Rheinisch Westfälische Technische Hochschule of Aachen University, there was also an increase in the rate of serious infections in the 82 patients who received the systemic corticosteroid prednisolone, as well as one infection-related death in the treatment cohort. In this trial, high-dose systemic corticosteroids were not observed to have a lasting effect on proteinuria and there was no significant difference in the decline in eGFR. The STOP IgAN trial concluded that the addition of immunosuppression, including systemic corticosteroids, to comprehensive supportive care was not beneficial in IgAN.

Profile	
✖	Genetic predisposition – not sufficient but necessary. Environmental, bacterial, dietary triggers.
✖	Incidence estimated at 2.5 per 100,000 – For the US market corresponding to approximately 6,000-7,000 new cases each year
✖	Normally presents in the 20-30s – more prevalent in men than in women. Up to 50% at risk of ESRD within 10-20 years.

Estimated prevalence			
Markets		US	130,000–150,000
		Europe	200,000
		China	2,000,000
		Japan	180,000

calliditas

Nefecon

Overview of Calliditas' lead product candidate

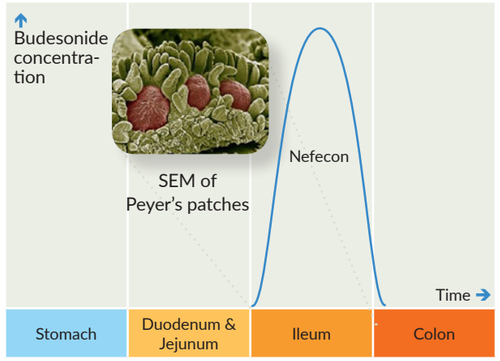
Nefecon is a proprietary, novel oral formulation of budesonide, designed to deliver a targeted and highly concentrated dose directly to the Peyer's patches that are predominantly found in the ileum. The high first pass metabolism of the active ingredient limits the adverse events typically associated with systemic corticosteroids, due to its limited spill over to the circulation. Calliditas has formulated Nefecon as a capsule with an enteric coating that prevents dissolution or disintegration in the gastric environment. The capsules are designed to travel intact through the stomach and intestine until they reach the ileum. Upon reaching the ileum, chemical and physical changes, such as acidity, trigger the disintegration of the Nefecon capsules and the release of the capsule's contents.

As illustrated below, Nefecon has two components: an enteric-coated capsule to deliver a local immunosuppressant to the ileum and sustained release beads that provide highly targeted exposure of the active ingredient. Nefecon capsules contain triple coated sustained-release beads that are designed to provide a targeted exposure of the active ingredient when they are released in the ileum, which we believe will locally suppress IgA antibody formation in the Peyer's patches and impair the appearance of the immune complexes in the blood. Nefecon is designed to block the initial step in the development of IgAN by preventing the formation of immune complexes that would otherwise become trapped in the glomerular membranes of the kidney, thereby having a disease-modifying effect and preserving kidney function.

Budesonide is an established, highly potent locally acting corticosteroid that can be used for local treatment with limited systemic side effects. This active ingredient was selected because of its local potency and high metabolization by the liver, with 90% being cleared in first pass metabolism, resulting in the inactivation of a majority of the active ingredient before the substance reaches the systemic circulation. This high metabolism limits systemic immunosuppressive activity and avoids the significant side effects associated with systemic corticosteroids that are currently used off-label to treat IgAN, of which only 20% to 30% are cleared in first pass metabolism.

Calliditas has combined its proprietary formulation technology with know-how developed internally to create Nefecon. Calliditas believes this proprietary formulation will constitute a barrier to entry that would require significant time, focus and investment for a competitor to overcome. In addition, Nefecon has been granted orphan drug designation in the US and the EU, which will provide marketing exclusivity for seven and ten years after approval, respectively. 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, Nefecon, if approved, would be eligible for an additional two years of marketing exclusivity in the EU, on top of the potential ten years of market exclusivity provided by orphan drug designation in the EU.

Release profile for the targeted substance for the Nefecon formulation



The formulation is designed to target B cells in the Peyer's patches residing in the ileum. Suppression of B cell activation and proliferation is intended to reduce the amount of galactose deficient-IgA that is free to circulate and deposit in the glomerulus.

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 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 Phase 2b study as well as 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 EMA and the FDA, achieving acceptance by FDA for the use of reduction in proteinuria as an approving endpoint for a pivotal Phase 3 study

2018

- First patient randomized in pivotal clinical Phase 3 study NefIgArd

2019

- All 200 patients enrolled in Part A 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

Interview with Bonnie Schneider, IgA Nephropathy Foundation of America

We have made great progress

Bonnie Schneider and her husband Ed founded the IgA Nephropathy Foundation of America. Bonnie currently lives in Wall Township, New Jersey. She has five adult children, ages from 25-36. Up until the diagnosis of one of her sons, Bonnie spent her life in sales and marketing, most of which was in New York.

Bonnie Schneider and her husband founded the IgA Nephropathy Foundation of America in 2004. Since that time, they have grown to a community of about 15,000 active, eager and dedicated members.

Bonnie, please describe the situation when your son was first diagnosed.

Fifteen years ago, my son Eddie, at age 13, came home from school after recovering from an upper respiratory infection to tell us that his urine was Coca-Cola colored. My husband and I couldn't imagine what he was referring to, until he showed us. Sure enough, his urine was Coca-Cola colored and murky, it almost looked like mud. At the time we didn't realize this, but it was at that point that our lives would change forever. After a kidney biopsy, only a few days later, Eddie was officially diagnosed with IgAN. We were petrified. We searched the internet and found out that there was very little we could do, and that they didn't have any specific treatments for this disease. We were left with questions, most of which our pediatrician and other doctors could not answer.

What did you do next? And how would you describe the typical patient journey for patients diagnosed with IgAN?

After going to the National Kidney Foundation and unsuccessfully trying to find other parents and patients like us, I decided it was time for a change. I quit my job in New York and dedicated my life to supporting families and patients with IgAN. My husband and I founded the IgA Nephropathy Foundation of America in 2004. Since that time, we have grown to a community of about 15,000 active, eager and dedicated members. While not all stories are the same, many of the patients have a similar story. Most commonly, patients and their families have many questions and are desperately searching for answers and treatments specifically designed to treat this horrible disease. They struggle to understand what to expect. They continue to see their nephrologist and watch the progression of this disease in fear of end stage kidney disease.

IgA nephropathy (IgAN) is a serious progressive autoimmune disease of the kidney, in which up to 50% of patients end up at risk of developing 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 which affects approximately 130,000 to 150,000 people in the US and approximately 200,000 people in Europe.

What do you see as the hardest items that these patients currently deal with?

That's an easy one: the lack of recognition, appreciation, and understanding of what it is like to have this not-so-common disease. You feel helpless. Medications that are being used were not made or developed for IgAN and many come with lots of side effects. It is difficult to see many patients struggle with the high doses of these systemic steroids like prednisone. It can be harsh and include severe mood changes, weight gain, and other side effects that lead to depression and fatigue. And that's not to mention your fears of infections. You must remember, many of these patients are first diagnosed when they are young, with the average age I'm told being in the twenties. As a parent, friend, caregiver, it is difficult to manage.

How have things changed for this market over the last 15 years?

I can't believe how far we've come. There is such excitement in the community that we finally feel we have been given some attention and have medications like Nefecon that we pray are close to being available. You have to remember, 15 years ago there were no clinical trials with new treatments being developed for IgAN – we felt alone. The Foundation members are a very motivated crew and feel we have made great progress. The FDA, pharma, and the cutting edge and leading nephrologists have gradually worked closer and closer with us towards a cure, or something that will stop the progression of IgAN.

What's going to be next?

A day when a patient gets diagnosed with IgAN and they are not terrified, confused and filled with questions. A day when the nephrologist treating these patients has the confidence to answer the patient's questions and know that they have treatments, like Nefecon, that we hope will help to either cure or stop IgAN progression without severe side effects that take over a patients' life.

Development program

The Phase 3 study NefIgArd

Completed studies

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, followed by 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 end of treatment; and an increase in eGFR of 8% as a result of the treatment was also observed.

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. This study was the largest double-blind trial ever conducted with an investigational candidate in IgAN patients. It is also the only successful randomized, placebo-controlled Phase 2b study to date.

The study had three treatment arms, 8mg, 16mg Nefecon and placebo. Patients had biopsy confirmed IgAN and were on optimized RAS blockade (blood pressure control). Nefecon or placebo was administered, as oral capsules, once a day for nine months. During that time, treatment with RAS blockade (inhibition of the renin-angiotensin system) continued.

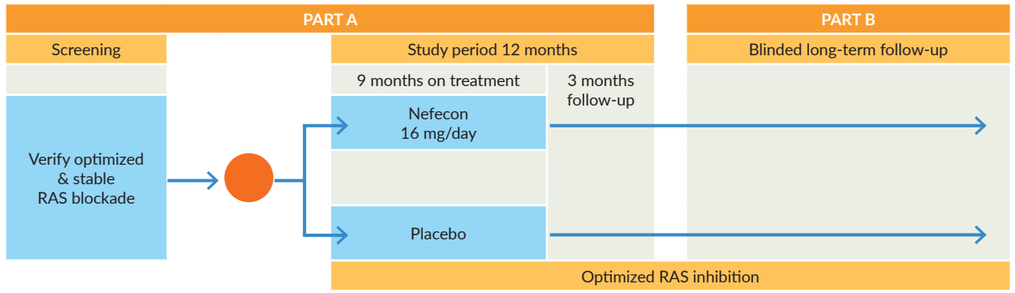
At the end of nine months' treatment of either Nefecon or placebo, the primary endpoint of reduction in proteinuria as measured by the urine protein creatinine ratio (UPCR) was reported. This endpoint was achieved during a predefined analysis after the first 90 patients had completed nine months of treatment. The 16 mg and 8 mg patients had an improved reduction in UPCR of 27.3 and 21.5%, respectively, while the placebo treated patients had an increase of 2.7%.

Significant differences in eGFR between the Nefecon and placebo treated groups were also observed. Patients in the placebo group experienced a deterioration of 9.8% decrease (4.7ml/min) in eGFR during the nine months of treatment while the 16 mg Nefecon group had an increase of 0.6% and the 8 mg Nefecon group had a decrease of 0.9%, which reflects stabilization. There were no severe adverse events such as severe infections or significant impact on the metabolic system (blood pressure, weight gain, diabetes etc.),

Key highlights NefIgArd	
→	Phase 3 study design replicates successful Ph2b
→	Top-line data of 200 patients compared to 150 patients in Ph2b
→	16mg Nefecon or placebo once-daily oral dose
→	Recognized surrogate marker for approval

Nefecon Phase 2b study design

NefIgArd Phase 3 study design



which are typical side systemic effects of systemic glucocorticosteroid treatment.

The trial findings supported Nefecon's ability to reduce protein leakage, counteract a decline in kidney function and potentially also promote a slight improvement. The effect of Nefecon supports our belief that it may have an important disease-modifying activity which could help delay onset of dialysis or potentially remove the need for such treatment. If the improvement observed with Nefecon is confirmed in the Phase 3 study, this may enable clinicians to treat patients with earlier stage disease to stabilize and possibly regain the existing kidney function.

Study design of phase 3 study NefIgArd

Calliditas is currently conducting a global pivotal Phase 3 clinical trial in IgAN called NefIgArd. On November 13, 2018, Calliditas announced that the first patient had been enrolled in the NefIgArd trial. NefIgArd is designed to evaluate reduction of the surrogate marker proteinuria as its primary endpoint, which is the same endpoint used in the Phase 2 study NEFIGAN. NefIgArd is a randomized, double-blind, placebo-controlled, two-part trial. The first part (Part A) is a pivotal efficacy and safety trial that is expected to form the basis for submissions of an NDA to the FDA and an MAA to EMA.

The primary endpoint of Part A is the decrease in proteinuria in the first 200 randomized and dosed patients. In addition, a secondary endpoint of Part A is the difference in kidney function between treated and placebo patients as measured by eGFR. Calliditas expects to report topline results from Part A in the fourth quarter of 2020. If these data are positive, and clinically relevant reductions in proteinuria are demonstrated, the company intends to file marketing applications in the first half of 2021 for accelerated approval in the US by the FDA and conditional approval in the EU by EMA.

Part B of the study is a post-approval confirmatory trial designed to validate proteinuria as a surrogate marker. Following completion of enrollment in Part A, which took place in December of 2019, Calliditas will continue to recruit an additional 160 patients during 2020 in order to power Part B 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. This eGFR outcome will also be informed by the eGFR reported as a secondary endpoint in Part A over a one-year period. Calliditas expects to report data from Part B in 2022.

A total of 360 patients with biopsy-confirmed IgAN will therefore be enrolled in NefIgArd at approximately 146 sites across 19 countries, including in North America, South America, Europe, Australia and Asia. In September 2019, the FDA accepted a protocol design modification that reduced the total trial size from 450 to 360 patients and shortened Part B to a fixed twelvemonth follow-up period for each patient, which is expected to reduce the total trial time-line from approximately six years to under four years. In addition, this protocol design modification results in a significantly lower capital spend on the development of Nefecon as compared to the original protocol. Under the amended trial protocol, patients on optimized RAS blockade are randomized to receive either 16 mg Nefecon or placebo, once daily for nine months. Across both parts, NefIgArd will enroll a total of 360 patients and generate nine months of dosing data as well as an aggregate of a total of 15 months of follow-up data from patients across Parts A and B.

Additional trials

Open-label extension trial

Calliditas will initiate an open-label extension trial for eligible patients who have completed treatment in Part A and Part B of NefIgArd. The open-label extension trial is expected to commence in Q4 2020, when the first patient has completed both Part A and Part B of NefIgArd.

Extended dosing

Calliditas intends to initiate an open-label extended dosing trial in 2020/2021 to provide safety and efficacy data for continued treatment with Nefecon, in addition to the nine-month treatment course documented in the NefIgArd trial. All patients enrolled in the open-label trial will be on active treatment, starting with 16 mg once daily for nine months of treatment, followed by a maintenance dose.

Potential in additional orphan indications

Beyond IgAN, Calliditas believes that Nefecon's patented formulation and release technology also offers potential in treatment of other select autoimmune diseases based on the concentrated release in the ilium and the high exposure to the liver, e.g. primary biliary cholangitis (PBC).

License agreement

Everest Medicines and the Chinese market

In June 2019, Calliditas and Everest Medicines entered into a license agreement under which Everest Medicines has the rights to develop and commercialize Nefecon for IgA Nephropathy (IgAN) in Greater China and Singapore.

Under the terms of the agreement, Calliditas received an initial upfront payment of USD 15 million at signing of the agreement, and will receive future payments upon the satisfaction of specific clinical, regulatory and commercial milestones of up to an additional USD 106 million, inclusive of option payments for the development of Nefecon in other potential indications. Everest Medicines will also pay typical tiered royalties on annual net sales.

In December 2019, Calliditas announced that a USD 5 million milestone payment from Everest Medicines was triggered under the licensing agreement. The National Medical Products Administration (NMPA, formerly known as CFDA) approved Everest Medicines' IND (Investigational New Drug application) for Nefecon in China, an important step toward approval in China, initially allowing Chinese clinical sites to recruit patients for the NefIgArd study. The agreement gives Everest Medicines exclusive rights to develop and commercialize Nefecon in China, Hong Kong, Macau, Taiwan and Singapore and may, after the NMPA IND approval, includes Chinese study centers in the ongoing Phase 3 NefIgArd study, with the aim of gaining registrational approval for the Chinese market following approval in the US and Europe. Subsequent to such registrational approval, Everest would be responsible for the commercialization of Nefecon in the licensed territories. While IgAN, is an orphan disease in the US and Europe, the prevalence is significantly higher in China, where IgAN as the most common primary glomerulonephritis, accounts for about 40% of renal biopsies.

