calliditas
THERAPEUTICS

ANNUAL REPORT
2018

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The Annual Report of Calliditas Therapeutics AB (publ), 556659-9766, is comprised of directors report, the group's and the parent company's financial statements with notes and audit report (pages 24-57).

Calliditas Therapeutics is a specialty pharmaceutical company based in Stockholm, Sweden. It is focused on developing high quality pharmaceutical products for patients with a significant unmet medical need in niche indications, 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 unique 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 in the US.

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

FOTO: SHUTTERSTOCK

2018 in brief

Business highlights

- On June 29, Calliditas was listed on Nasdaq Stockholm's main list. The interest was very strong, both from Scandinavian and international institutional investors as well as the general public in Sweden. The offering was substantially over-subscribed.

- In September, post-hoc results from the company's successful clinical Phase 2b study NEFIGAN with its lead candidate Nefecon, were presented by Prof. Jon Barratt and Prof. Bengt Fellström at the International IgA Nephropathy Network meeting (IIgANN) in Buenos Aires. The oral presentations highlighted, among other things, that Nefecon demonstrates effect on circulating autoimmune complexes, and has a potential to become an effective IgA nephropathy (IgAN) specific treatment by targeting the origin of the disease.

- In November, the first patient was enrolled in the company's pivotal clinical phase 3 study NefIgArd in patients with IgAN. The NefIgArd trial will study the effect of Nefecon versus placebo on the primary variable proteinuria in patients with IgAN. Based on positive results from the first 200 dosed patients, Calliditas plans to file for market approval with regulatory agencies. Top line data is expected in H2 2020.

- During the second quarter, 2018, the company filed a new patent application which covers method of use for treatment of autoimmune diseases.

Significant events after the full year

- In February 2019, Calliditas was granted orphan drug designation (ODD) for the treatment of Autoimmune hepatitis (AIH) by the US Food and Drug Administration (FDA). It is estimated that the patient population in the US amounts to approximately 50,000 – 80,000. The company plans to agree the regulatory pathway for this indication in consultation with the FDA later in 2019.

- In February 2019, Calliditas was also granted ODD for the treatment of Primary biliary cholangitis (PBC) by the FDA. The company plans to discuss the regulatory pathway for this indication in consultation with the FDA and investigate the most appropriate way forward for this patient population.

Financial summary for the Group

	2018	2017	2016	2015	2014
Operating profit (loss) (SEK 000s)	-	-	-	-	-
Net income (loss) for the period (SEK 000s)	-132,049	-86,794	-56,912	-51,014	-48,696
Equity (SEK 000s)	646,175	57,352	24,241	25,162	19,197
Total assets (SEK 000s)	648,417	62,288	27,298	28,128	20,799
Solidity (%)	95%	53%	Neg	64%	67%
Average number of employees	10	10	9	6	5

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 fulfill 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 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 IgA nephropathy patients at risk of progressing to ESRD (up to 50%) • Earlier stage treatment to prevent progression and preserve kidney function		• Focus on nephrologists who treat IgA nephropathy 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	• Desire for early stage and safer treatments	• Sizeable socioeconomic benefits
	• Orphan drug	• Specialist target market	• Disease modifying potential

CEO Statement

A transformational year

PHOTO: JANN LIPKA

»We have great hopes of becoming the first company to be able to offer patients a safe and effective medicine that specifically targets IgAN.«

Renée Aguiar-Lucander, CEO

2018 was an exciting and transformational year for Calliditas. We listed on Nasdaq Stockholm and raised sufficient capital to fund our pivotal clinical Phase 3 study NefIgArd through top line data read-out and regulatory filing. We subsequently started the study and announced the recruitment of the first patient in November.

NefIgArd is a large pivotal study of the effect of our candidate drug Nefecon in the orphan drug indication IgA nephropathy (IgAN) and comprises 149 clinics in 19 countries in North, South America and Europe, as well as Australia and parts of Asia. In order to successfully launch the study and manage this complex enterprise, our experienced internal teams work in conjunction with large third-party providers, specialized in successfully delivering multinational clinical projects. Through one of largest life science IPOs in Europe in 2018, we secured financing to allow us not only to complete the safety and efficacy part of the Phase 3 study, but also to advance other projects in our pipeline. We also initiated a broad program in late 2018 to raise Calliditas' profile internationally, targeting the patient community as well as patient and advocacy organizations and the investment community. We are grateful to all our shareholders for their support in making this journey possible. We will continue our efforts in in 2019 and onward to successfully develop and expand the company and its assets.

IgAN is a large orphan disease

The prevalence for IgAN is around 130,000-150,000 people in the US and around 200,000 in Europe. Initially diagnosed when patients are in their 20s to 30s. It has a devastating effect on the kidney function over time, resulting in the need for dialysis or transplantation for up to 50% of those afflicted. With no approved drugs for this indication today, it is often a frustrating experience for most patients, reduced to waiting for an efficacious and safe drug, or trying off-label alternatives – the use of an existing drug on a non-approved indication – which in this population come with risks which most often are incompatible with the disease. It is therefore with a great deal of responsibility that we are focusing all necessary efforts and resources on the successful outcome of NefIgArd. Our aim is to recruit 200 patients over the next year and to be in a position to read out top-line data in the second half of 2020. Based on a successful outcome, we will file for market approval with regulatory authorities and subsequently launch the product ourselves in the US, and with partners in other countries.

Our large Phase 2b study, published in the Lancet in 2017, is still the only randomized, placebo-controlled phase 2b study in the world that achieved primary and secondary endpoints in this indication, based on 150 patients. In addition, recent exploratory data made available at the IIgANN symposium in Buenos Aires in 2018 support the unique mode of action. Nefecon targets the origin of the disease in the mucosa of the intestine, offering real potential for disease modification. We have great hopes of being able to replicate these results in our ongoing Phase 3 study NefIgArd and thus become the first company to be able to offer patients a safe and effective medicine that specifically targets IgAN.

Looking ahead

In 2019, considerable emphasis will be placed on patient recruitment for NefIgArd, with a variety of activities and actions specifically aimed at ensuring that we deliver the study on plan. Having signed up and initiated a significant number of sites already by the year-end 2018, we are committed to reach our goals with our global partners and sustain positive momentum for the study.

We will also work to build and expand our organization in preparation for regulatory filing and our product launch in the US. We have already strengthened the organization with the appointments of Andrew Udell as Vice President, North America Commercial, and Dr. Frank Bringstrup as Vice President Regulatory Affairs, effective February 2019. Mr. Udell will be key as we build up our US commercial presence in advance of launching Nefecon and Dr. Bringstrup will have a leading role in the regulatory discussions and approval process of the NefIgArd study.

During 2019, we expect to put in place much of what is required at the pre-commercial stage, such as scientific publication/communications, health economics plans and land-scape mapping. We will also seek to work with patient communities, physicians and interest organizations to help build a better understanding of the disease and its progression. We will also spend time and resources on further developing our pipeline products by establishing the regulatory pathway forward for additional niche indications, where we, for example, recently was granted orphan drug designation in US for the treatment of autoimmune hepatitis (AIH) and primary biliary cholangitis (PBC). Finally, we would look to opportunistically expand our pipeline with compatible orphan products that fit in our portfolio.

I would like to thank all of our co-workers for their incredibly hard work during the year, as well as our distinguished Advisory Board which has been a great source of inspiration and has provided great insights. We look forward to the continuing challenges and successes during an exciting and stimulating 2019, as we focus on bringing the first new treatment option for IgAN to the market and maximize the potential of Nefecon to generate value for patients and investors.

Stockholm April 3, 2019

Renée Aguiar-Lucander, CEO

IgA nephropathy

Overview of the disease

IgA nephropathy (IgAN) – also known as Berger's disease – is the most common form of glomerulonephritis, a chronic inflammatory condition of the kidney, in the Western world. IgAN is a serious autoimmune, progressive disease and up to 50 percent of patients diagnosed with IgAN will within 20 years progress to end-stage renal disease (ESRD), a disease state requiring dialysis or kidney transplant.

IgAN is an orphan disease, designated as an orphan indication in both the US and Europe. IgAN affects approximately 130,000–150,000 people in the US and about 200,000 people in Europe. Calliditas' lead product candidate, Nefecon, has been granted orphan drug designation for the treatment of IgA nephropathy in the US and the EU.

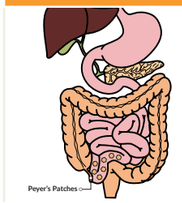
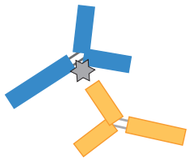
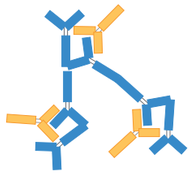
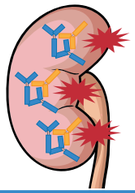
Pathogenesis, origins and disease mechanism of IgA nephropathy

The kidney is a complex organ and it´s functions include production of hormones, absorption of minerals, filtration of the blood and removal of waste products. According to the most predominant theory on disease origin and progression, IgA nephropathy is a disease that starts in the intestine and not in the kidney itself, i.e. the disease's origin is in the ileum where the Peyer's patches are located.

Immunoglobulin A (IgA) is an antibody that plays a key role in the immune system by protecting the body from foreign substances such as bacteria and viruses. Patients with IgAN have elevated levels of specific IgA molecules lacking certain galactose units (a type of sugar). In IgAN patients, a combination of genetic predisposition, environmental and dietary factors is presumed to cause disease development and progression.

The galactose-deficient spot at the hinge region of the IgA molecule is immunogenic, i e it causes a defense reaction of the immune system. The antibody therefore attracts other antibodies, forming immune complexes that become stuck in the filtration membranes of the kidney, known as the glomeruli. The trapped immune complexes then initiate an inflammatory reaction which damages the kidney and ultimately destroys the kidney's filtration mechanism.

The first symptoms for IgAN are appearance of protein and/or blood in the urine (proteinuria and hematuria, respectively), indicating leakage through the damaged membranes in the kidney. The risk of ESRD is related to the level of proteinuria, which reflects the fact that as the kidney function deteriorates, waste products, of which creatinine is a marker, accumulates in the blood.

Peyer's Patches	1. Sugar deficient IgA	2. Immune recognition	3. IgA – dependent immune complex	4. IgA nephropathy
				
Follicles of lymphoid tissue Peyer's patches (PP) in the distal part of the small intestine (ileum) produce secretory IgA antibodies. PP are mainly located in the Ileum and some 46% of the PP are located in the distal 25 cm of the ileum.	Patients with IgA nephropathy, have an increased appearance in the blood of aberrant IgA antibodies that lack a specific sugar modification (galactose deficient IgA) in the "hinge region", which makes the antibody immunogenic.	These aberrantly glycosylated IgA antibodies self-aggregate, triggers auto-antigen production and form antigen-antibody complexes with IgG antibodies directed against the aberrant IgA "hinge region".	These aggregates form pathogenic immune complexes that will precipitate in the glomeruli, which constitute the filtration apparatus of the kidney.	The deposits of immune complexes in the glomeruli, cause an inflammatory cascade that destroys the glomeruli and eventually results 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.