»Calliditas and Everest Medicines entered into a license agreement to develop and commercialize Nefecon in Greater China and Singapore for IgAN.«

China is believed to be the world's single largest market in terms of the number of IgAN patients which extracts a significant economic and social impact. As kidney biopsies today mainly can be carried out only in the very large hospitals, the actual number of patients, and hence the market opportunity, we believe, is significantly larger than what can be derived solely from the existing renal biopsy numbers. Calliditas estimates that IgAN prevalence in China amounts to approximately two million people in Greater China.

China has a population of over 1.4 bn people, which represents about 18% of the world's population and has the second largest prescription drug market in the world, behind the US. In contrast to the US however, the Chinese drug prescription market is estimated to grow at significant double-digit rate on an annual basis over the next five years, setting it on a course to become the largest market.

The changing regulatory landscape in China

In August of 2015, the China State Council issued the "Opinion of Reform of the Drug and Medical device Approval System". The opinion had several stated targets, such as to shorten the IND and NDA timelines, encourage drug innovation, accelerate market authorizations of medical innovations and minimize drug lag. The changes seen since this publication have been nothing but revolutionary. According to a publication by Deloitte Insights, the drug lag from EMA and FDA approved products (the amount of time between an approved product in one jurisdiction achieves approval in another jurisdiction) was in 2016 approximately 85 months, which over just a couple of years has been cut to an average of 30 months. The number of products approved in China grew from five in 2016 to 40 in 2017 and 51 in 2018, with over 180 drugs being granted Priority Review in 2018. Similar trends of acceleration and focus can be seen also in other areas related to the regulatory process.

Three of the specific actions taken by the National Medical Products Administration (NMPA), formerly known as CFDA, stand out for a special mention. Firstly, the clinical trial application period was formally set to be 60 days. Secondly, NMPA became a full regulatory member of The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and finally, the number of reviewers were increased from 200 to 600, with a target of reaching 2,000. The rate at which these reforms are taking place is amazing by any standard, and it is making companies both outside and inside of China sit up and take notice, as the opportunities and market landscape is changing in front of our eyes.

This shift in stance will, according to many experts, lead to a rapidly changing landscape related to both drug development, reimbursement and commercialization in China, resulting in significant reduction of pricing for established generics, shifting reimbursement dollars to more innovative products and promoting development of innovative medicines. One thing to keep in mind however when using the definition of "innovative drugs", is that this reflects the existing basis of available drugs in China today and is not necessarily equivalent to the definition used in Europe or the US. This is therefore likely to be significantly broader and encompass many drug categories which we take for granted, having had the benefit of access.

Commercialization plan and IQVIA research summary

Positive market opportunity

»If approved, Calliditas intends to commercialize Nefecon in the US independently.«

Commercialization plan

Calliditas retains global rights to Nefecon other than in Greater China and Singapore. If approved, Calliditas intends to commercialize Nefecon in the US independently. Calliditas estimates the US market opportunity to be approximately USD 9.0 billion to USD 10.0 billion annually, based on our estimate of the prevalence of the disease in the US and primary market research conducted by IQVIA that Calliditas commissioned to assess preliminary reimbursement levels perceived acceptable by U.S.-based payors. As described more in detail below, such primary market research indicated that the estimated pricing of a course of treatment of Nefecon could range from USD 55,000 to USD 85,000 per patient.

Out of the estimated U.S. IgAN market, Calliditas intends to commercialize Nefecon in the US with a targeted commercial infrastructure and with a primary focus on 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 fulfill 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 approximately 3,700 nephrologists focused on our target patient population in the US.

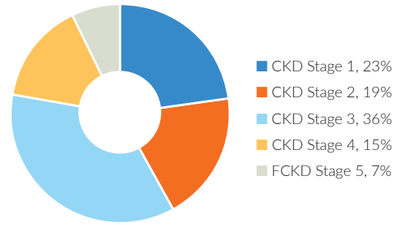
In 2019, Calliditas entered into an agreement with Everest Medicines, pursuant to which Calliditas granted Everest Medicines an exclusive license to develop and commercialize Nefecon for IgAN in Greater China and Singapore. Everest Medicines may exercise its option to develop Nefecon in additional indications subject to additional payment by Everest Medicines. In other key territories such as Europe, Calliditas intends to commercialize Nefecon through either a broad regional partnership or on a country-by-country basis.

IQVIA research summary

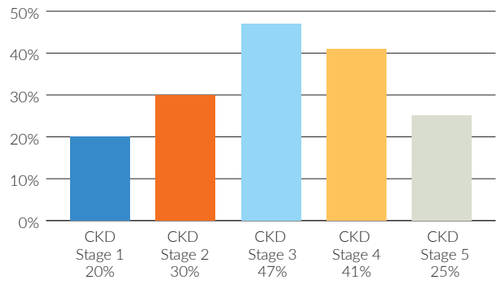
During the second and third quarters of 2019, Calliditas conducted a US market landscape research project with IQVIA, a leading global provider of advanced analytics, technology solutions and contract research services to the life sciences industry, formerly known as IMS Health Consulting / QuintilesIMS. The research included qualitative interviews with payors and nephrologists, and a quantitative survey of 102 nephrologists that treat on average 14 IgAN patients per month. The payors interviewed were from organizations responsible for the management of over 225 million lives including commercial, Medicare, and Medicaid.

The objectives of the study were to gain a deep understanding of the current IgAN landscape in the US and to evaluate relevant implications for Nefecon's commercial strategy. Specifically, we wanted to explore the current IgAN current landscape/patient journey, evaluate the rare disease pricing and reimbursement dynamics, validate nephrologist perceptions and selection drivers when treating IgAN, and obtain nephrologist and payor perceptions to a Nefecon product profile that was based on our Phase 2b trial results.

CKD Stage of IgAN Patient at Time of First Nephrologist Visit



Of their current patients, where nephrologists see Nefecon being appropriate:



Results from the research with the nephrologists included:

- While patients may be seen initially by a primary care physician, the official diagnosis comes after a biopsy, which is ordered by the nephrologists.
- On average it takes seven to eight months for a patient to get to the nephrologist and get officially diagnosed with IgAN.
- At the time of first diagnosis by the nephrologists, patients are in varying stages of chronic kidney disease (CKD), with vast majority being in the first three stages and the largest portion being in CKD stage 3. (see pie chart)
- Nephrologists confirmed that the NefIgArd trial endpoints are indeed the most important items they look at when assessing disease progress and determining treatment.
- Based on the product profile alone:
  - 68% of nephrologists would prescribe Nefecon during the first year on the market
  - Nephrologists plan to prescribe Nefecon as the first agent after, or in conjunction with blood pressure lowering medications (ACE/ARB).
- Nephrologists feel Nefecon will be appropriate for patients at all stages of CKD – with it being appropriate for almost 50% of their CKD 3 patients. (see bar graph)

Results from the research with payers included:

- A lack of experience and knowledge base surrounding IgAN, which results in their request for key opinion leader and specialist education on the disease.
- Currently, IgAN is not a priority to manage. No products have an IgAN indication, it is a relatively small population, and a slow progressing disease.
- Treatments that would delay or help avoid dialysis would be important and would be welcomed due to the high cost of dialysis.
- Based on the profile and a price range between $55,000 and $85,000, they would anticipate managing Nefecon to label. This would require the product to be prescribed by a nephrologist for a patient with a confirmed IgAN diagnosis, after a trial of blood pressure lowering medication was sub-optimal.
- Results from the Phase 3 NefIgArd study will assist in providing payers understanding of the longer-term effects of Nefecon.
- Calliditas sees the results of the landscape research as highly encouraging, considering the physicians and payers surveyed had limited education regarding IgAN disease origin, the Nefecon targeted delivery system and the longer-term clinical benefits that are being examined in the NefIgArd trial. Ongoing educational efforts and further research will be conducted as Calliditas prepares for commercialization.

Orphan liver indications

Potential in selected autoimmune diseases

Beyond IgAN, Calliditas believes that Nefecon and budesonide also has potential in treating other select autoimmune diseases based on the release in the intestine and the high exposure to the liver, e.g. the liver diseases primary biliary cholangitis (PBC) and Autoimmune hepatitis (AIH).

Primary biliary cholangitis (PBC)

Calliditas is exploring applications of Nefecon for other autoimmune diseases in which it may have therapeutic potential, such as PBC, a progressive and chronic autoimmune disease of the liver. There are currently no approved therapies that specifically address 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. Nefecon is designed to deliver high peak concentrations of the local immunosuppressant budesonide to the intestine, where it is then transported directly to the liver in order to locally suppress the autoimmune response associated with PBC and counteract the inflammation resulting from increased and toxic levels of bile acid. Calliditas has received orphan drug designation for the treatment of PBC by the FDA and anticipates discussing our development plans for PBC with the FDA in 2020/2021.

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 the 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 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, resulting in destruction of liver cells and fibrosis. PBC can culminate in liver failure, necessitating the need for a liver transplant. PBC is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 140,000 patients in the US. The annual incidence for PBC ranges from 0.3 to 5.8 cases per 100,000 in the US.

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

Current 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 analogs whose mechanisms of action aim to protect the liver from damage caused by 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 adequately and are at risk of requiring liver transplant. Despite showing improvements in liver values in the blood, Ocaliva has not been proven in clinical testing to delay or avoid the need for liver transplant. Although systemic corticosteroids have been shown to alleviate PBC symptoms, their adverse event profile limits their treatment potential.

Nefecon in PBC

Based on current knowledge of PBC's pathophysiology, Calliditas believes that targeted exposure of budesonide in the liver may counteract the original autoimmune response that is believed to drive PBC, as well as the inflammation resulting from increased and toxic levels of bile acid. In addition, while historical trials have shown that systemic corticosteroids may alleviate symptoms and improve biochemical and histologic parameters, no targeted immunosuppressive anti-inflammatory therapy is currently approved for PBC in the US or Europe. Nefecon is designed to deliver high peak concentrations of budesonide to the intestine that is then transported directly to the liver, where it can have a local anti-inflammatory effect to reduce the inflammation associated with PBC, while minimizing systemic exposure and reducing systemic corticosteroid-related adverse events. Calliditas believes that Nefecon can address the significant unmet medical need to improve outcomes for PBC patients as a second line therapy.

»Beyond IgA nephropathy, Calliditas assesses that Nefecon and budesonide also offer potential in treatment of other select autoimmune diseases based on the concentrated release in the ilium and the high exposure to the liver«

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 license 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 acute episodes of collagenous colitis in Europe, but regulatory approval

Orphan drugs

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

The American Orphan Drug Act of 1983 introduced several incentives for drug companies developing drugs to prevent, diagnose or treat orphan diseases that affect less than 200,000 individuals 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 waiver and eligibility for FDA grants.

The European Parliament adopted the Orphan Regulation on December 16, 1999 to lay down the EU procedure for designation of orphan medicines and stimulate the development of orphan medicinal products.

An orphan disease is defined in Europe as a disease or condition affecting no more than five in 10,000 individuals with no satisfactory method of diagnosis, prevention or treatment.

The adopted 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.

was never pursued in the US. 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, and we anticipate discussing our development plans for AIH with the FDA in 2020.

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 production of cytotoxic T-cells and B-cell derived autoantibodies directed towards liver cells or its components, resulting in inflammation of the liver cells that eventually destroys the cell and leads to fibrosis. AIH often presents as a slow progressing disease of the liver, leading to cirrhosis at variable rates 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 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. The annual incidence of AIH ranges from 0.1 to 1.9 cases per 100,000 in the US. The disease is at least three times as common in women as in men and can occur at any time during life.

Current Treatments for AIH

There are currently no approved therapies for 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 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 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. Furthermore, 50% to 90% of patients relapse if treatment is stopped. In addition, 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 high rates of relapse among AIH patients, there is a significant unmet need among AIH patients.

Calliditas is exploring applications of Nefecon for other autoimmune diseases in which it may have therapeutic potential. These include primary biliary cholangitis (PBC), a progressive and chronic autommune disease of the liver.

FOTO: SHUTTERSTOCK

»The analysis concluded that Nefecon is unlikely to infringe on any granted third-party patent rights.«

Patents

For Nefecon, Calliditas co-owns with Kyowa Kirin Services Ltd., (formerly Archimedes Development Ltd) a patent family and has the 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. The patents in this family include a US 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 US because the active ingredient is used in existing approved drugs. In Europe, extension of the patents remains possible, subject to the outcome of litigation in the EU related to the degree to which it is possible to obtain a Supplementary Protection Certificate for a previously authorized active ingredient.

Freedom-to-Operate

On behalf of Calliditas, a Freedom-to-Operate analysis was performed which comprised of a review of published patent and patent applications in the US and Europe. The analysis concluded that Nefecon is unlikely to infringe on any granted third-party patent rights and no pending third-party applications were deemed a clear threat from a Freedom-to-Operate perspective.

The share

Share performance

Calliditas was listed on Nasdaq Stockholm Mid-Cap, on June 29, 2018. As of December 30, 2019, the closing rate was SEK 75.7, yielding an increase of 76% in 2019. During the same period, the OMXSPI increased by 29%. The highest closing rate during the year was SEK 75.7 and the lowest SEK 41.0.

Turnover

A total of 10,898,013 shares were traded during the year, with a total value of SEK 604 million. On average, 43,592 shares were traded each day.

Share performance 2019

Calliditas
OMX Stockholm PI
OMX Stockholm Pharmaceuticals & Biotechnology PI
Number of shares traded in 000s per week

Source: Modular Finance

Shareholders

As of December 31, 2019, Calliditas had 2,835 shareholders. The 15 largest shareholders controlled 79.6% of the capital and voting rights at year-end. The three largest shareholders were Stiftelsen Industrifonden, Investinor AS and Linc AB / Bengt Julander. Foreign shareholders accounted for 29.5% of voting rights and capital.

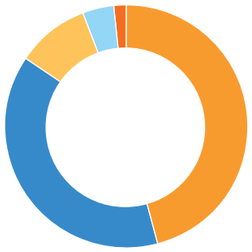
Share Capital

As of December 31, 2019, share capital in Calliditas amounted to SEK 1,548 thousand. The number of shares was 38,707,638 corresponding to a quotient value per share of SEK 0.4. 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 56% at year-end.

Investor Relations Work

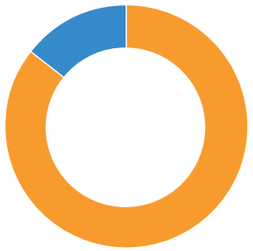
In 2019, Investor Relations efforts focused on establishing Calliditas on the capital market both in the Nordic region and internationally. Management took part in several sector-specific conferences, with the JP Morgan Healthcare Conference in San Francisco and the Jefferies Healthcare Conference in London being two of the more prominent. Calliditas also held a large number of meetings on both the selling and buying side as a means of educating the market and ensuring broad knowledge of the company in the market. During the year, Calliditas visited London, New York, San Francisco, Boston, Zürich, Berlin, Paris and Amsterdam, in addition to Stockholm.