Creatinine levels in the blood are used to calculate the eGFR (estimated glomerular filtration rate), which is a measure of the kidney's capacity to filter the blood. Hence, eGFR is a measure of renal function (the lower eGFR, the less renal function remains). As the disease progresses the eGFR deteriorates and a large proportion of the patients will eventually be afflicted by ESRD. A patient with ESRD will need dialysis or a renal transplant in order to survive.

Clinical symptoms, diagnosis and disease progression

The clinical course of IgAN can exist without any obvious signs or symptoms for an extended period of time. IgAN is often diagnosed either through routine health checks, or by the patient presenting symptoms such as visible hematuria or proteinuria. Calliditas estimates that the majority of patients are diagnosed when they exhibit symptoms or through routine health controls, while the remaining cohort is discovered at a much later point in time.

A patient journey typically begins within the primary care, culminating in diagnosis taking place at a nephrologist. The nephrologist's standard diagnostic method for determining the underlying cause of the observed increased urine protein level is to perform a kidney biopsy followed by a histopathologic evaluation. The diagnosis of IgAN can then be determined from the histopathologic characteristics of the biopsy.

IgAN normally presents in the patient's twenties or thirties and is more common in men than in women in the Western world, with patients following a variety of progression paths over several years. It results in deterioration of kidney function that in a significant part of the population eventually leads to ESRD.

ESRD is associated with significant risks of complications and considerable quality of life deterioration as well as an increased risk of premature death. Persistent proteinuria is a defined characteristic of patients progressing to ESRD. A decrease of proteinuria levels has shown to markedly reduce the risk of progression.

Prevalence and incidence

Prevalence measures how common a disease is in a population at a particular point in time. Calliditas therefore estimates the prevalence of IgAN in the US to between 130,000–150,000.

The estimated European prevalence is equivalent to approximately 4 in 10,000, resulting in an estimate of 200,000 people.

Beyond the US and Europe, high prevalence rates have been observed in China, Singapore, Japan, Australia and Hong Kong. In China, IgAN was long the leading cause of ESRD, and the prevalence rate is estimated to at least around 3 times the prevalence rate in Europe. Even in Japan, IgAN has a much greater prevalence than in the Western world, with an estimate of at least 190,000 people. This higher prevalence in Asia is presumed to be a result of the interplay of a genetic predisposition, environmental, bacterial and dietary impact. In some geographic areas there are also general health screenings being performed which often impact diagnosis rates.

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			
Main markets		US	130,000–150,000
		Europe	200,000
Potential markets		China	~ 2,100,000
		Japan	~ 190,000

Incidence measures the rate of occurrence of new cases of a disease in a specified time period (usually a year). Calliditas estimates an annual incidence to be 2.5 per 100,00 resulting in around 6,000–7,000 new cases each year in the US.

The variability of estimated IgAN prevalence and incidence rates for IgAN between geographical regions is in Calliditas' assessment partly due to varying clinical practice in performing kidney biopsy. A kidney biopsy is an invasive procedure and is not a requirement in all geographical regions for patients exhibiting elevated

PHOTO: JONAS GUNNARSSON/JOHNER BILDBYRÅ

IgAN usually occurs in the 20-30s and is more common in men than in women in the western world. The patients follow a variable disease course over a period of many years.

levels of proteinuria, but necessary to confirm the diagnosis of IgAN.

ESRD treatment options and burden on the healthcare system

IgAN is a significant burden on the healthcare system in the US. Glomerulonephritis is the largest disease-related cause of ESRD after diabetes and is responsible for 25–30 per cent of all annual ESRD cases. Glomerulonephritis comprises to several kidney diseases, usually affecting both kidneys, where the majority of the diseases are characterized by inflammation of the glomeruli, i e or the small bundles of thin blood vessels that filter and purify the blood from residual products.

IgAN is established as being the largest condition within glomerulonephritis. IgAN is hence a major cause of ESRD, causing a significant number of ESRD cases in the US each year. According to the US Renal Data System (USRDS) ESRD quarterly update in January 2019, the number of ESRD patients in the US amounted to 757,219 in the second quarter of 2018, with an incidence during 2017 of 124,762 patients per annum.

There are an estimated 2 million patients suffering from ESRD worldwide. Patients that live with ESRD in the US constitute 1 per cent of the US Medicare population, but account for 7 per cent of the Medicare budget. More than 100,000 patients in the US are on the kidney transplant list, but each year there are less than 20,000 available donor kidneys and the need for donor kidneys in the US is increasing at 8 per cent per year. After one year of treatment, those on dialysis have a 20–25 per cent mortality rate, with a 5-year survival rate of 35 per cent.

IgA nephropathy – A high unmet medical need

There are at present no approved treatments for IgAN. A variety of off label approaches are used for IgAN to reduce the blood pressure and systemically suppress the immune system.

Against this background, Calliditas assesses that there is a clear unmet need for new treatments showing both efficacy and safety in large randomized, controlled trials and thus can be approved and used on label, i e within approved indication, specifically for IgAN patients. Nefecon's targeted release, which focuses on treating the supposed source of the disease in the intestinal immune system and has the potential to affect the course of the disease in the kidney's glomeruli, provides a completely new treatment method for IgAN. Calliditas demonstrated in a large Phase 2b study involving 150 patients that Nefecon has the potential to be an efficacious and safe therapy to patients with IgAN. In the fourth quarter of 2018, the company started the recruitment for a global pivotal Phase 3 study of Nefecon.

Overview of Nefecon

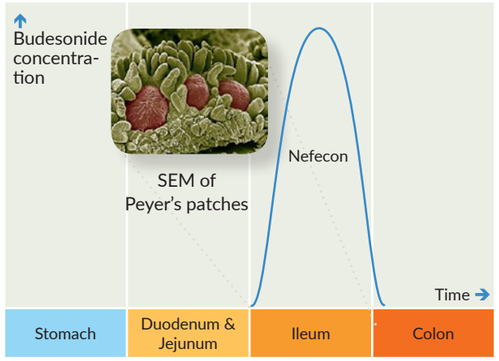
Calliditas' lead product candidate

Nefecon is a patented oral formulation of a potent and well-known active substance – budesonide – for targeted release. The formulation is designed to deliver the drug to the Peyer's patch region – a part of the body's immune system – of the lower small intestine, where the disease originates, as per the predominant pathogenesis models. Nefecon is derived from the TARGIT technology, which allows for the substance to pass through the stomach and intestine without being absorbed, and to be released in a pulse like fashion, during a defined time period, only when it reaches the lower small intestine.

The combination of dose and optimized release profile is required to be effective in patients with IgAN, as shown in a large Phase 2b study, NEFIGAN, completed by the company. In addition to its potent local effect, another advantage of using this active substance is that it has very low inherent bioavailability. Around 90% of the active substance is inactivated in the liver before it reaches the systemic circulation. This means for Nefecon that a high concentration can be applied locally where needed but with only very limited systemic exposure and side effects. Another example where this approach has proven to be successful is in asthma treatment where budesonide is successfully used to locally treat the airways and lung tissue.

Calliditas is now sponsoring NefIgArd – a large global Phase 3 trial of Nefecon in IgAN. Patient recruitment to NefIgArd was initiated in the fourth quarter of 2018.

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
- The company collaborates with KHI (American Society of Nephrology) on proteinuria as a surrogate endpoint in IgA nephropathy
- Calliditas announces initial results from Phase 2b study as well as achieves the primary endpoint in a planned interim analysis

2016
- Calliditas obtains orphan drug designation for Nefecon in Europe
- Tufts Medical Center publishes the meta-analysis study related to changes of proteinuria as a surrogate endpoint in IgAN in American Journal of Kidney Disease

2017
- Publication of results from the Phase 2b study in The Lancet
- Calliditas completes a number of End of Phase 2 meetings with the FDA and the EMA

2018
- First patient enrolled in pivotal clinical phase 3 study NefIgArd

Interview with Professor Rosanna Coppo, M.D.

Nefecon is an attractive choice

Professor Rosanna Coppo, M.D., is a highly respected and well-known scientist in the field of nephrology. Prof. Coppo graduated from the Turin University, Italy, created a distinguished international career and retired in 2015 as Head of Nephrology, Dialysis and Transplantation, Regina Margherita Children's Hospital, Turin (Italy). Prof. Coppo is now a Member of the Research Foundation Molinette, Turin (Italy) which she uses as a base for continued research in glomerular disease in general and in IgAN in particular. Prof. Coppo is the author of 315 original scientific papers and has led several important international efforts in nephrology, ranging from large multicenter studies and clinical research projects to international nephrology organizations. She has always had a special interest in pediatric kidney disease.

Prof. Coppo is now a Member of the Research Foundation Molinette, Turin (Italy) which she uses as a base for continued research in glomerular disease in general and in IgAN in particular.

How big is the medical need in this field?

IgA nephropathy, or IgAN, is a rare disease in most parts of the world except Asia, it is however the most common glomerular disease. The prevalence in Europe is approximately 200,000 patients. About 30-50% of the patients progress to end-stage renal disease (ESRD) and half of them enter dialysis before 50 years of age, in Europe.

Today there is no approved medication especially for IgAN anywhere in the world. There is no effective cure, nor disease modifying medical treatment for IgAN, there is merely symptomatic treatment. As we only hold back symptoms, the unmet medical need is high.

Why is IgAN such a serious disease?

IgAN has a devastating outcome, in many cases progression to ESRD. ESRD requires dialysis or kidney transplantation, also known as renal replacement treatment (RRT). The disease mostly affects young adults, but it can have a long previous subclinical history. In Europe, 50% of the IgAN dialysis patients are aged less than 50 years. Hence, in their full social, working and affective life. In addition, the disease can recur in a transplanted kidney, contributing to the loss of the new kidney. Apart from the need of RRT, most patients with IgAN develop some degree of chronic kidney disease (CKD) during their life, with decreased glomerular filtration rate (GFR), ie the capacity to filter and cleanse blood, though not reaching the need of RRT. These patients are obviously exposed to all the severe cardiovascular risks of patients with CKD, including a high risk of premature death.

In conclusion, albeit mostly without overt symptoms at early stages, the disease is serious, and the benefits of current treatment is often inadequate to the need. Hence, there is an unmet medical need for more effective treatments of patients with IgAN of any age.

How difficult is it to treat IgAN?

It is difficult to determine progression rates in individual patients, and the suitable treatment options are limited with the medications at hand. The good news is that every day we learn more about the disease. Recent progress in pathology and tailormade treatment modalities will most likely help develop new and more effective ways to diagnose and treat patients with IgAN.

What are the treatment options today?

The international KDIGO 2012 guidelines are largely followed on a global scale. Some IgAN patients have little risk of progression and these patients are managed with supportive care only. Mostly with antihypertensive renin-angiotensin blockers, RASB. The RASB treatment is mainly symptomatic. In patients with progressive disease, the disease process continues, and symptoms eventually re-appear.

In the patients with moderate to high risk of progression, the treatment options are to adopt a supportive care alone (RASB), or to combine supportive care with high doses of systemic corticosteroid treatment with or without other immunosuppressive drugs.