Ownership per category, %



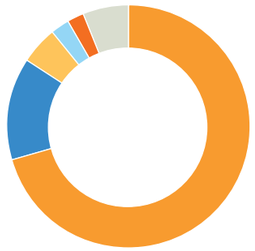
Swedish institutional owners 46.0%
Other 38.5%
Swedish private persons 9.9%
Foreign institutional owners 4.2%
Anonymous ownership 1.4%

Trading platforms, %



Nasdaq OMX 85.7%
Cboe Global Markets 14.3%

Ownership per country, %



Sweden 70.5%
Norway 13.8%
US 4.8%
Great Britain 2.6%
Canada 2.3%
Other 5.9%

Source: Monitor by Modular Finance and Fidessa

The 15 largest shareholders per December 31, 2019

Shareholders	Total number of shares	Holding, %	Votes, %
Stiftelsen Industrifonden	7 117 746	18,4%	18,4%
Investinor AS	5 091 243	13,2%	13,2%
Linc AB / Bengt Julander	4 836 108	12,5%	12,5%
Gladiator	2 150 000	5,6%	5,6%
Fjärde AP-fonden	2 110 227	5,5%	5,5%
BVF Partners LP	1 866 000	4,8%	4,8%
Handelsbanken Fonder	1 678 000	4,3%	4,3%
AFA Försäkring	1 640 000	4,2%	4,2%
Unionen	1 078 798	2,8%	2,8%
Mikael Bender	700 000	1,8%	1,8%
Zaragatero LTD	688 817	1,8%	1,8%
Staffan Rasjö	625 000	1,6%	1,6%
SEB-Stiftelsen	585 000	1,5%	1,5%
Avanza Pension	342 960	0,9%	0,9%
Danica Pension	313 302	0,8%	0,8%
Total share of the 15 largest shareholders	**30 823 201**	**79,6%**	**79,6%**
Other shareholders	7 884 437	20,4%	20,4%
Total	**38 707 638**	**100,0%**	**100,0%**

Share data 2019

Low, SEK	41,00
High, SEK	75,7
VWAP	55,41
Number of shares traded	10 898 013
Average number of shares traded per day	43 592
Number of trades	35 678
Average number of trades per day	143
Average value per trade, SEK	16 927
Average daily turnover, SEK	2 415 620
Daily turnover rel. mcap, %	0,13%
Part Nasdaq (ordinary trade), %	72,20%
Part block transaction, %	26,90%
Part dark pools (Nasdaq), %	0,90%

Analysts

Calliditas is covered by Carnegie, Stifel, Kempen and Redeye.

Size classes as per December 31, 2019

Size classes	No. of known shareholders	No. of shares	Holding, %	Votes, %	Proportion of known shareholders
1 - 100	848	35 855	0,1%	0,1%	29,9%
101 - 200	348	58 437	0,2%	0,2%	12,3%
201 - 500	734	251 662	0,7%	0,7%	25,9%
501 - 1000	359	303 117	0,8%	0,8%	12,7%
1001 - 2000	241	394 231	1,0%	1,0%	8,5%
2001 - 5000	161	550 458	1,4%	1,4%	5,7%
5001 - 10000	57	437 590	1,1%	1,1%	2,0%
10001 - 20000	35	505 008	1,3%	1,3%	1,2%
20001 - 50000	20	651 647	1,7%	1,7%	0,7%
50001 - 100000	3	226 450	0,6%	0,6%	0,1%
100001 - 200000	7	1 095 549	2,8%	2,8%	0,2%
200001 - 500000	8	2 275 071	5,9%	5,9%	0,3%
500001 - 1000000	5	3 498 820	9,0%	9,0%	0,2%
1000001 - 4000000	6	10 523 025	27,2%	27,2%	0,2%
4000001 -	3	17 045 097	44,0%	44,0%	0,1%
Anonymous ownership		855 621	2,2%	2,2%	
TOTAL	**2 835**	**38 707 638**	**100,0%**	**100,0%**	**100,0%**

Board of Directors' Report

Multi-Year Summary, Group

	2019	2018	2017	2016	2015
Net sales (SEK in thousands)	184,829	-	-	-	-
Loss before income tax (SEK in thousands)	(32,501)	(132,049)	(86,794)	(56,912)	(51,014)
Total assets (SEK in thousands)	845,200	648,417	62,288	27,298	28,128
Equity ratio at the end of the year (%)	93%	95%	53%	Neg.	64%
Average number of employees	14	10	10	9	6

Multi-Year Summary, Parent Company

	2019	2018	2017	2016	2015
Net sales (SEK in thousands)	184,829	-	-	-	-
Loss before income tax (SEK in thousands)	(36,186)	(131,923)	(86,848)	(58,313)	(49,982)
Total assets (SEK in thousands)	838,249	651,633	65,366	30,325	32,216
Equity ratio at the end of the year (%)	94%	95%	55%	Neg.	70%
Average number of employees	13	10	9	8	5

For definitions of key figures, see Note 29 Definition of key ratios and alternative performance measures on page 55.

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 2019. All amounts are expressed in SEK millions unless otherwise stated.

Operations

Calliditas is a 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 and where Calliditas can partially or entirely take part in the commercialization. The focus is primarily on developing and commercializing the product candidate Nefecon, a unique formulation optimized to combine a delayed delivery with a concentrated release of the active substance budesonide, in a specific target area. This patented, locally applied formulation is intended to treat patients with the inflammatory kidney disease IgA nephropathy (IgAN). Calliditas is running a global Phase 3 study within IgAN and aims to commercialize Nefecon in the United States, if approved, and through collaboration with partners in the EU and Asia. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX).

The results of the clinical Phase 2b trial showed that Nefecon has the potential to preserve kidney function in patients with IgA nephropathy by targeting the source of the disease. The study showed a statistically significant and clinically relevant reduction in proteinuria levels, meaning the level of protein in the urine, and a stabilizing of the glomerular filtration rate (eGFR), an indication of kidney function. Proteinuria is a recognized marker to identify and monitor kidney disease. This marker shows damage to the kidney's filtering function resulting in the leakage of protein into the urine. Calliditas intends to take Nefecon through a global Phase 3 trial and onward to commercialization. In 2019, Calliditas mainly focused on the development of Nefecon and for the ongoing pivotal Phase 3 trial NefIgArd and in December 2019 it was announced that 200 patients have been randomized, which means that all patients necessary for an analysis of the efficacy and safety of Part A of the Phase 3 study have been recruited.

Although the Group had revenue of SEK 184.8 million in 2019 from the out-licensing of Nefecon in Greater China and Singapore, the Group is until Nefecon starts to generate revenue dependent on external financing to ensure continued operations. During the year, a new share issue was conducted yielding proceeds of SEK 210.3 million before issue costs.

The Group consists of Parent Company Calliditas Therapeutics AB and the U.S. subsidiary Calliditas Therapeutics Inc and the Swedish subsidiary Nefecon AB and the Norwegian subsidiary Pharmalink Oncology AB, where there are no operating activities. During the year, Busulipo AB and Pharmalink Nordic AB have been merged with the Parent Company.

Significant Events During the Year

FDA orphan drug designation

In February, Calliditas was granted orphan drug designation (ODD) for the treatment of Autoimmune Hepatitis (AIH) and Primary Biliary Cholangitis (PBC) by the FDA.

License agreement with Everest Medicines

In June, Calliditas and Everest Medicines entered into a license agreement to develop and commercialize Calliditas' leading drug candidate Nefecon in Greater China and Singapore for IgA Nephropathy (IgAN). Under the terms of the agreement, Calliditas received an initial payment of USD 15 million at signing of the agreement, as well as future payments linked to predefined development, regulatory and commercialization milestones up to an additional USD 86 million plus an option worth up to additional USD 20 million for the development of Nefecon in other potential indications. Everest will also pay typical tiered royalties on future sales. In December, a USD 5 million milestone payment from Everest Medicines was triggered after approved IND (Investigational New Drug application) for Nefecon in China.

New share issue

In July, Calliditas completed a directed new share issue of 3.5 million shares, raising SEK 210 million before issuance costs with the aim of expanding ongoing research programs and accelerating activities related to the pipeline. The new issue was subscribed by Swedish and international institutional investors, including BVF Partners L.P.

License agreement with Dr. Falk Pharma

In August, Calliditas entered into an exclusive in-licensing agreement of Budenofalk 3mg oral capsule

Board of Directors' Report

for the US market with Dr Falk Pharma. Calliditas will leverage Dr. Falk's clinical trial data and expertise in the liver indication Autoimmune hepatitis (AIH) with a view to accelerate approval and market access. This enables Calliditas to potentially accelerate its development of the pipeline portfolio related to orphan liver disease, such as Autoimmune hepatitis (AIH). The deal had an upfront payment of EUR 1.5 million and foresees additional regulatory related payments, subject to market approval from the FDA. The total deal value amounts to EUR 40 million, including future sales milestones.

Positive regulatory message from the FDA and EMA

In September, Calliditas obtained positive feedback from the FDA that has a significant impact on the confirmatory part of the ongoing pivotal Phase 3 study, NefIgArd. The FDA accepted a two-year eGFR based end point for the Part B of the study, reducing the overall time from six to under four years, and a reduction from 450 to 360 patients with significant positive impact on overall costs.

In October, Calliditas obtained positive advice from EMA in which the agency expressed support for a conditional marketing authorization (CMA) of Nefecon, subject to the strength of the full data set presented at the time of filing.

The recruitment completed for Part A of the pivotal Phase 3 study NefIgArd

In December, the recruitment of the 200 patients needed for Part A of the company's pivotal Phase 3 study NefIgArd was completed. Topline readout of part A of the study is expected in Q4 2020.

Sales and Earnings

The revenues for the year ended December 31, 2019 were SEK 184.8 million and derived from the out-licensing of Nefecon for Greater China and Singapore to Everest Medicines. No revenues were recognized for the year ended December 31, 2018.

Research and development expenses

Expenses for research and development amounted to SEK 149.8 million and SEK 99.3 million for the years ended December 31, 2019 and 2018, respectively. The increase was primarily explained by increased cost for clinical trials for operating the company's Phase 3 study NefIgArd in the form of study-related activities, as well as costs for the development and manufacture of drugs.

Administrative and selling expenses

Administrative and selling expenses amounted to SEK 62.9 million and SEK 31.1 million for the years ended December 31, 2019 and 2018, respectively. The increase compared to the previous year is mainly due to the pre-commercial activities for a potential future launch of Nefecon in the United States, as well as transaction-related costs in connection with the out-licensing agreement of Nefecon to Everest Medicines in China. A generally increased level of activity resulting from increased activity in business development and a growing organization has also resulted in increased administrative expenses during the year.

Other operating income / expenses

Other operating income increased by SEK 4.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily relates to more favorable exchange rates on operating receivables. Other operating expenses amounted to SEK 4.5 million and SEK 2.1 million for the years ended December 31, 2019 and 2018, respectively. The increase was primarily explained by currency losses on operating liabilities.

Financial income / expenses

Financial income amounted to SEK 0.9 million and SEK 0.4 for the years ended December 31, 2019 and 2018, respectively. The increase is primarily due to interest income earned on cash accounts. Financial expenses increased by SEK 5.4 million for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to realized and unrealized losses on derivative instruments and exchange rate losses.

Earnings

For the years ended December 31, 2019 and December 31, 2018, the Group had a net loss of SEK 32.6 million and SEK 132.0 million, respectively and corresponding loss per share before and after dilution amounted to SEK 0.88 and SEK 5.09 for the years, respectively.

Liquidity and Financial Position

Cash amounted to SEK 753.5 million and SEK 646.2 as of December 31, 2019 and 2018, respectively. In mid-2019, a new share issue was conducted of 3.5 million shares. The total issue amount was SEK 210.3 million, which yielded proceeds to the company of SEK 199.4 million net after issuance costs.

Shareholders' equity amounted to SEK 788.1 million and SEK 618.2 million as of December 31, 2019 and 2018, respectively.

Cash Flow

Net cash used for operating activities was SEK 71.0 million and SEK 128.2 million for the years ended December 31, 2019 and 2018, respectively. During the year ended December 31, 2019, net cash used for investing activities was SEK 18.1 million and derives from the acquisition of a license from Dr. Falk Pharma to develop the product candidate Budenofalk 3mg in the United States. During the year ended December 31, 2018, Calliditas did not use or receive any cash from investing activities.

During the year ended December 31, 2019, net cash provided by financing activities was SEK 198.8 million, primarily consisting of the new share issue in July 2019. During the year ended December 31, 2018, net cash provided by financing activities was SEK 716.6 million, primarily consisting of the initial public offering on the Nasdaq Stockholm exchange in June 2018.

Net increase in cash amounted to SEK 109.8 million and SEK 588.4 million for the years ended December 31, 2019 and 2018, respectively.

Personnel

The total number of employees in the Group amounted to 16 and 10 for the years ended December 31, 2019 and 2018, respectively of which 62% are women and 38% are men. The average number of employees was 14 and 10 during the years ended December 31, 2019 and 2018, respectively.

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 three warrant programs outstanding, issued in 2017, 2018 and 2019. The warrant program issued in 2017 was addressed to employees, consultants and certain board members and expires in June 2020. 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 issued in 2017, option holders may exercise the warrants at any time during the term of the warrant, while participants in the program from 2018 and 2019 cannot exercise the warrants until the first quarter of 2022 and fourth quarter 2022, respectively. As of December 31, 2019, the total number of warrants outstanding, if fully subscribed, corresponded to 2,575,586 shares. For further information about the warrants program, refer to Note 10 Share-Based Payments.

Share Capital and Shareholders

As of December 31, 2019, share capital amounted to SEK 1.5 million distributed between 38,707,638 shares with a quotient value of SEK 0.04. All of the shares are common shares and hold the same entitlement to the company's profit and every share has one vote at the Annual General Meeting (AGM). Calliditas' share was admitted to trading on Nasdaq Stockholm, Mid Cap, on June 29, 2018. At the end of 2019, Calliditas had 2,835 shareholders and the ten largest shareholders held 73.0% of all shares outstanding. As of December 31, 2019, the largest individual shareholders in the company were Stiftelsen Industrifonden (7,117,746 shares), Investinor AS (5,091,243 shares) and Linc AB / Bengt Julander (4,836,108 shares), corresponding to 18.4%, 13.2% and 12.5% of voting rights and capital respectively.

Holdings of Treasury Shares and Warrants

No shares were held in treasury by Calliditas in 2019. The subsidiary Nefecon AB holds 70,000 warrants pending any distribution to future participants in the Board LTIP 2019 program.

Work of the Board of Directors

Calliditas' Board of Directors consists of six board members including the Chairman, who is elected for the period until the 2020 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.

Board of Directors' Report

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

The Board of Directors meets according to an annual 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 2019, activity on the Board was higher than normal due to the company's licensing agreements and capital raise. The Board of Directors met 15 times in 2019. Other than the board meetings, the Chairman of the Board and CEO maintain 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 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

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

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

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

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

Pension shall be premium based. Variable cash remuneration shall not qualify for pension benefits. For the CEO and other executives, the premium may, in situations where premium-based pension is applicable, amount to a maximum of 30 percent of the annual fixed cash salary. Notwithstanding the above, the Board of Directors is entitled to offer other solutions which, in terms of cost, are equivalent to the above. Executives may be awarded customary other benefits, such as company car, occupational health service, etc. Such other benefits may amount to not more than 15 percent of the fixed annual cash salary.

Long-term share-related incentive plans for employees, consultants and certain board members have been implemented in Calliditas. Such plans have been resolved by the general meeting and are therefore excluded from these guidelines. The long-term share-related incentive plan resolved upon by the extraordinary general meeting 2020 is excluded for the same reason. 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.

To the extent a board member conducts work for Calliditas, in addition to the board work, consulting fees and other compensation for such work may be payable.

For employments governed by rules other than Swedish, pension benefits and other benefits may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of these guidelines.