In conclusion, the treatment option presently considered to be most beneficial for preventing loss of renal function in patients with IgAN at risk of progression, is systemic corticosteroid therapy. However, the side effects of the systemic corticosteroid treatment, sometimes severe, makes me worry.

How may Nefecon help?

Nefecon is fresh air in the IgAN landscape. Something new, something targeting the site where the pathogenic, or disease causing, mechanisms initiate the IgAN disease process.

Malfunction of the gut-associated lymphoid tissue (GALT), ie the immune system of the gut, may play an important role in the pathogenesis of IgAN as reported by several studies. IgAN is an autoimmune disease where the malfunctioning GALT is the culprit and the kidney is the innocent bystander.

Nefecon targets release of the drug compound in the ileum, the far end of the small intestine, where it affects the local gut immune system, the GALT. The drug compound has high first-pass metabolism in the liver resulting in low systemic exposure. Ie the systemic side effects are minimized by design.

The Phase 2b NEFIGAN trial evaluated Nefecon in patients with progressive IgAN despite optimized RASB treatment. In this trial, Nefecon reduced proteinuria and maintained eGFR, suggesting a reduced risk of future progression to ESRD. In addition, the NEFIGAN trial reported minimal side effects, with frequency and severity not different from those observed in the placebo arm.

To summarize, the possibility of targeting the GALT at the ileum with a locally acting drug like Nefecon is an attractive modality to treat patients with IgAN. In particular, in children and adolescents, in which the side effects of systemic corticosteroids may be devastating for growth, for bones and vessels, and for the possible long-lasting cardiovascular side effects.

If IgAN is a chronic autoimmune disease of the gut immune system, why are the kidneys damaged?

The lesions observed at kidney biopsy examination are the result of the disease causing chain of events initiated by the increase in circulation of immunoglobulin A (IgA) with galactose deficient (Gd-IgA1) (a.k.a. the "first hit"), followed by the formation immunoglobulin G (IgG) or IgA directed against Gd-IgA1 ("second hit") leading to circulating immune complexes (IgAIC) and renal deposition of the IgAIC ("third hit"). The glomerular deposition of IgAIC triggers the inflammation and the kidney damage ("fourth hit"). The filtration apparatus ceases to function properly and the blood is no longer properly filtered and cleansed.

The medical thesis built for Nefecon of blocking the dysregulated synthesis of Gd-IgA1 may represent the key for treating IgAN by halting the initiating disease-causing events.

There are no products approved specifically for IgAN. How would Nefecon compare to the current standard of care?

For patients at high risk of progression despite optimized RASB treatment, the only drugs supported ("suggested" not "recommended") by KDIGO 2012, are systemic corticosteroids.

Nefecon fits well with the current guidelines as an add-on to RASB treatment. Nefecon will not only replace systemic corticosteroids but will also be used to lower the risk of progression earlier in the disease process. I would personally be very pleased if Nefecon demonstrates early benefit with low side effects, in IgAN patients with persistent proteinuria.

Professor Rosanna Coppo, M.D.

NefIgArd, the pivotal Phase 3 trial with Nefecon is ongoing and patients are recruited as we speak. The protocol is innovative with new end-points developed by the team and agreed with FDA. The trial design will help detecting a safe and effective treatment. The frequency and severity of side effects is an extremely relevant aspect of such an RCT. I am looking forward to the results.

What would you like to be able to offer a patient?

I would like to be able to offer a personalized treatment, based on the specific phase of activity of his/her IgAN.

In early cases, I would like to offer the possibility of inducing remission of proteinuria, maintaining normal GFR.

In more advanced cases, I would like to offer stabilization of GFR without further decline, reduction in proteinuria as much as possible and optimal control of hypertension.

In advanced cases, I would like to offer a decrease in rate of progression and prevention of the need of a randomized controlled trial (RRT).

I would like to offer a good risk/benefit balance of the treatments prescribed.

How well would Nefecon fit in your arsenal of treatment modalities?