Salary and employment conditions for employees

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

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

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

Derogation from the guidelines

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

Risk Management

Calliditas' Board of Directors and management work continuously to identify and assess risks for the Groups' 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 finan-

cial 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 operation is research and development of pharmaceuticals, which is a field that is both high-risk and very capital intensive. Calliditas has one product candidate, Nefecon, for the treatment of IgA nephropathy and there is a risk that the project will never reach market registration due to the risk of insufficient efficacy or the presence of unwanted side effects. Even after the launch of pharmaceuticals, the market registration can be revoked if side effects arise.

Calliditas is conducting clinical trials concerning its product candidate Nefecon. Clinical trials are costly and time consuming and subject to risks that include difficulties finding clinics, difficulties in recruiting suitable patients, costs per patient exceeding budget and shortcomings in conducting the trials by clinics taking part in the study. Nefecon is a drug candidate with orphan designation in IgA nephropathy. The number of suitable patients for clinical trials is therefore lower than for common diseases and it may be challenging for Calliditas to enroll patients to conduct the Phase 3 study.

If competing pharmaceuticals gain market shares or competing research projects achieve greater efficacy and reach the market faster, the future value of the product portfolio may be lower than anticipated. Patent applications submitted by Calliditas may not be approved and approved patents may be cancelled, which may lead to Calliditas losing patent protection. Operations are also impacted by official decisions, such as approvals and price changes. There is an ongoing political debate about perceived excessive pricing of orphan drugs, particularly in the United States. There is a risk that new rules may have an adverse effect on orphan drug pricing moving forward.

There is also a risk related to manufacturing the product, where the chosen manufacturer may experience problems in delivering sufficient quality and/or quantity or lose the required manufacturing permits.

Part of Calliditas' strategy is to assess the potential to develop products in other indications. However, Calliditas is yet to conduct any clinical trials. Conducting clinical trials is always associated with risks related to carrying out the trial, the result and approval by the supervisory authorities and consequently it is currently uncertain whether Calliditas' ambition to develop products for the treatment of other indications will be realized.

COVID-19

A novel strain coronavirus, now known as COVID-19, has rapidly spread from an initial event in Wuhan, China, and infections have been reported globally. Calliditas have clinical trial sites in the NefIgArd trial based in areas currently affected by this coronavirus. Calliditas has not yet experienced any major disturbances in the NefIgArd trial, but expects to see an impact as the present situation continues and potentially deteriorates further. The extent to which the coronavirus impacts the operations and the NefIgArd trial will depend on the type, degree and duration of the various restrictions put in place to contain the virus or treat those affected. This today varies in different geographies, and future developments cannot be predicted with reasonable assurance.

The pandemic may negatively impact our trial 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. Moreover, as a result of coronavirus, there is a general unease in many affected countries of conducting any trial-related activities in medical centers which may cause a delay in recruitment for the Part B of the NefIgArd trial.

It is too early to assess the full impact of the coronavirus outbreak for Calliditas, but the continued spread of the coronavirus globally, may negatively impact our operations, including our trials. It could also negatively affect the operations of key governmental agencies, such as the FDA and EMA, which may delay the development 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 drawn up by the Board of Directors and creates a framework of guidelines and rules in the form of a risk mandate and limits for financial activities. Calliditas is primarily impacted by foreign-currency risk. Most of Calliditas' future costs are in U.S. dollar and Euro. In compliance with the financial policy, currency options have been used during 2019. The financial policy is updated at least once annually.

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 since all operations in the Group are conducted in the Parent Company. 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, 2019 and December 31, 2018, the Parent Company had a net loss of SEK 36.2 million and SEK 131.9 million, respectively.

The Parent Company had cash of SEK 752.4 million and SEK 645.9 million as of December 31, 2019 and 2018, respectively.

Outlook

Calliditas' candidate drug Nefecon has substantial market potential. The product is currently in a clinical Phase 3 trial that may provide a basis for market approval in the event of positive results. Part A of the registration-based Phase 3 study was fully recruited in December 2019 and top-line data is expected during the fourth quarter of 2020. Operations are capital intensive and until Nefecon begins to generate revenue, external financing will be required. In 2019, a new share issue was conducted yielding proceeds of SEK 210.3 million before issue costs and conditions are therefore favorable for Calliditas to conclude the ongoing Phase 3 trial and to apply for market approval. The project commands therefore a substantial market value at present.

Proposed appropriation of the company's earnings

Proposed appropriation of earnings

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

Share premium reserve	1,268,333,646
Retained earnings	(448,989,755)
Net loss for the year	**(36,185,923)**
	783,157,968

The Board of Directors proposes that SEK 783,157,968 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 be paid for the 2019 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, 2019	2018
Net sales	3	184,829	-
Research and development expenses	9,10	(149,826)	(99,260)
Administrative and selling expenses	6,8,9,10	(62,882)	(31,132)
Other operating income	4	4,385	-
Other operating expenses	5	(4,525)	(2,090)
Operating loss	7	**(28,019)**	**(132,482)**
Financial income	11	926	441
Financial expenses	12	(5,408)	(8)
Loss before income tax		**(32,501)**	**(132,049)**
Income tax expense	13	(77)	-
Loss for the year attributable to shareholders of the Parent Company		**(32,578)**	**(132,049)**
Loss per share before and after dilution	14	(0.88)	(5.09)

Consolidated Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31, 2019	2018
Loss for the year		(32,578)	(132,049)
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	19,23	(11)	(6)
Total other comprehensive income/(loss)		**(11)**	**(6)**
Total comprehensive loss attributable to shareholders of the Parent Company		**(32,589)**	**(132,043)**

Group

Consolidated Statements of Financial Position

(SEK in thousands)	Note	December 31, 2019	2018
ASSETS			
Non-current assets			
Intangible assets	15	16,066	-
Equipment	16	104	107
Right-of-use assets	8	5,959	-
Non-current financial assets	17,18,27	1,939	341
Total non-current assets		**24,068**	**448**
Current assets			
Accounts receivables	19	46,586	-
Other current assets	18	2,719	1,630
Prepaid expenses	20	18,287	164
Cash	21	753,540	646,175
Total current assets		**821,132**	**647,969**
TOTAL ASSETS		**845,200**	**648,417**
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders equity	23		
Share capital		1,548	1,408
Additional paid-in capital		1,274,664	1,072,319
Reserves		(45)	(34)
Retained earnings including net loss for the year		(488,096)	(455,518)
Total equity attributable to shareholders of the Parent Company		**788,071**	**618,175**
Non-current liabilities			
Provisions	24	175	-
Other non-current liabilities	8,18	3,584	-
Total non-current liabilities		**3,759**	**-**
Current liabilities			
Accounts payable	18,19	24,384	22,643
Current tax liabilities		77	-
Other current liabilities	8,18	3,394	904
Accrued expenses and deferred revenue	25	25,515	6,695
Total current liabilities		**53,370**	**30,242**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**845,200**	**648,417**

Group

Consolidated Statements of Changes in Equity

(SEK in thousands, except per share amounts)	Note	Share Capital	Additional Paid-in Capital	Translation Reserve	Retained Earnings Including Net Loss for the Year	Total
Opening shareholders equity January 1, 2018		**667**	**352,959**	**(40)**	**(320,410)**	**33,176**
Loss for the year		-	-	-	(132,049)	(132,049)
Other comprehensive income/(loss)		-	-	6	-	6
Total comprehensive income/(loss)		**-**	**-**	**6**	**(132,049)**	**(132,043)**
Transactions with owners:						
New share issue		741	737,909	-	-	738,650
Cost attributable to new share issue		-	(54,433)	-	-	(54,433)
Premiums received from warrants	*10*	-	2,826	-	-	2,826
Contributions from shareholders	*23*	-	29,999	-	-	29,999
Interest from capital contributions from shareholders	*23*	-	3,059	-	(3,059)	-
Total transactions with owners		**741**	**719,360**	**(-)**	**(3,059)**	**717,042**
Closing shareholders equity December 31, 2018		**1,408**	**1,072,319**	**(34)**	**(455,518)**	**618,175**
Opening shareholders equity January 1, 2019		**1,408**	**1,072,319**	**(34)**	**(455,518)**	**618,175**
Loss for the year		-	-	-	(32,578)	(32,578)
Other comprehensive income/(loss)		-	-	(11)	-	(11)
Total comprehensive income/(loss)		**-**	**-**	**(11)**	**(32,578)**	**(32,589)**
Transactions with owners:						
New share issue		140	210,177	-	-	210,317
Cost attributable to new share issue		-	(10,915)	-	-	(10,915)
Premiums received from warrants	*10*	-	2,834	-	-	2,834
Share-based payments	*10*	-	249	-	-	249
Total transactions with owners		**140**	**202,345**	**(-)**	**(-)**	**202,485**
Closing shareholders equity December 31, 2019	*10,23*	**1,548**	**1,274,664**	**(45)**	**(488,096)**	**788,071**

Equity is fully attributable to the shareholders of the Parent Company.

Group

Consolidated Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31, 2019	2018
Operating activities			
Operating loss		(28,019)	(132,482)
Adjustments for non-cash items	*21*	2,308	51
Interest received		926	6
Interest paid		(325)	(8)
Cash flow from operating activities before changes in working capital		**(25,110)**	**(132,433)**
Cash flow from changes in working capital			
Changes in operating receivables		(53,546)	2,642
Changes in operating liabilities		7,645	1,600
Cash flow from operating activities		**(71,011)**	**(128,191)**
Investing activities			
Purchase of equipment	*16*	(118)	-
Investments in non-current financial assets	*17*	(1,888)	-
Purchase of intangible assets	*15*	(16,066)	-
Cash flow from investing activities		**(18,072)**	**–**
Financing activities			
New share issue		210,317	738,650
Cost attributable to new share issue		(10,915)	(54,433)
Repayment of loans		(1,652)	(470)
Premiums received from warrants		2,834	2,826
Transaction costs, paid		(1,748)	-
Contributions from shareholders		-	29,999
Cash flow from financing activities		**198,835**	**716,572**
Net increase (decrease) in cash		**109,752**	**588,381**
Cash at beginning of the year		**646,175**	**57,352**
Exchange-rate difference in cash		(2,387)	442
Cash at the end of the year	*21*	**753,540**	**646,175**

Group

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, 2019 and December 31, 2018. 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, 2019, Calliditas is the Parent Company of three wholly owned subsidiaries located in Sweden, Norway and in the United States. The Swedish subsidiary is Nefecon AB and the Norwegian subsidiary is Pharmalink Oncology AS. There were no operating activities in these subsidiaries. During February 2019, the Group established a new subsidiary in the United States (Calliditas Therapeutics Inc.) and during May 2019, the Group completed a merger of Busulipo AB and Pharmalink Nordic AB with the Parent Company.

The Board of Directors (the "Board") approved, and authorized for issuance, these consolidated financial statements on April 27, 2020, which will be presented for adoption at the Annual General Meeting on June 25, 2020.

New Issue and Listing on Nasdaq Stockholm

In July 2019, Calliditas completed a directed new share issue of 3.5 million shares for gross proceeds of SEK 210,317, before issuance costs of SEK 10,915.

On June 29, 2018, the Parent Company was listed on the main list of Nasdaq Stockholm and completed a share issue, which included the over-allotment option amounting to SEK 738,650, before issuance costs of SEK 54,433.

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), 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 at December 31, 2019. 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 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
The Group applied for the first time the new and amended standards and interpretations to be applied for the financial year beginning on or after January 1, 2019. The nature and effect of the changes as a result of adoption of the new accounting standards are described below. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

IFRS 16 Leases
From January 1, 2019, IFRS 16 supersedes IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases — Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to recognize most leases on the consolidated statement of financial position.

The Group adopted IFRS 16 using the modified retrospective method of adoption, meaning that comparative information of previous periods is not presented. The lease liability consists of the discounted remaining lease payments as of January 1, 2019. The right-of-use assets contains all agreements to an amount corresponding to the lease liability adjusted by the amount of any prepaid or accrued lease payments recognized in the consolidated statement of financial position at the date of initial application. Therefore, the transition to IFRS 16 had no effect on equity.

The Group's material lease agreements consist of leased premises. At the transition to IFRS 16, the Group's statement of financial position increased by the right-of-use assets and lease liabilities in the Group's consolidated statement of financial position. Prior to the adoption, lease payments were recognized as administrative expenses in the consolidated statement of income. The presentation of these expenses in the consolidated statement of income in the period prior to adoption was not changed. Subsequent to adoption, lease expenses consist of depreciation on the right-of-use assets, which are recognized as an administrative expense, and interest on the lease liability, which is recognized as a financial expense. Lease payments are recorded as a reduction of the lease liability to the extent they exceed the interest expense. Agreements that ended in 2019, but which originally had a maturity exceeding 12 months, have been taken into account in the calculation of lease liability and right-of-use asset. The Group applies recognition exemptions for lease agreements that, at the commencement date, have a lease term of 12 months or less (short-term lease), and lease agreements for which the underlying asset is of low value (lease of low-value assets). Lease of low-value assets consists mainly of storage and copiers. When assessing the agreements length when there are extension and termination options, both business strategy and contract-specific conditions are considered to determine if the Group is reasonably certain to utilize them. With regard to identified non-leasing components in a leasing agreement, the Group applied the main rule in IFRS 16, i.e. to recognize them separately from the leasing component.

At the transition to IFRS 16, all remaining lease payments have been calculated at present value using the Group's incremental borrowing rate. The weighted-average borrowing rate as of January 1, 2019 was 5.05 percent.

The effect of adopting IFRS 16 is as follows:

	December 31, 2018	Adjustments	January 1, 2019
Assets			
Non-current assets			
Equipment	107	-	107
Right-of-use assets	-	1,819	1,819
Non-current financial assets	341	-	341
Total non-current assets	*448*	*1,819*	*2,267*
Current assets	*647,969*	*-*	*647,969*
Total assets	**648,417**	**1,819**	**650,236**
Shareholders' equity and liabilities			
Shareholders' equity	*618,175*	*-*	*618,175*
Other non-current liabilities	-	1,290	1,290
Current liabilities			
Accounts payable	22,643	-	22,643
Other current liabilities	904	529	1,433
Accrued expenses	6,695	-	6,695
Total current liabilities	*30,242*	*529*	*30,771*
Total Shareholders' equity and liabilities	**648,417**	**1,819**	**650,236**

As a result of the transition to IFRS 16, the Group's assets and liabilities increased by SEK 1,819 as of January 1, 2019.

Reconciliation of operational lease commitments:

Commitments for operating leases as of December 31, 2018	**1,983**
Discounting effects	(164)
Recorded leasing liabilities as per January 1, 2019	**1,819**

For additional information concerning the transition to IFRS 16 see Note 8 Leases.

IFRIC 23 Uncertainty over Income Tax Treatment
The Interpretation addresses the accounting for income taxes when tax treatments involve uncertainty that affects the application of income taxes and is applied from January 1, 2019. The interpretation has not had any significant effects on the Group's financial statements.

Other new or amended standards or interpretations published by the IASB are not expected to have a significant impact on the Group's financial statements.

Change in Accounting Principle
From January 1, 2019, the Group has switched to presenting costs in the consolidated statement of income based on function instead of cost by nature. The purpose of the change is to provide more relevant information about the Group's financial results, as a function-divided presentation better reflects the practice in the industry in which the Group operates. The change constitutes a voluntary change of accounting principle and has been applied retrospectively. Accordingly, the Group has conformed to current year presentation the consolidated statement of income for the year ended in December 31, 2018 to reflect the changes adopted for the year ended December 31, 2019. The change in accounting principle had no effect on the Group's consolidated statement of financial position, results of operations, or liquidity. Below are the effects of the previously issued consolidated statement of income that were reclassified for the year ended December 31, 2018 in the Group:

	Year Ended December 31, 2018		
	Before adjustments	Adjustments	After adjustments
Research and development expenses	-	(99,260)	(99,260)
Administrative and selling expenses	-	(31,132)	(31,132)
Other operating income	715	(715)	-
Other operating expenses	-	(2,090)	(2,090)
Other external expenses	(114,056)	114,056	-
Personnel cost	(19,090)	19,090	-
Depreciation	(51)	51	-
Total operating expenses	**(132,482)**	**-**	**(132,482)**

Revenue
The Group recognizes revenue as the identified performance obligations are performed. The Group's revenue for the financial year relates to the out-licensing of intellectual property rights. Revenue for out-licensing is recognized at a point in time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreement with Everest Medicines was signed. 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. Revenue attributable to the supply of drug is recognized at a point in time when the control of the goods is transferred to the counterparty.

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. Swedish research and development tax credits on social security costs are recorded as an offset to research and development expenses.

Notes to Consolidated Financial Statements – Group

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

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's pension obligations consist solely of defined-contribution 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.

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 warrant programs and a performance-based share award program, 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 warrants is determined at the allotment date using the Black-Scholes model for pricing of warrants. 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.

Until December 31, 2018, the Group classified leasing as operational, meaning leases whereby the lessor essentially retains all risks and rewards associated with ownership of the asset. Any incentives received when signing leases were included in the calculation of the total expense of the agreement. Lease payments were expensed through the statement of income on a straight-line basis over the contract period.

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 is currently three years for the Group's only lease.

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 (see Note 8 Leases and 18 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 subsidiaries that are not expected to be reversed in the foreseeable future are not taken into account.

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. 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.

Licenses and similar rights
The Group has acquired licenses and similar rights connected to the product candidate Budenofalk 3 mg. Since the asset has been separately acquired, it has been recognized as an intangible asset in the consolidated statement of financial position.

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.

Research and development expense
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 – 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
Since amortization has not yet begun for intangible assets, the Group assesses for impairment at each reporting date, or when there is an indication that an asset may be impaired. Equipment that is amortized 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 valuation 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 for the next 15 years from commercialization and does not include calculation of any residual value thereafter. The valuation is a Level 3-valuation and the essential assumptions will be specified, but the most critical assumptions mainly consist of assumptions about the size, market share and probability of the market.

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
Financial liabilities at amortized costs are initially measured at fair value, net after transaction costs. Subsequently periods are measured at amortized cost using the effective interest (EIR) method.

The Group's financial liabilities (accounts payable and other current liabilities) are recognized at amortized cost.

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 19 Financial Risks for information on considerations relating to accounts receivable and deposits.

Notes to Consolidated Financial Statements – Group

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

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. During the year ended December 31, 2018, Calliditas raised mandatory convertible bridge loans with required conversion classified as equity in the Group's statement of financial position. Interest expenses on the bridge loans is recorded in equity as a transfer from additional paid-in capital to retained earnings.

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 an addition to equity, based on the warrant premium, at the date when the warrant was transferred to the counterparty.

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 other 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 and non-current assets are attributable only to Swedish companies and are all located in Sweden.

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.

i. 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, 2019 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 has not yet been obtained for any products and, accordingly, the conditions for capitalizing development expenditures are not met.

ii. 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, 2019. 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.

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 during the year consisted of revenues for the out-licensing of Nefecon within the framework of the agreement with Everest Medicines to Greater China and Singapore. Revenue for out-licensing is recognized at a point in time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreement with Everest Medicines was signed. Furthermore, the Group recognized revenue in connection with variable remuneration when the criteria for a regulatory milestone was met, which was in connection with the approval of Everest Medicines IND (Investigational New Drug application) for Nefecon in China.

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 share of the transaction amount attributable to the supply of the drug for clinical trial has not been recognized as revenue and has been measured by the acquisition price based on the cost of the goods, plus a fair market margin. The proportion attributable to out-licensing has been measured as a residual of the remaining transaction price after deduction of other performance obligations, since the product candidate has not been approved for market by the regulatory authorities and no commercial pricing occur.

The Group's remaining performance obligations relate to future deliveries of study-related drugs within the framework of the licensing agreement with Everest Medicine amounting to SEK 874, which is recognized as deferred revenue in the Group's statement of financial position. See also Note 25 Accrued Expenses and Deferred Revenue. The performance obligations are expected to be satisfied during 2020 – 2021 when the drug will be delivered within the framework of Everest Medicine's study.

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

	Year Ended December 31,	
	2019	2018
Type of goods or service		
Out-licensing	184,829	-
Total	**184,829**	**-**
Geographical markets		
China, Hong Kong, Macau, Taiwan and Singapore	184,829	-
Total	**184,829**	**-**

Note 4 Other Operating Income

	Year Ended December 31,	
	2019	2018
Exchange rate differences	4,385	-
Total	**4,385**	**-**

Note 5 Other Operating Expenses

	Year Ended December 31,	
	2019	2018
Exchange rate differences	4,465	2,090
Net loss on disposal of equipment	61	-
Total	**4,525**	**2,090**

Note 6 Auditors' Fee

	Year Ended December 31,	
	2019	2018
Ernst & Young AB		
Audit services	645	509
Other audit activities	3,343	1,861
Other services	98	-
Total	**4,086**	**2,370**

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 per Cost Type

	Year Ended December 31,	
	2019	2018
Other external expenses	176,729	111,251
Personnel costs	34,157	19,090
Depreciation on equipment's and right-of-use assets	1,822	51
Other operating expenses	4,525	2,090
Total	**217,233**	**132,482**

Notes to Consolidated Financial Statements – Group

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

Note 8 Leases

At the transition to IFRS 16, the Group's right-of-use assets and lease liabilities increased by SEK 1,819 as of January 1, 2019. See Note 1 Significant Accounting Policies. Further, due to the adoption of IFRS 16, the Group's operating loss decreased by SEK 196 for the year ended December 31, 2019, and the Group's net loss for the year increased by SEK 111, compared with the corresponding accounting policies from the previous year if they had been applied.

The effect of adopting IFRS 16 is as follows:

Impact on the consolidated statement of income (increase/ (decrease)) at the year ended December 31, 2019

	According to Prior Principles	Effect of IFRS 16	Year Ended December 31, 2019
Net sales	184,829	-	184,829
Research and development expenses	(149,826)	-	(149,826)
Administrative and selling expenses	(63,078)	196	(62,882)
Other operating income	4,385	-	4,385
Other operating expenses	(4,525)	-	(4,525)
Operating loss	*(28,215)*	*196*	*(28,019)*
Financial income	926	-	926
Financial expenses	(5,101)	(307)	(5,408)
Income tax expense	(77)	-	(77)
Loss for the year	**(32,467)**	**(111)**	**(32,578)**

Impact on the consolidated statement of financial position (increase/(decrease)) as per December 31, 2019:

	According to Prior Principles	Effect of IFRS 16	December 31, 2019
Assets			
Non-current assets			
Intangible assets	16,066	-	16,066
Equipment	104	-	104
Right-of-use assets	-	5,959	5,959
Non-current financial assets	1,939	-	1,939
Total non-current assets	*18,109*	*5,959*	*24,068*
Current assets	821,132	-	821,132
Total Assets	**839,241**	**5,959**	**845,200**
Total Shareholders' Equity & Liabilities			
Shareholders' equity	*788,182*	*(111)*	*788,071*
Non-current liabilities			
Provisions	175	-	175
Other non-current liabilities	-	3,584	3,584
Total non-current liabilities	*175*	*3,584*	*3,759*
Current liabilities			
Accounts payable	24,384	-	24,384
Current tax liabilities	77	-	77
Other current liabilities	908	2,486	3,394
Accrued expenses and deferred revenue	25,515	-	25,515
Total current liabilities	*50,884*	*2,486*	*53,370*
Total Shareholders' Equity & Liabilities	**839,241**	**5,959**	**845,200**

Right-of-use assets

	December 31,2019
Cost	
At January 1, 2019	1,819
Additional agreements	7,527
Termination of agreement	(1,819)
At December 31, 2019	**7,527**
Depreciation	
At January 1, 2019	-
Depreciation	(1,778)
Termination of agreement	210
At December 31, 2019	**(1,568)**
Net book value	**5,959**

Depreciation on right-of-use assets are included in the consolidated statement of income under Administrative and selling expenses amounted to SEK 1,778.

Lease liabilities

	December 31,2019
At January 1, 2019	1,819
Additional agreements	7,527
Termination of agreement	(1,624)
Amortization	(1,652)
At December 31, 2019	**6,070**

Maturity analysis on future lease liabilities

	December 31,2019
<12 months	3,816
1-2 years	2,306
>2 year	533
	6,655

Changes in liabilities arising from financing activities, see Note 21 Cash for further information on leasing liabilities.

This year's leases consist of leased premises. During the year, a reassessment of the agreement was performed when the lease was terminated prematurely. The Group also entered into additional agreements pertain to lease agreements for premises with a contract period until May 31, 2022. The lease agreement can be extended by three years unless one of the parties terminates the lease agreement at least nine months before. The Group cannot determine with reasonable certainty whether the extension will take place based on the Group's development and has therefore not expected utilization after May 2022. 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 copiers.

	Year Ended December 31,2019
Interest expenses attributable to lease liabilities	307
Expenses attributable to short-term lease	265
Expenses attributable to leasing agreements with low value	96
Expenses attributable to variable lease payments that are not included in lease liabilities	187
This year's lease payments in the Group	2,343

Notes to Consolidated Financial Statements – Group

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

Note 9 Employees and Personnel Costs

Average Number of Employees

	Year Ended December 31,			
	2019		2018	
	Number of Employees	Percentage of Male Employees	Number of Employees	Percentage of Male Employees
Parent Company				
Sweden	13	38%	10	30%
	13	**38%**	**10**	**30%**
Subsidiaries				
United States	1	100%	-	-
	1	**100%**	**-**	**-**
Total for the Group	**14**	**43%**	**10**	**30%**

Wages and salaries, pension costs and social security costs to the Board, senior executives and other employees

Wages and Salaries

	Year Ended December 31,	
	2019	2018
Parent Company		
Board and senior executives[1)]	13,109	9,875
Other employees	6,091	3,789
Subsidiaries		
Board and senior executives	2,973	-
Total	**22,173**	**13,664**

[1)] *Senior executives includes the Board, CEO and other senior executives.*

Social Security Costs and Pension Costs

	Year Ended December 31,	
	2019	2018
Parent Company		
Pension costs for the Board and senior executives	1,644	1,429
Pension costs to other employees	1,180	699
Social security costs	3,008	2,843
Subsidiaries		
Social security expenses	299	-
Total	**6,131**	**4,971**

Gender Distribution Among the Board and Senior Executives

	Year Ended December 31,	
	2019	2018
Percentage of women on the Board	33%	33%
Percentage of men on the Board	67%	67%
Percentage of women among other senior executives	33%	43%
Percentage of men among other senior executives	67%	57%

Disclosures Regarding Total Remuneration of The Board and Senior Executives

	Year Ended December 31, 2019					
	Base 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
Senior executives						
CEO	2,634	510	956	-	-	4,100
Other senior executives (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**

	Year Ended December 31, 2018					
	Basic Salary, Board Fee	Pension Costs	Variable Remuneration	Other Remuneration	Share-based Payments	Total
Chairman of the Board						
Thomas Eklund	413	-	-	-	-	413
Board members [1)]						
Olav Hellebø	160	-	-	-	-	160
Hilde Furberg	173	-	-	-	-	173
Senior executives						
CEO	2,462	456	692	-	-	3,610
Other senior executives (7 people)	5,301	973	674	6,001	-	12,949
Total	**8,509**	**1,429**	**1,366**	**6,001**	**-**	**17,305**

[1)] *Bengt Julander and Lennart Hansson received no reimbursement for 2018.*

Other Remuneration
Other remuneration comprises of fees for services rendered to the Parent Company. Management services purchased from Jedako Consult AB amounted to SEK 3,848 (SEK 3,425) and relate to the functions of a Chief Medical Officer that were outsourced to this entity. Management services purchased from Cordcom Consultants KB amounted to SEK 853 (SEK 951) and relate to the functions of a Head of Communications and Investor Relations that were outsourced to this entity. Management services purchased from Skepparhagen AB amounted to SEK 0 (SEK 1,625).

Remuneration of Senior Executives
Remuneration of the CEO and other senior executives comprises base salary, pension benefits, variable remuneration and remuneration in the form of consultancy fees. Other senior executives comprise the eight individuals who, together with the CEO, comprise Executive Management. Other senior executives are: Chief Financial Officer, Chief Medical Officer, Vice President North America Commercial, Vice President Regulatory Affairs, Chief Scientific Officer, VP Project Management, VP Pharmaceutical Development and Head of Communications and Investor Relations.

Pensions
All pension commitments are defined-contribution plans. 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 senior executives are between 15% and 20% of base salary. The age of retirement is 65 for all other senior executives. 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 senior executives is 40% according to the guidelines for remuneration to senior executives.

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 senior executives. No severance pay is paid to Board members.

Guidelines for Executive Remuneration
At the 2019 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 40 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.

Notes to Consolidated Financial Statements – Group

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

Note 10 Share-Based Payments

Warrants
The Group has three 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 program initiated in 2017, the warrants can be exercised at any time until their expiration date without having to fulfill any conditions, while the programs initiated in 2018 and 2019 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 program initiated in 2017, quoted prices were not available to use when calculating volatility. The volatility was then based on a calculated average for comparable listed companies. 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 2017/2020
In 2017, a total of 1,296,500 warrants were issued to certain Board members, employees and key consultants in the Group. The warrants in the warrants program 2017/2020 can be exercised continuously up to and including June 30, 2020, where each warrants entitle the participant to subscribe for a new share in the company at a subscription price of SEK 42.36 per share.

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
On December 31, 2018	2,518,086	56
On December 31, 2019	2,575,586	58

The allocated weighted-average exercise price for warrants that are outstanding on the opening and closing date amounts to SEK 56 and SEK 58, respectively. During 2019, 365,000 warrants in Warrant program 2015/2019 expired without exercise.

	Warrants Outstanding as of		Inputs used for the Black & Scholes valuation					
Outstanding Warrants per Year	December 31, 2018	December 31, 2019	Exercise Price, SEK	Price per Warrant in SEK	Value per Share in SEK	Risk-Free Rate	Volatility	Expiration Date
Warrant program 2015/2019[1)]	365 000	-						Apr 30, 2019
Warrant program 2017/2020	1,296,500	1,296,500	42.36	0.28	21.18	(0.42)%	27%	Jun 30, 2020
Warrant program 2018/2022	856,586	856,586	74.30	3.29	46.50	(0.28)%	33%	Mar 31, 2022
Warrant program 2019/2022	-	422,500	74.50	6.69*	54.39*	(0.55)%*	36%*	Dec 31, 2022
Total	**2,518,086**	**2,575,586**						

[1)] *Warrant program 2015/2019 meets the definition of equity instruments since no vesting period or other features that required any future service from the employees exist.*
** Average value*

Changes and holdings of warrants for the Board, CEO, other senior executives and other employess and consultants on the opening and closing date are presented below.

	Warrants Outstanding as of				
Holder	January 1, 2018	Change	December 31, 2018	Change	December 31, 2019
CEO Renée Lucander	369,500	350,000	719,500	195,000	914,500
Board member Thomas Eklund	111,250	0	111,250	0	111,250
Board member Hilde Furberg	29,500	0	29,500	0	29,500
Other senior executives	538,500	188,586	727,086	107,500	834,586
Other employees, consultants and external parties	612,750	318,000	930,750	(245,000)	685,750
Total	**1,661,500**	**856,586**	**2,518,086**	**57,500**	**2,575,586**

Share-based payments
Board LTIP 2019
This is a performance-based long-term incentive program for some members of the Board of Directors in Calliditas. A total of 57,032 share rights have been granted under the program during the year of 2019. The share rights are gradually vested over three years until the AGM 2022 or June 1, 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 rights 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 rights 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 rights shall be earned, and if the share price has increased by 20 percent, 33 percent of the share rights 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 right 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.