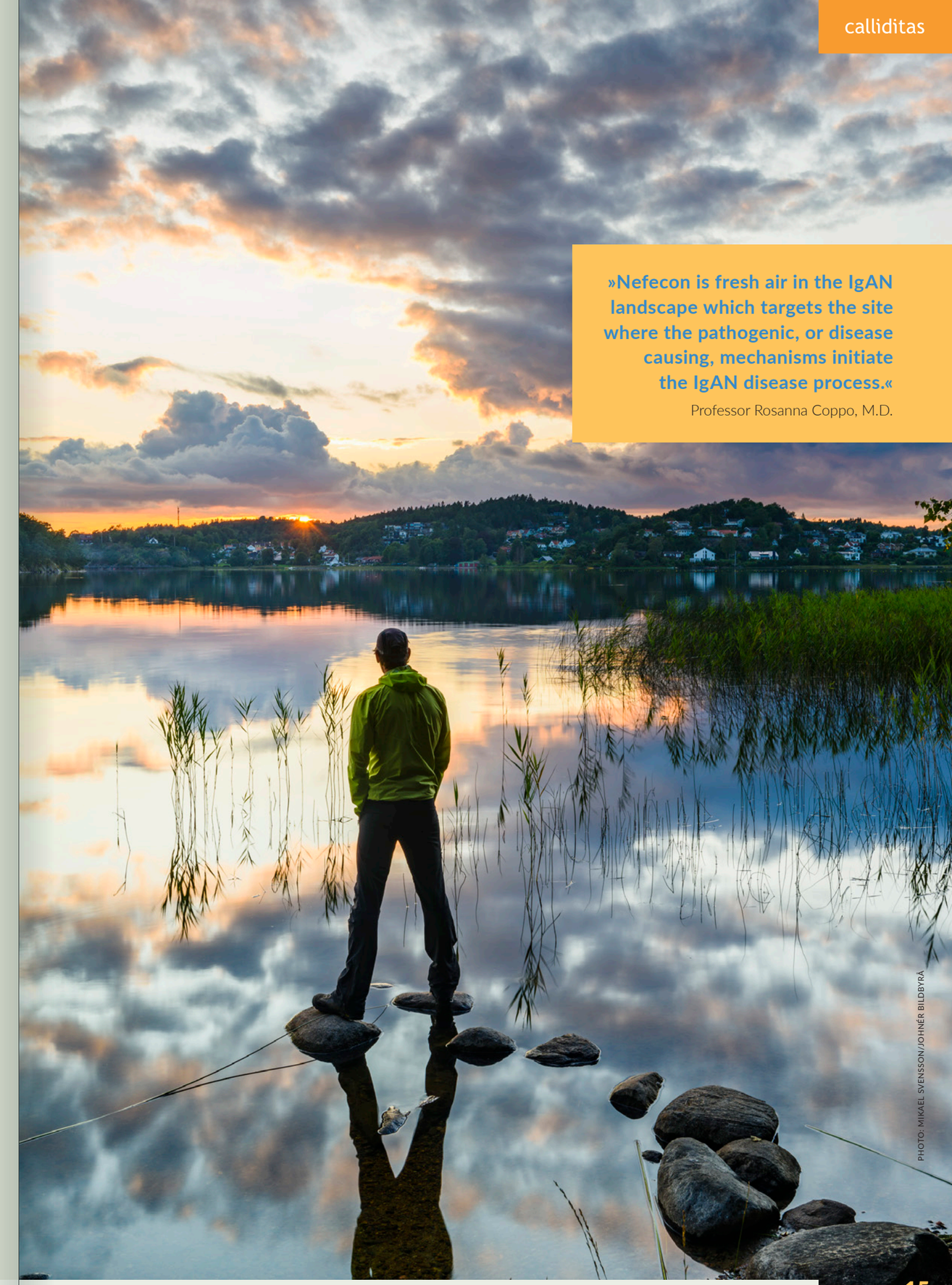
Nefecon is an attractive choice since it targets the disease-causing events which lead to the development of IgAN, limiting the aberrant response of the mucosal immune system.

Nefecon would be an ideal drug to use to prevent the early progression of IgAN in stages with minimal urinary abnormalities, but also a drug to prevent progression in stable cases showing a relentless GFR decline.

I see Nefecon as a treatment with high possibility of success, the rationale is strong, the immunological modifications observed confirm the potential benefits. It is a tempting option, since the efficacy is there, and the side effects are theoretically very low.

Hence, I would use Nefecon in early and active IgAN as a first line treatment, leaving the option for methylprednisolone pulses (a systemic corticosteroid modality) to cases without response to Nefecon. I would use Nefecon also in progressed cases, but in that case in patients with some still active pathology lesions, ie in patients that have not crossed the Rubicon to irreversible damage.

calliditas



»Nefecon is fresh air in the IgAN landscape which targets the site where the pathogenic, or disease causing, mechanisms initiate the IgAN disease process.«

Professor Rosanna Coppo, M.D.

PHOTO: MIKAEL SVENSSON/JOHNÉR BILDBYRÅ

Development program

The Phase 3 study NefIgArd was initiated in 2018

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 per cent at end of treatment with a further reduction to 40 per cent below the base level two months after end of treatment; and an increase in eGFR of 8 per cent 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 is still the largest completed double-blind study ever conducted with an experimental product specifically for 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 blood pressure control. Nefecon or placebo was administered, as oral capsules, once a day for nine months. During that time, treatment with RAS blockade continued (inhibition of the renin-angiotensin system).

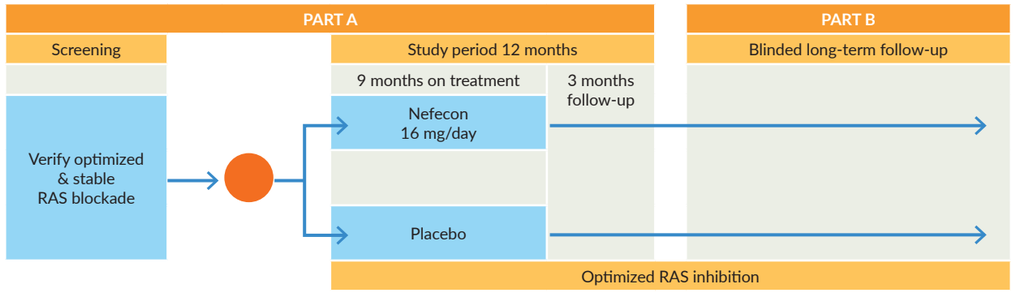
At the end of nine months' treatment of either Nefecon or placebo, the patients were followed for an additional three months. The primary endpoint was reduction in proteinuria as measured by the urine protein creatinine ratio (UPCR). This endpoint was achieved during a planned interim analysis after 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 per cent, respectively, while the placebo treated patients had an increase of 2.7 per cent.

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 per cent decrease in eGFR during the nine months of treatment while the 16 mg Nefecon group had an increase of 0.6 per cent and the 8 mg Nefecon group had a decrease of 0.9 per cent, which is a stabilization. There were no severe adverse events such as severe infections or significant impact on the metabolic system (blood pressure, weight gain, diabetes etc.), which are typical side systemic effects of systemic glucocorticosteroid treatment.