The Board's holding of share awards as of the closing day is shown below.

	Share Awards Outstanding as of				
Holder	January 1, 2018	Change	December 31, 2018	Change	December 31, 2019
Elmar Schnee, Chairman of the Board	-	-	-	23,236	23,236
Thomas Eklund, Board member	-	-	-	8,449	8,449
Hilde Furberg, Board member	-	-	-	8,449	8,449
Lennart Hansson, Board member	-	-	-	8,449	8,449
Diane Parks, Board member	-	-	-	8,449	8,449
Total	**-**	**-**	**-**	**57,032**	**57,032**

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).

	Grant Date	Exercised Date	Fair Value at Grant Date	Number of Share Awards
Board LTIP 2019	May 10, 2019	June 1, 2022	22.49	57,032

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 23 Shareholders' Equity.

	Year Ended December 31,	
	2019	2018
Personnel cost, IFRS 2 Share-based payments	249	-
Provisions attributable to social security costs, IFRS 2 Share-based payments	175	-
	424	**-**

Note 11 Financial Income

	Year Ended December 31,	
	2019	2018
Interest income	929	6
Exchange rate differences	-	435
Total	**926**	**441**

Note 12 Financial Expenses

	Year Ended December 31,	
	2019	2018
Interest on lease liabilities	(307)	-
Other interest expenses	(18)	(8)
Exchange rate differences	(2,383)	-
Changes in FX options measured at fair value	(2,700)	-
Total	**(5,408)**	**(8)**

Notes to Consolidated Financial Statements – Group

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

Note 13 Income Tax

	Year Ended December 31,	
	2019	2018
Current income taxes	(77)	-
Income tax expense recorded in the statement of income	**(77)**	**-**
Reconciliation of effective tax rate		
Accounting loss before income tax	(32,501)	(132,049)
Tax in accordance with applicable tax rate in Sweden 21,4% (22%)	6,955	29,051
Effect of other tax rates for foreign subsidiaries	2	-
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(6,316)	(29,069)
Non-deductible expenses	(782)	(35)
Non-taxable income	64	53
Income tax expense recorded in the statement of income	**(77)**	**-**
At the effective income tax rate	**0%**	**0%**

The Group has costs attributable to new share issue amounted to SEK 10,915, which are recognized directly against equity. These costs are however deductible for tax purposes, despite not being charged against the statement of income.

As of December 31, 2019, the Group has SEK 578,117 (SEK 535,802) of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

Note 14 Earnings Per Share

	Year Ended December 31,	
	2019	2018
Loss per share before and after dilution		
Net loss for the year attributable to shareholders of the Parent Company	(32,578)	(132,049)
Weighted-average number of common shares outstanding	36,940,587	25,948,037
Loss per share before and after dilution	**(0.88)**	**(5.09)**

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 2017 – 2019. 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 with entitlement to subscribe to 2,575,586 shares and 2,518,086 shares, since the Group is in a loss position for the years ended December 31, 2019 and December 31, 2018, respectively. Further, there is no dilution effect for issued share awards with entitlement to receive 57,032 shares, due to performance-based vesting for the year ended December 31, 2019.

For disclosures regarding the number of outstanding shares, refer to Note 23 Shareholders' Equity.

Note 15 Intangible Assets

	December 31,	
	2019	2018
Licenses and similar rights		
Cost at opening balance	-	-
Acquisition for the year	16,066	-
Cost at closing balance	**16,066**	**-**
Amortization at closing balance	**-**	**-**
Net book value	16,066	-

Acquisition during the year
The Group licensed Budenofalk 3 mg oral capsule from the German pharmaceutical company Dr Falk Pharma GmbH, for development in the United States. The agreement covers all indications for the United States, excluding orphan indications who are not liver related. The Group paid an initial payment of EUR 1.5 million for the license. In addition, one-off payments, which are paid if certain regulatory milestones are achieved and if potential future sales reach certain predetermined milestones, totaling EUR 38.5 million may be paid together with royalties on future sales.

The initial payment of EUR 1.5 million (SEK 16,066) has been recognized as an intangible asset according to IAS 38. The Group will include future one-off payments in the acquisition cost if and when a decision has been made to take the measures that triggers additional payment, meaning only payments the Group has control over if they will occur, are included in the acquisition cost of intangible assets.

Note 16 Equipment

	December 31,	
	2019	2018
Cost at opening balance	813	813
Acquisition for the year	118	-
Disposal for the year	(813)	-
Cost at closing balance	**118**	**813**
Depreciation at opening balance	(706)	(655)
Deprecation for the year	(44)	(51)
Disposal for the year	736	-
Depreciation at closing balance	**(14)**	**(706)**
Net book value	**104**	**107**

Depreciation on equipment are included in the consolidated statement of income under Administrative and selling expenses amounted to SEK 44 (SEK 51).

Note 17 Non-Current Financial Assets

	December 31,	
	2019	2018
Cost at opening balance	341	341
Bank guarantees granted	1,888	–
Reimbursement security deposit	(290)	–
Net book value	**1,939**	**341**

Non-current financial assets comprise of bank guarantees/deposits paid of SEK 1,938 (SEK 340).

Note 18 Financial and Non-Financial Assets and Liabilities

Financial and non-financial assets and liabilities at 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				
Fixed assets	-	-	22,129	22,129
Non-current financial assets	-	1,939	-	1,939
Account receivables	-	46,586	-	46,586
Other current assets	399	-	2,320	2,719
Prepaid expenses	-	-	18,287	18,287
Cash	-	753,540	-	753,540
	399	**802,065**	**42,736**	**845,200**

	Financial Liabilities Measured at Amortized Cost	Non-Financial Liabilities	Total Carrying Amount
Liabilities			
Provisions	-	175	175
Non-current lease liabilities	3,584	-	3,584
Accounts payable	24,384	-	24,384
Current lease liabilities	2,486	-	2,486
Other current liabilities	-	985	985
Accrued expenses and deferred revenue	14,837	10,678	25,515
	45,291	**11,838**	**57,129**

Financial and non-financial assets and liabilities at December 31, 2018

	Financial Assets Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Assets			
Equipment	-	107	107
Non-current financial assets	341	-	341
Other current assets	-	1,630	1,630
Prepaid expenses	-	164	164
Cash	646,175	-	646,175
	646,516	**1,901**	**648,417**

	Financial Liabilities Measured at Amortized Cost	Non-Financial Assets	Total Carrying Amount
Liabilities			
Accounts payable	22,643	-	22,643
Other current liabilities	-	904	904
Accrued expenses and deferred revenue	944	5,751	6,695
	23,587	**6,655**	**30,242**

Financial assets valued at fair value through profit or loss consist of currency options amounting to SEK 399 (SEK 0). Currency options are valued based on quoted prices in active markets for similar assets and liabilities at year-end.

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.

Notes to Consolidated Financial Statements – Group

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

Note 19 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,	
	2019	2018
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. The accounts receivable refers to Everest Medicines and is settled after the balance sheet date, see also Note 3 Revenue from Contracts with Customers.

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

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

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

Currency exposure 2018 (%)	Revenue	Operating expenses
USD	-	10%
EUR	-	52%
GBP	-	2%
SEK	-	36%

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 10,246 (SEK 6,006). A 10% stronger U.S. dollar against the Swedish Krona would have a positive impact on profit after tax and equity of approximately SEK 14,359 (neg. SEK 1,115).

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. This translation exposure exists against U.S. dollar and amounted to a loss of SEK 359 on the closing date. A 10% stronger Swedish Krona against the U.S. dollar would have a negative impact on equity of approximately SEK 36.

The Group also has a translation exposure arising from the translation of foreign trade debt to the Swedish Kronor. This exposure amounted to SEK 5,866 (SEK 3,202) at the closing date in U.S. dollars and SEK 14,817 (SEK 15,701) 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 587 (SEK 320). A 10% stronger Euro against the Swedish Krona would have a negative impact on profit after tax and equity of approximately SEK 1,482 (SEK 1,570).

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, 2019		
	<6 months	6-12 months	>12 months
Accounts payable	24,384	–	–
Other current liabilities	908	–	–
Accrued expenses	21,982	2,659	–

	December 31, 2018		
	<6 months	6-12 months	>12 months
Accounts payable	22,643	-	-
Other current liabilities	904	-	-
Accrued expenses	4,409	2,286	-

Note 20 Prepaid Expenses

	December 31,	
	2019	2018
Prepaid rental charges	771	164
Prepaid expenses for research and development	2,854	–
Prepaid transaction costs	14,662	–
Total	**18,287**	**164**

Note 21 Cash

	December 31,	
	2019	2018
Available balances	753,540	646,175
Total	**753,540**	**646,175**

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

Adjustments for non-cash items

	Year Ended December 31,	
	2019	2018
Depreciation	1,822	51
Chage in Provisions	175	–
Share-based payments	249	–
Other	62	–
Total	**2,308**	**51**

Note 21 – Reconciliation of liabilities from financing activities

			Non-Cash-Items		
	January 1, 2019	Cash-Flow	Additional Agreement	Termination of Agreement	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**

			Non-Cash-Items		
	January 1, 2018	Cash-Flow	Interest on Loan	Offsetting of New Shares	December 31, 2018
Shareholder loans	470	(470)	–	–	–
	470	**(470)**	**–**	**–**	**–**

Note 22 Group Companies

Company	Principal Activities	Country of Incorporation	% Equity Interest 2019	% Equity Interest 2018
Parent Company				
Calliditas Therapeutics AB	Research and development of pharmaceuticals	Sweden		
Nefecon AB	Administration of incentive programs issued by the Parent Company	Sweden	100%	100%
Calliditas Therapeutics INC	Pre-commercialization activities in the United States	USA	100%	-
Pharmalink Oncology AS	No activities as of December 31, 2019 and December 31, 2018	Norway	100%	100%

The Group established a new subsidiary in the United States (Calliditas Therapeutics Inc.) and the Group completed a merger of Busulipo AB and Pharmalink Nordic AB with the Parent Company.

Notes to Consolidated Financial Statements – Group

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

Note 23 Shareholders' Equity

Share capital and other contributed capital

	Number of Shares	Share Capital	Additional Paid-in Capital
At January 1, 2018	16,673,000	667	352,959
Premiums received from warrants			2,826
Contributions from shareholders			29,999
Interest from capital contributions from shareholders			3,059
Offset issue approved in June 2018	2,114,903	84	(84)
New share issue[1]	16,414,444	657	683,560
At December 31, 2018	**35,202,347**	**1,408**	**1,072,319**
Premiums received from warrants			2,834
Share-based payment			249
New share issue	3,505,291	140	199,262
At December 31, 2019	**38,707,638**	**1,548**	**1,274,664**

1) Initial public offering on Nasdaq Stockholm exchange in June 2018

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.

Bridge Loans
In connection with the listing on June 29, 2018, all outstanding bridge loans in total SEK 95.2 million, including accrued interest, were converted into shares at a conversion price of SEK 45 per share, which corresponded to the listing price for the Group's share at the Nasdaq Stockholm listing. These loans were subscribed by the company in 2017 and 2018 with a total amount of SEK 91.6 million and an annual interest rate of eight percent with a maturity of twelve months.

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,	
	2019	2018
Balance at January 1	(34)	(40)
Change for the year ended	(11)	6
Balance at December 31	**(45)**	**(34)**

Note 24 Provisions

	December 31,	
	2019	2018
Opening balance	–	–
Provisions for the year	175	–
Total	**175**	**–**

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

Note 25 Accrued Expenses and Deferred Revenue

	December 31,	
	2019	2018
Accrued salaries and Board fees	4,726	2,286
Vacation pay liability	1,904	1,347
Social security costs	2,975	2,098
Accrued expenses for research and development	1,176	944
Deffered revenue	874	-
Other accrued expenses	13,860	20
Total	**25,515**	**6,695**

Other accrued expenses as of December 31, 2019 are mainly attributable to accrued transaction costs of SEK 9,716 and amounts owed to external suppliers of SEK 4,144.

Note 26 Related-Party Transactions

For information regarding remuneration of senior executives, 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 27 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 all products, including Nefecon, if approved, covered by the license granted to us pursuant to our agreement with Archimedes pursuant to which we 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 amounting to SEK 1,938 (SEK 340), which consist of restricted bank accounts of SEK 1,938. The Group has no other obligations.

Note 28 Events After the Reporting Period

In January 2020, our Board of Directors determined to investigate whether there are conditions for a potential offering of the company's securities in the United States and a press release with the title "Calliditas submits draft registration statement for the listing of ADSs in the U.S." was published.

In March 2020, Calliditas held an Extra General Meeting where authorization for board of directors to issue up to 11.0 million new shares for a potential offering and listing in the United States, adoption of new articles of association and adoption of a new incentive program of up to 1.5 million stock options was approved.

Note 29 Key Figure Definitions and Reconciliations of Alternative Performance Measures

Equity ratio	The ratio is calculated by dividing total shareholders' equity by total assets.	The equity ratio measures the proportion of the total assets that are financed by stockholders.
Expenses relating to research and development/ operating expenses, %	The total operating expenses attributable to research and development, divided by the total operating expenses.	The key performance indicator helps the reader of the financial statements to analyse the portion of the company's expenses that are attributable to the Company's core business.

Expenses relating to research and development/operating expenses, %

	Year Ended December 31,	
	2019	2018
Research and development expenses	(149,826)	(99,260)
Administarative and selling expenses	(62,882)	(31,132)
Other operating expenses	(4,525)	(2,090)
Total operating expenses	**(217,233)**	**(132,482)**
Expenses relating to research and development/operating expenses, %	*69%*	*75%*

Equity ratio at the end of the period %

	December 31,	
	2019	2018
Total shareholders' equity at the end of the period	788,071	618,175
Total assets at the end of the period	**845,200**	**648,417**
Equity ratio at the end of the period %	*93%*	*95%*

Parent Company

Statements of Income

(SEK in thousands, except per share amounts)	Note	Year Ended December 31, 2019	2018
Net sales	2	184,829	-
Research and development expenses	7	(149,826)	(99,260)
Administrative and selling expenses	5,6,7	(63,410)	(31,000)
Other operating income	3	4,385	-
Other operating expenses	4	(4,540)	(2,090)
Operating loss		**(28,562)**	**(132,350)**
Profit/(loss) from financial items			
Profit/loss from participations in Group companies	8	(3,439)	(20)
Other interest received and similar items	9	926	454
Interest expense and similar items	10	(5,111)	(7)
Loss before income tax		**(36,186)**	**(131,923)**
Income tax expense	11	-	-
Loss for the year		**(36,186)**	**(131,923)**

Statements of Comprehensive Income

(SEK in thousands)	Note	Year Ended December 31, 2019	2018
Loss for the year		(36,186)	(131,923)
Other comprehensive income/(loss)		-	-
Total comprehensive loss		**(36,186)**	**(131,923)**

Parent Company

Balance Sheet

(SEK in thousands)	Note	December 31, 2019	2018
ASSETS			
Non-current assets			
Intangible Assets			
Licenses and similar rights	12	16,066	-
		16,066	**-**
Tangible Assets			
Equipment	13	104	107
		104	**107**
Non-Current Financial Assets			
Participations in Group companies	14	101	3,489
Other non-current financial assets	15	1,939	341
		2,040	**3,830**
Total non-current assets		**18,210**	**3,937**
Current assets			
Accounts receivables		46,586	-
Other current assets		2,718	1,629
Prepaid expenses	16	18,287	164
		67,591	**1,793**
Cash	17	752,448	645,903
Total current assets		**820,039**	**647,696**
TOTAL ASSETS		**838,249**	**651,633**

Parent Company

Balance Sheet

(SEK in thousands)	Note	December 31, 2019	2018
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity	18		
Restricted shareholders' equity			
Share capital		1,548	1,408
Statutory reserve		3,092	3,092
		4,640	**4,500**
Non-restricted shareholders' equity			
Share premium reserve		1,268,334	1,069,072
Retained earnings		(448,989)	(320,299)
Net loss for the year		(36,186)	(131,923)
		783,159	**616,850**
Total shareholders' equity		**787,799**	**621,350**
Non-current liabilities			
Liabilities to Group companies	22	50	77
Provisions	19	175	-
Total non-current liabilities		**225**	**77**
Current liabilities			
Accounts payable		24,362	22,628
Liabilities to Group companies	22	425	-
Other current liabilities		907	903
Accrued expenses and deferred revenue	20	24,531	6,675
Total current liabilities		**50,225**	**30,206**
TOTAL SHAREHOLDERS EQUITY AND LIABILITIES		**838,249**	**651,633**

Parent Company

Statements of Changes in Shareholders' Equity

(SEK in thousands)	Restricted Shareholders' Equity: Share Capital	Restricted Shareholders' Equity: Statutory Reserve	Non-Restricted Shareholders' Equity: Share Premium Reserve	Non-Restricted Shareholders' Equity: Retained Earnings	Non-Restricted Shareholders' Equity: Net Loss For the Year	Total
Opening shareholders' equity January 1, 2018	**667**	**3,092**	**290,426**	**(171,106)**	**(86,848)**	**36,231**
Transfer of previous year's loss				(86,848)	86,848	-
Loss for the year					(131,923)	(131,923)
Other comprehensive income/(loss)	-	-	-	-	-	-
Total comprehensive income/(loss)	**-**	**-**	**-**	**-**	**(131,923)**	**(131,923)**
Transactions with owners:						
New share issue	741	-	833,079	(95,170)	-	738,650
Cost attributable to new share issue	-	-	(54,433)	-	-	(54,433)
Premiums received from warrants	-	-	-	2,826	-	2,826
Contributions from shareholders	-	-	-	29,999	-	29,999
Total transactions with owners	**741**	**-**	**778,646**	**(62,346)**	**-**	**717,041**
Closing shareholders' equity December 31, 2018	**1,408**	**3,092**	**1,069,072**	**(320,299)**	**(131,923)**	**621,350**
Opening shareholders' 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)	-	-	-	-	-	-
Total comprehensive income/(loss)	**-**	**-**	**-**	**-**	**(36,186)**	**(36,186)**
Profit on merger of subsidiaries				150		150
Transactions with owners:						
New share issue	140	-	210,177	-	-	210,317
Cost attributable to new share issue	-	-	(10,915)	-	-	(10,915)
Premiums received from warrants	-	-	-	2,834	-	2,834
Share-based payments	-	-	-	249	-	249
Total transactions with owners	**140**	**-**	**199,262**	**(3,083)**	**-**	**202,486**
Closing shareholders' equity December 31, 2019	**1,548**	**3,092**	**1,268,334**	**(448,989)**	**(36,186)**	**787,799**

Parent Company

Statements of Cash Flows

(SEK in thousands)	Note	Year Ended December 31, 2019	2018
Operating activities			
Operating loss		(28,562)	(132,350)
Adjustments for non-cash items	17	546	51
Interest received		926	6
Interest paid		(18)	(7)
Cash flow from operating activities before changes in working capital		**(27,108)**	**(132,300)**
Cash flow from changes in working capital			
Changes in operating receivables		(53,546)	2,600
Changes in operating liabilities		7,105	1,618
Cash flow from operating activities		**(73,549)**	**(128,082)**
Investing activities			
Funds acquired from merger with Group companies		72	-
Purchase of equipment	13	(118)	-
Investments in non-current financial assets [1)]	15	(1,888)	-
Purchase of intangible assets	12	(16,066)	-
Cash flow from investing activities		**(18,000)**	**–**
Financing activities			
New share issue		210,317	738,650
Cost attributable to new share issue		(10,915)	(54,433)
Repayment of loans		-	(470)
Premiums received from warrants		2,834	2,826
Transaction costs, paid		(1,748)	-
Contributions from shareholders		-	29,999
Cash flow from financing activities		**200,488**	**716,572**
Net increase (decrease) in cash		**108,939**	**588,490**
Cash at beginning of the year		**645,903**	**56,984**
Exchange-rate difference in cash		(2,394)	429
Cash at the end of the year	17	**752,448**	**645,903**

1) Investments in non-current financial assets consist of bank guarantee provided of SEK 1,888 (SEK 0)

Parent Company

Notes to Financial Statements

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

Note 1 Accounting Policies

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

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

Change in Accounting Principle
From January 1, 2019, the Parent Company has switched to presenting costs in the consolidated statement of income based on function instead of cost by nature. The purpose of the change is to provide more relevant information about the Parent Company's financial results, as a function-divided presentation better reflects the practice in the industry in which the Parent Company operates. The change constitutes a voluntary change of accounting principle and has been applied retrospectively. Accordingly, the Parent Company has conformed to current year presentation the consolidated statement of income for the year ended in December 31, 2018 to reflect the changes adopted for the year ended December 31, 2019. The change in accounting principle had no effect on the Parent Company's consolidated statement of financial position, results of operations, or liquidity. Below are the effects of the previously issued consolidated statement of income that were reclassified for the year ended December 31, 2018 in the Parent Company:

	Year Ended December 31, 2018		
	Before adjustments	Adjustments	After adjustments
Research and development expenses	-	(99,260)	(99,260)
Administrative and selling expenses	-	(31,000)	(31,000)
Other operating income	715	(715)	-
Other operating expenses	-	(2,090)	(2,090)
Other external expenses	(113,927)	113,927	-
Personnel cost	(19,087)	19,087	-
Depreciation	(51)	51	-
Total	**(132,350)**	**-**	**(132,350)**

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
Regardless of the transition to IFRS 16, the Parent Company will continue to apply 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. Therefore, the transition to IFRS 16 had no effect on the Parent Company. Going forward, the Parent Company will 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 by Geographic Market

	Year Ended December 31, 2019	2018
Type of goods or service		
Out-licensing	184,829	-
Total	**184,829**	**-**
Geographical markets		
China, Hong Kong, Macau, Taiwan and Singapore	184,829	-
Total	**184,829**	**-**

Note 3 Other Operating Income

	Year Ended December 31, 2019	2018
Exchange rate differences	4,385	-
Total	**4,385**	**-**

Note 4 Other Operating Expense

	Year Ended December 31, 2019	2018
Exchange rate differences	4,464	2,090
Net loss on disposal of equipment	76	-
Total	**4,540**	**2,090**

Notes to Financial Statements – Parent Company

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

Note 5 Auditors' Fee

	Year Ended December 31,	
	2019	2018
Ernst & Young AB		
Audit services	645	509
Other audit activities	3,343	1,861
Other services	98	-
Total	**4,086**	**2,370**

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 2,508 (SEK 713). Future payment commitments for operating leases as at December 31 are specified as follows:

	Year Ended December 31,	
	2019	2018
Future minimum lease payments		
Within 1 year	3,284	610
Between 1 and 5 years	3,808	1,373
More than 5 years	-	-
Total	**7,092**	**1,983**

Note 7 Employees and Personnel Costs

For salaries and benefits to employees and senior executives 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.

Note 8 Profit/Loss from Participations in Group Companies

	Year Ended December 31,	
	2019	2018
Impairment of participations in Group companies	(3,739)	-
Impairment of receivables within the Group companies	-	(20)
Reversal of impairment of receivables within the Group companies	300	-
Total	**(3,439)**	**(20)**

The Parent Company has written down the value of the shares in the subsidiary Nefecon AB by SEK 3,739, due to the patent related to method and use for treating glomerulonephritis expired during the year.

Note 9 Other Interest Received and Similar Items

	Year Ended December 31,	
	2019	2018
Interest income	926	19
Exchange rate differences	-	435
Total	**926**	**454**

Note 10 Interest Expense and Similar Items

	Year Ended December 31,	
	2019	2018
Interest expense	(18)	-
Exchange rate differences	(2,393)	(7)
Changes in FX options measured at fair value	(2,700)	-
Total	**(5,111)**	**(7)**

Note 11 Income Tax

	Year Ended December 31,	
	2019	2018
Current tax taxes	-	-
Income tax expense recorded in the statement of income	**-**	**-**
Reconciliation of effective tax rate		
Accounting loss before tax	(36,186)	(131,923)
Tax in accordance with applicable tax rate for Parent Company 21,4% (22%)	7,744	29,023
Tax attributable to non-deductible tax losses carried forward and unrecognized deferred tax assets	(6,290)	(28,989)
Non-deductible expenses	(1,518)	(35)
Non-taxable income	64	1
Income tax expense recorded in the statement of income	**-**	**-**
At the effective income tax rate	**0%**	**0%**

The Parent Company has costs attributable to new share issue amounted to SEK 10,915, which are recognized directly against equity. These costs are however deductible for tax purposes, despite not being charged against the statement of income.

As of December 31, 2019, the Parent Company has SEK 574,422 (SEK 532,976) of tax losses carried forward for which deferred tax assets have not been recognized in the statement of financial position. 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,	
	2019	2018
Licenses and similar rights		
Cost at opening balance	-	-
Acquisition for the year	16,066	-
Cost at closing balance	**16,066**	**-**
Amortization at closing balance	**-**	**-**
Net book value	**16,066**	**-**

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

Note 13 Equipment

	December 31,	
	2019	2018
Cost at opening balance	813	813
Acquisition for the year	118	-
Disposal for the year	(813)	-
Cost at closing balance	**118**	**813**
Depreciation at opening balance	(706)	(655)
Deprecation for the year	(44)	(51)
Disposal for the year	736	-
Depreciation at closing balance	**(14)**	**(706)**
Net book value	**104**	**107**

Note 14 Participations in Group Companies

	December 31,	
	2019	2018
Cost at opening balance	5,924	5,924
Acquisition for the year	1	-
Shareholders' contributions	350	-
Reclassification by merger	(904)	-
Cost at closing balance	**5,371**	**5,924**
Impairment at opening balance	(2,435)	(2,435)
Impairment for the year	(3,739)	-
Reclassification by merger	904	-
Impairment at closing balance	**(5,270)**	**(2,435)**
Net book value	**101**	**3,489**

	December 31,	
Company / Corporate Registration Number / Registered office	**2019**	**2018**
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**	**3,489**
Pharmalink Oncology AS, 913317904, Oslo		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	30	30
Net book value	**0**	**0**
Calliditas Therapeutics Inc., 83-4094951, USA		
Share of equity	100%	-
Share of voting power	100%	-
Number of participation rights	1,000	-
Net book value	**1**	**-**

In May 8, 2019, the Group completed a merger of Pharmalink Nordic AB (556957–5235) and Busulipo AB (556697-2179) with the Parent Company. At the time for the merger Pharmalink Nordic AB's total assets amounted to SEK 50 and the profit for the year amounted to SEK 0. The subsidiary had none non-current or current liabilities. For Busulipo AB the total assets amounted to SEK 99 and the loss for the year amounted to SEK (1) at the time of the merger. The subsidiary had none non-current or current liabilities.

Notes to Financial Statements – Parent Company

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

Note 15 Other Non-Current Financial Assets

	December 31,	
	2019	2018
Cost at opening balance	341	341
Bank guarantees granted	1,888	-
Reimbursement security deposit	(290)	-
Net book value	**1,939**	**341**

Note 16 Prepaid Expenses

	December 31,	
	2019	2018
Prepaid rental charges	771	164
Prepaid expenses for research and development	2,854	-
Prepaid transaction costs	14,662	-
Total	**18,287**	**164**

Note 17 Cash

	December 31,	
	2019	2018
Available balances	752,448	645,903
Total	**752,448**	**645,903**

Adjustments for non-cash items

	Year Ended December 31,	
	2019	2018
Depreciation	44	51
Chage in Provisions	175	–
Share-based payments	249	–
Other	78	–
Total	**546**	**51**

Reconciliation of liabilities from financing activities

	January 1, 2018	Cash Flow	Non-Cash-Items	December 31, 2018
Shareholder loans	470	(470)	–	–
	470	**(470)**	**–**	**–**

No liabilities from financing activities for the year ended December 31, 2019.

Note 18 Shareholders' Equity

At December 31, 2019
Share capital consists of 38,707,638 (35,202,347) shares with a quotient value of SEK 0.04 (0.04). All shares hold has the same entitlement to the company's profits. For additional information see the Group's Note 23 Shareholders' 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,	
	2019	2018
Share premium reserve	1,268,334	1,069,072
Retained earnings	(448,989)	(320,299)
Net loss for the year	(36,186)	(131,923)
	783,159	**616,850**
To be distributed as follows:		
To be carried forward	**783,159**	**616,850**

Note 19 Provisions

	December 31,	
	2019	2018
Opening balance	–	–
Provisions for the year	175	–
Total	**175**	**–**

Note 20 Accrued Expenses and Deferred Revenue

	December 31,	
	2019	2018
Accrued salaries and Board fees	4,143	2,286
Vacation pay liability	1,502	1,347
Social security costs	2,975	2,098
Accrued expenses for research and development	1,177	944
Deffered revenue	874	-
Other accrued expenses	13,860	-
Total	**24,531**	**6,675**

Note 21 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 27 Assets Pledged, Contingent Liabilities and Other Obligations. In the Parent Company restricted bank accounts amounts to SEK 1,938 (SEK 340).

Note 22 Related-Party Transactions

	Sales of Goods/ Services	Purchase of Goods/ Services	Other	Receivables on Closing Balance	Liabilities on Closing Balance
Subsidiaries					
2019	-	4,086	-	-	475
2018	-	-	-	-	77

For information regarding remuneration of senior executives, 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, 2020

Elmar Schnee
Board Chairman

Thomas Eklund
Board member

Hilde Furberg
Board member

Lennart Hansson
Board member

Bengt Julander
Board member

Diane Parks
Board member

Renée Aguiar-Lucander
CEO

Our audit report was submitted in April 27, 2020

Ernst & Young AB

Fredrik Norrman
Authorized Public Accountant

Auditor's report

To the general meeting of the shareholders of Calliditas Therapeutics AB (Publ), 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 2019. The annual accounts and consolidated accounts of the company are included on pages 26-65 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 2018 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 2018 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 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.

We have determined that that there are no key audit matters that need to be communicated in the auditor's 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 1-25 and 70-84. The Board of Directors and the Managing Director are responsible for this other information.

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

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

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

Responsibilities of the Board of Directors and the Managing Director

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

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

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

Auditor's responsibility

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

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

Auditor's report

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 2018 and the proposed appropriations of the company's profit or loss.

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

Basis for opinions

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

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

Responsibilities of the Board of Directors and the Managing Director

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

Auditor's responsibility

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

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

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

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

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Ernst & Young AB, Jakobsbergsgatan 24, Stockholm, was appointed auditor of Calliditas Therapeutics AB (Publ) by the general meeting of the shareholders on the 9 May 2018 and has been the company's auditor since the 15 April 2004. Calliditas Therapeutics AB (Publ) has been a public interest entity since 29 June 2018.

Stockholm, 27 April 2020

Ernst & Young AB

Fredrik Norrman
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 is traded under the ticker CALTX. This report pertains to the financial year of 2019 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.