Key highlights NefIgArd	
→	Phase 3 study design replicates successful Ph2b
→	Top-line data of 200 patients compared to 150 patients in Ph2
→	16mg Nefecon or placebo once-daily oral dose
→	Recognized surrogate marker for approval

Nefecon Phase 2b study design

NefIgArd Phase 3 study design



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 suggests 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 NefIgArd

The planned randomized double-blind and placebo-controlled Phase 3 study NefIgArd will have a substantially similar design to the completed Phase 2b study. The study is divided into a treatment part (Part A) and a long-term observational part (Part B). Up to 450 patients with biopsy-confirmed IgAN and on optimal dosing or highest tolerable dose of blood pressure medication will be randomized in this study across 19 countries in North and South America, Europe and Asia, as well as Australia. In the first part of the study, Part A, the patients will receive orally either 16 mg Nefecon or placebo, once daily for 9 months, on the background of optimized RAS treatment, and then be followed for three months. Subsequently, the patients will continue into Part B, which is an observational long-term follow up period where the patients' renal function as measured by eGFR will be followed and measured.

The data from the study will be analyzed in two parts. The first analysis will be conducted after the first 200 randomized patients have completed Part A. The primary endpoint will be reduction in proteinuria and will form the basis for accelerated approval in the US and conditional approval in the EU. Based on positive data, this can enable marketing and commercialization of the drug in the US and EU, after the expected processing time for a New Drug Application (NDA) and Marketing-Authorisation Application (MAA) with the FDA and the EMA, respectively.

The Part B study analysis is designed to validate proteinuria as a surrogate marker and is event based. An event is defined as a relevant reduction in eGFR from baseline and we expect less events in the Nefecon treated group. The company plans to conduct an interim read out of Part B regarding eGFR following approximately 18 months after top line data are available.

Potential in additional orphan indications

Beyond IgAN, Calliditas assesses that Nefecon's patented formulation and re-lease 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. autoimmune hepatitis (AIH) and primary biliary cholangitis (PBC).

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.

»Calliditas have been granted ODD in the US for the treatment of AIH and PBC.«

Autoimmune hepatitis (AIH)

AIH is a rare and chronic inflammation of the liver. The cause of the disease is unknown, but it has been proposed that environmental triggers, autoimmune reactions and genetic predisposition act together to cause inflammatory and fibrotic processes in the liver. The disease often presents as a slowly progressing disease of the liver, leading at variable rates to cirrhosis with complications like liver failure and liver cancer.

It is an orphan disease and population-based epidemiology studies are limited. Prevalence rates of 17 per 100,000 have been reported, suggesting there may be approximately 50,000 - 80,000 patients in the US, meeting the criteria for an orphan disease.

There are presently no products approved for treatment of AIH in the US. Calliditas therefore assesses that budesonide has a promising profile to meet this medical need and therefore believes that this might be an attractive opportunity to reach the market within a relatively short period of time. Calliditas have been granted ODD in the US for the treatment of AIH.

Primary biliary cholangitis (PBC)

PBC is a progressive and chronic autoimmune disease of the liver that predominantly affects women. The disease starts in the bile ducts within the liver. As these ducts are destroyed by inflammatory processes, bile accumulates in the liver causing an increase in the liver volume, a phenomenon known as cholestasis. If untreated, the active liver tissue is destroyed and replaced by fibrous tissue. The disease will culminate with end-stage biliary cirrhosis and the need for a liver transplant. UDCA and Ocaliva are the only FDA-approved medical treatments for PBC in the USA. Ocaliva has been granted ODD for the treatment of PBC.

It is known from previous studies that treatment with systemic steroids may alleviate symptoms of the disease and improve biochemical and histologic findings. No targeted steroid therapy is registered for PBC in the US, nor in Europe. Calliditas assesses that there is a significant unmet medical need to improve outcomes as second-line therapy to the approved therapies with UDCA and Ocaliva. Calliditas estimates that this segment comprises approximately 42,000 patients in the US. Calliditas have been granted ODD in the US for the treatment of PBC.

FOTO: SHUTTERSTOCK

»During the second quarter, 2018, the company filed a new patent application which covers method of use for treatment of autoimmune diseases.«

Patents

The patent family related to the formulation technology relating to a targeted release in the ileum after the oral administration and its medicinal use, consisting of 19 patents, is an intellectual property right jointly owned with Archimedes. The patent family was developed as a joint intellectual property under a co-development agreement with Archimedes dated 2004. In 2011, Calliditas and Archimedes entered into a new license agreement pursuant to which Calliditas has an exclusive license to develop, use and market products under the patent family. The patents of the family expire in 2029. Essentially, the patent family covers the composition, characteristics and use of a fundamental component in the Nefecon formulation. The patents have been approved in the US, Europe, Japan, China and Hong Kong.

The patent family related to method and use for treating glomerulonephritis is owned by Nefecon AB, a wholly owned subsidiary of Calliditas, and Calliditas has an exclusive license to the patent family from the subsidiary. The patents of the family expire in March 2019, except for the Swedish patent that has already expired.

New patent applications

During the second quarter, 2018, the company filed a new patent application which covers method of use for treatment of autoimmune diseases.

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.

»In our industry, we need to make sure that the treating physicians and payers are onboard and understand the value the drug brings to these patients.«

Andrew Udell

FOTO: SHUTTERSTOCK

Interview with Andrew Udell
Vice President North America Commercial at Calliditas Therapeutics:

Nefecon has the potential to address an unmet need

I have spent over 20 years working on the commercial side of the pharma and biotech industry. The first half of my career was spent working at a large, privately held, mid-sized pharmaceutical company called Purdue Pharma. During my time there, I learned the commercial side of the business working in sales operations, sales, and marketing.