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
- Swedish Code of Corporate Governance

Shareholders

Calliditas' shares were admitted to trading on Nasdaq Stockholm, Mid Cap, in June 2018. At the end of 2019, the total number of shares and voting rights amounted to 38,707,638, distributed between 2,835 shareholders. The ten largest shareholders held 73.0% of shares outstanding and other shareholders 27.0%. As of December 31, 2019, three shareholders owned shares that each represented 10% or more of the total number of shares and voting rights in the company: Stiftelsen Industrifonden, 18.4%, Investinor AS 13.2% and Linc AB / Bengt Julander 12.5%.

Dividend Policy

The company has so far not paid out any dividend.

Any future dividend and the size thereof, will be determined based on long-term growth, earnings trends and capital requirements of Calliditas. It is the view of the Board of Directors, that 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 five workdays 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 2020

Calliditas' 2019 AGM will be held on Thursday, June 25, 2020, at 4:30 p.m. at Hotel Frey's premises on Bryggaregatan 12, Stockholm, Sweden.

The minutes from the AGM will be made available at www.calliditas.se.

Participation at the Annual General Meeting

The notification must be made in writing by e-mail to finance@calliditas.com, or by post to Calliditas Therapeutics, "General meeting", Kungsbron 1, SE-111 22 Stockholm, Sweden. The notification must be done no later than June 18, 2020.

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 2019 consists of:

- Patrik Sobocki, appointed by Stiftelsen Industrifonden (Chairman)
- Ann-Tove Kongsnes, appointed by Investinor AS
- 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 2020 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 2019 AGM elected the registered firm of accountants Ernst & Young AB as auditor, up to the 2019 AGM. The Auditor-in-Charge is Fredrik Norrman. The auditor examines the Parent Company's and the Group's accounts and administration on behalf of the AGM. The external audit of the Parent Company's and the Group's accounts and the Board's and CEO's administration is conducted using generally accepted auditing standards in Sweden. The company entrusted the auditor to review one interim reports in 2019, which satisfies the requirements of the Code. For information about remuneration of the auditor, refer to Note 6 Auditors' Fee.

Corporate governance

Board of Directors

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

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

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

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

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

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

Board Independence

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

Work of the Board in 2019

During 2019, the Board of Directors held a total of 15 meetings, of which 6 were ordinary and 9 extraordinary meetings. Calliditas' CEO participates in Board meetings, as does the company's CFO, 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 license affairs and capital raise.

Board Remuneration

Fees to members elected by the AGM are decided by the AGM. The AGM of May 8, 2019, 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 550,000 to the chairman of the board of directors and SEK 160,000 to each one of the other members who are not employed in the group, SEK 40,000 to the chairman of the audit committee and SEK 20,000 to the other members of the audit committee who are not employed in the group as well as SEK 30,000 to the chairman of the remuneration committee and SEK 15,000 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 46.

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 thousand
Elmar Schnee	Board Chairman	2019	Yes	Yes	10/10	-	2/2	503
Thomas Eklund	Board member	2017	Yes	Yes	15/15	6/7	1/2	317
Lennart Hansson	Board member	2009	Yes	Yes	14/15	-	1/2	139
Ann-Tove Kongsnes	Board member (until May)	2013	Yes	No	5/5	3/3	-	-
Bengt Julander	Board member	2004	Yes	No	15/15	-	2/2	102
Hilde Furberg	Board member	2014	Yes	Yes	14/15	7/7	-	217
Olav Hellebö	Board member (until May)	2014	Yes	Yes	5/5	-	-	58
Diane Parks	Board member	2019	Yes	Yes	10/10	-	2/2	238

Board Committees

Audit Committee

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

The Committee held seven meetings in 2019. The company's auditors took part in six 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 two members: Elmar Schnee (Chairman) 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 2019. At these meetings, the Committee discussed the current compensation system in the company, including a proposal for remuneration of the CEO and senior executives and the direction and terms of the incentive program that was approved for implementation by the Annual General Meeting on May 8, 2019.

Remuneration of the CEO and Executive Management 2019

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 40% of the annual fixed remuneration. Variable remunerations shall be connected to predetermined and measurable criteria, designed with the aim of promoting the company's long-term value creation.

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

Evaluation of the Board and CEO

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

Corporate governance

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 nine individuals and includes, in addition to the CEO, the Chief Financial Officer, Vice President of Pharmaceutical Development, Vice President Project Management, Chief Medical Officer, Chief Science Officer, Vice President Regulatory Affairs, Vice President North America Commerce and Head of Investor Relations. For information about current senior executives at Calliditas, when these assumed their positions, and date of birth, education, experience, shareholding in the company and current and previous assignments, refer to page 78 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 2019 on pages 70-75 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 auditing standard RevU 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, 27 April 2020

Ernst & Young AB

Fredrik Norrman
Authorized Public Accountant

Board of Directors

Elmar Schnee

Chairman

Born 1959.
Board member since 2019.

Education: Master's degree in marketing and management from IMD.

Board Committees: Chairman of the Remuneration Committee.

Experience: Elmar Schnee was previously CEO of Merck Serono and was instrumental in the acquisition of Serono by Merck KGaA. He has also served as General Partner and member of the Executive Board of Merck KGaA and has held previously several senior global management positions with UCB and Sanofi. Other current assignments: Chairman of the board of directors of Santhera Pharmaceutical, ProCom Rx SA, Moleac Pte Lts and Noorik Biopharmaceuticals AG as well a member of the board of directors of Jazz Pharmaceuticals, Stallergenes Greer and Damian Pharma AG.

Holdings in the Company: Elmar Schnee holds 23,236 share awards in board LTIP 2019.
Independent in relation to the Company and its management and in relation to major shareholders.

Thomas Eklund

Non-executive Director

Born 1967.
Board member since 2017.

Education: MBA from Stockholm School of Economics.

Board Committees: Chairman of the Audit Committee.

Education: Thomas Eklund has extensive experience in the pharmaceutical and medtech industry as well as the financial sector. He has held different executive positions, including CEO and Head of Europe at Investor Growth Capital AB. His previous positions include Investment Director at Alfred Berg ABN AMRO Capital Investment AB and Vice President at Handelsbanken Markets.

Other current assignments:
Chairman of the Board of Directors of Itrim Holding AB, Moberg Pharma AB (publ) and Sedana Medical AB (publ). Member of the Board of Directors of Biotage AB, Boule Diagnostics AB, Eklund konsulting AB, Excillum Aktiebolag, Memira Holding AB, Neoventa Medical AB, Rodebjer Form AB, SciBase Holding AB (publ), Surgical Science Sweden AB, Swedencare AB (publ) and TEDCAP AB.

Holdings in the Company: Thomas Eklund holds 445 warrants of Warrant Program 2017/2020* and 8,449 share awards in board LTIP 2019.

Hilde Furberg

Non-executive Director

Born 1958.
Board member since 2014.

Education: Master of Science in Engineering from Oslo University, Norway.

Board Committees: Member of the Audit Committee.

Experience: Hilde Furberg is an independent consultant and professional Board member. She has extensive experience of leadership from her 35 years in sales, marketing, strategy and management in Pharma / Biotech. Her experience is in various fields of rare diseases, which she gained working in small companies and large global corporations. Hilde has worked in companies such as Genzyme and Baxter, she was most recently SVP and General 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, CombiGene and PCI Biotech.

Holdings in the Company: Hilde Furberg holds 15,250 shares in the company, 118 warrants of Warrant Program 2017/2020* and 8,449 share awards in board LTIP 2019.Independent in relation to the Company and its management and in relation to major shareholders.

One warrant in Warrant program 2017/2020 entitles to subscription of 250 shares.

Lennart Hansson

Non-executive Director

Born 1956.
Board member since 2009.

Education: PhD in Genetics from the University of Umeå.

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 and Ignitus AB. Member of the Board of Directors of Cinclus AB, 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. Independent in relation to the Company and its management and in relation to major shareholders.

Bengt Julander

Non-executive Director

Born 1953.
Board member since 2004.

Education: Master of Pharmacy from Uppsala University.

Experience: Bengt Julander is a pharmacist and has worked in the pharmaceutical industry since 1978. He is the CEO of Linc AB, which invests in life sciences, including in Calliditas. Since 1990, Bengt Julander has been primarily active as an investor in, and a Board member of, pharmaceutical development companies. He has experience of developing and commercializing pharmaceutical products.

Other current assignments: Chairman of the Board of Directors of Knil AB. Member of the Board of Directors of Linc AB, Medivir Aktiebolag, Stille AB, Nefecon AB, Swevet AB, ProEquo AB, Sedana Medical AB (publ), Busulipo AB, nWise AB, Swevet Holding AB, Pharmalink Nordic AB and Cronhamn Invest AB. Deputy member of the board of Kv Eldstaden i Bromma AB, Algarvefastigheter AB, Eriksbergskliniken Gam AB, Linc Global AB, Linc International AB, Korkyl Holding AB, Eriksbergskliniken AB and Linc Trade AB.

Holdings in the Company: Bengt Julander holds (directly and indirectly through company) 4,836,108 shares in the Company. Independent in relation to the Company and its senior management, but not 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: –

Holdings in the Company: Diane Parks holds 8,449 share awards in board LTIP 2019. 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 42,500 shares in the Company, 1,478 warrants of Warrant Program 2017/2020*, 350,000 warrants of Warrant Program 2018/2022 and 195,000 warrants of Warrant Program 2019/2022.

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.

Other current assignments: Chairman of the board of directors of Truference AB. Holder of Fountainpark Consulting.

Holdings in the Company: Fredrik Johansson holds 7,000 shares in the Company, 325 warrants of Warrant Program 2017/2020*, 90,000 warrants of Warrant Program 2018/2022 and 50,000 warrants of Warrant Program 2019/2022.

Frank Bringstrup

Vice President Regulatory Affairs

Born 1959.
VP Regulatory Affairs since 2019.

Education: Medical education from the University of Copenhagen. He has a diploma in Managing Medical Product Innovation (MMPI) from the Copenhagen School of Economics, a diploma in business administration from Warwick University, and a post graduate specialist course in public health science from the National Board of Health, Denmark.

Experience: Frank Bringstrup has over 17 years of experience in the pharmaceutical industry within regulatory affairs and health authority interactions. Prior to joining Calliditas, he worked in various positions at Novo Nordisk A / S. He started his professional career first as a clinic doctor and then Frederiksborg County Medical Advisor.

Holding in the Company: Frank Bringstrup holds 7,500 warrants of Warrant Program 2019/2022.

One warrant in Warrant program 2017/2020 entitles to subscription of 250 shares.

Krassimir Mitchev

Chief Medical Officer (acting)

Born 1959.
Chief Medical Officer since 2019.

Education: University of Medicine, Medical Academy, Sofia. Bulgaria

Experience: Dr Krassimir Mitchev is an MD and PhD certified in internal and pulmonary medicine. He has a broad and extensive academic and nearly 20 years pharmaceutical industry career experience including GlaxoSmithKline and UCB Pharma. His previous position was as Therapy Area Haemophilia Medical Head at SOBI (Swedish Orphan Biovitrum) where he was responsible for leading the development and execution of the full scale global clinical and medical strategy as well as the operational activities. He joined Calliditas in March 2019.

Holding in the Company: Krassimir Mitchev does not hold any shares in the Company.

Johan Häggblad

Chief Scientific Officer

Born 1958.
VP Licensing, IP & Legal since 2017.

Education: PhD in Neurochemistry and Neurotoxicology from Stockholm University.

Experience: Johan Häggblad joined Calliditas in 2007. He has more than 25 years' experience in the pharmaceutical industry in managerial and executive roles at Karo Bio AB (1989-1997), Pharmacia Corporation (1997-2001) and NeuroNova (2001-2007). Johan Häggblad also served as CEO in Calliditas between 2007 and 2017.

Other current assignments: Member of the board of directors of Pharmalink Oncology AS. Deputy board member of Nefecon AB.

Holdings in the Company: Johan Häggblad holds 14,250 shares in the Company, 739 warrants of Warrant Program 2017/2020* and 45,000 warrants of Warrant Program 2018/2022.

Ann-Kristin Myde

VP Head of Clinical Development & Project Management

Born 1955. VP Project Management since 2016

Education: Bachelor of Science in Chemistry from Stockholm University.

Experience: Ann-Kristin Myde has more than 25 years of experience from different global pharmaceutical companies, which included leading several global drug development and clinical project teams from Phase 1 to Phase 3 and launch, in senior clinical and project management positions at Kabi Pharmacia and AstraZeneca. She was also the Alliance Director in charge of a two-project collaboration with Bristol-Myers Squibb, where she managed the relationship and the strategy with the partner.

Holdings in the Company:
Ann-Kristin Myde holds 295 warrants of Warrant Program 2017/2020* and 3,586 warrants of Warrant Program 2018/2022.

One warrant in Warrant program 2017/2020 entitles to subscription of 250 shares.

Management team

Andrew Udell

Vice President North America Commercial

Born 1970. VP 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 200,000 warrants of Warrant Program 2018/2022 and 20,000 warrants of Warrant Program 2019/2022.

Mikael Widell

Head of Communications and IR

Born 1958.
Head of Communication and IR since 2017.

Education: MA in English from Lund University and studies in Economics at Lund University.

Experience: Mikael Widell has more than 30 years' experience within communications, including journalism with 14 years within financial media, e.g. Dagens Industri, and has had different positions within in-house corporate communications, e.g. AstraZeneca, Biovitrum (Sobi) and Nordic Capital as well as strategic work as a communications advisor within financial PR and IR. Mikael is a partner and co-founder of the IR/PR firm Cord Communications.

Other current assignments: Member of the board of directors of CordCom Consultants AB. General partner of WZ Kommunikation Kommanditbolag.

Holdings in the Company: Mikael Widell does not hold any shares in the Company.

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 of Warrant Program 2019/2022.

Scientific advisory board

Some of the most prominent IgA nephropathy specialists in the world serve as external advisors and members of the Company's advisory board.

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

Daniel C. Cattran

Professor of Medicine, University of Toronto; Senior Scientist, Toronto General Research Institute, Toronto, Ontario, Canada

Bengt Fellström

Senior professor at Department of Medical Sciences, Uppsala University, Uppsala, Sweden

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

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

Vladimir Tesar

Professor, Head of the Department of Nephrology, 1st Faculty of Medicine, Charles University, Prague, Czech Republic

Hérnan Trimarchi

Professor of Medicine, Universidad Católica Argentina; Head, Nephrology Service, Hospital Británico; Head, Kidney transplant unit, Hospital Británico, Buenos Aires, Argentina

Glossary

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

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

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. Used to calculate eGFR. High creatinine corresponds to low eGFR

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

FDA: US Food and Drug Administration

Galactose: a type of sugar that is similar to glucose. Antibodies such as IgA have sugar chains attached to them. These sugar chains contain, among other things, galactose.

Glomerulus: An anatomical structure of the kidney. Blood vessel bundles where the blood is filtered to urine.

Glomerulonephritis: an inflammation of the glomeruli, the kidney's filtration function

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

IgA: Immunoglobulin A (an antibody)

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

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 family

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

Orphan disease: a rare disease that falls within the criteria of orphan drug law

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

RAS: Renin-angiotensin system, which regulates blood pressure and fluid in the body; a RAS blocker lowers blood pressure

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

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

Financial calendar

Interim report for the period January 1–March 31, 2020	May 14, 2020
Annual General Meeting 2020	June 25, 2020
Interim report for the period January 1–June 30, 2020	August 13, 2020
Interim report for the period January 1–September 30, 2020	November 12, 2020
Year-end report for the period January 1–December 31, 2020	February 18, 2021

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