After 10 years, I went to work for a small biotech company, Clinical Data Inc. I was the only commercial person working on their lead asset, an anti-depressant in Phase 3. After FDA approval, the company was purchased by Forest Laboratories, who effectively launched the lead product three months after acquisition. Since that time, I have worked and consulted for several small biotech companies. Most recently I worked for the Israeli company Neuroderm.

How do you look on your new role at Calliditas?

I am very excited about my new role at Calliditas. I am very impressed with the team and their commitment to making the company and Nefecon a success. I will be responsible for leading our company's commercial efforts to support our pipeline strategy and development. This work includes the execution for commercialization of our lead investigational therapy for the treatment of IgAN.

It is clear that the IgAN space is in desperate need for a product like Nefecon, which addresses the origin of the disease. Nefecon was safe and efficacious in Phase 2 and has great potential for treating IgAN patients. The next few years will be very exciting as we build our company, our brands, and help patients, physicians, and caregivers in the IgAN, but also in other indications that we hope to address.

What are the biggest opportunities/challenges?

We have a product with the potential to address an unmet need for IgAN patients, which is a great and rewarding opportunity. Every combination of disease and product development program is different. The unique characteristics will determine the challenges and items that influence and impact how we approach our commercialization. Common product obstacles often include market access and different reimbursement systems that exist.

I look forward to helping our company to grow, and not the least to meet and eliminate all challenges we will face along the way. As long as we listen to our stakeholders and maintain focus on the patients and their need, we will position our company for success.

How do you build a long-term commercialization platform?

Building a long-term commercialization platform always begins with truly understanding all stakeholders – including patients, treating physicians, caregivers, and payers. Once you have done your work to gain a deep understanding of the market, and how your product meets everybody's needs, you can begin to develop and execute a commercial plan. A successful plan includes education, community engagement, and market/product access which results in product awareness followed by product adoption.

Who will be your main targets?

Our patients are our target. In our industry, we need to make sure that the treating physicians and payers are onboard and understand the value the drug brings to these patients. Physicians and payers are the decision makers that will enable the appropriate patient access to our drug.

IgAN is a rare disease in the Western hemisphere. How will that make you adapt the marketing platform?

Most orphan/rare diseases do not have an abundance of data. It is very important that we seek out and continue to work with the most important stakeholders. This eventually leads to a targeted and efficient penetration. We have already seen the IgAN community is a very motivated, engaged and active group. The more we connect and listen to patients and members in these communities, the more value we can bring.

The share

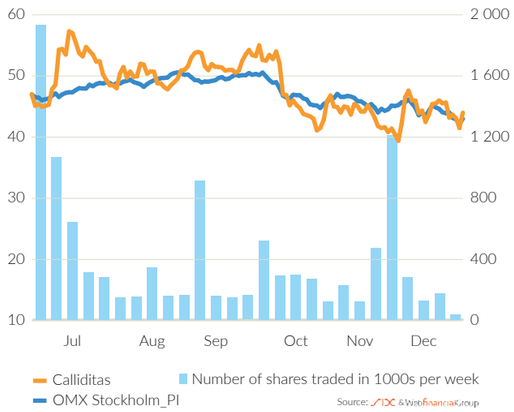
Share performance

Calliditas was listed on Nasdaq Stockholm Mid-Cap, on June 29, 2018. On December 28, 2018, the closing rate was SEK 44.0, yielding a decrease of 2% in 2018. During the same period, the OMXSPI fell 8%. The highest closing rate during the year was SEK 59 and the lowest SEK 39.

Turnover

A total of 10,663,440 shares were traded during the year, with a total value of SEK 508 million. On average, 83,308 shares were traded each day.

Share performance July–December 2018



Shareholders

At December 31, 2018, Calliditas had 2,345 shareholders. The 15 largest shareholders controlled 84% 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 28% of voting rights and capital.

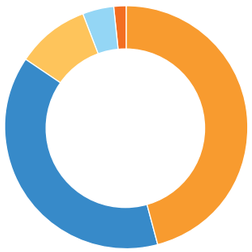
Share capital

Share capital in Calliditas amounted to SEK 1,408 thousand on December 31, 2018. The number of shares was 35,202,347, 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 600 thousand and not more than SEK 2,400 thousand, distributed between at least 15,000,000 shares and not exceed 60,000,000 shares. The proportion of shares available for trade (free float) amounted to about 40% at year-end.

IR work

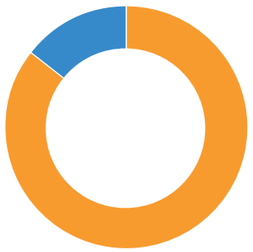
In 2018, IR efforts focused on establishing Calliditas on the capital market both in the Nordic region and internationally. Management took part in several sector-specific conferences, with the JP Morgan Healthcare Conference in San Francisco and the Jefferies Healthcare Conference in London being two 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, Paris, Amsterdam and Oslo, in addition to Stockholm.

Ownership per category, %



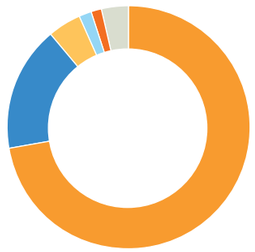
Swedish institutional owners	46.0%
Other	38.5%
Swedish private persons	9.9%
Foreign institutional owners	4.2%
Anonymous ownership	1.4%

Trading platforms, %



Nasdaq OMX	85.7%
Cboe Global Markets	14.3%

Ownership per country, %



Sweden	72.5%
Norway	16.4%
Cyprus	4.7%
Denmark	1.5%
US	1.5%
Other	3.4%

Source: Monitor by Modular Finance and Fidessa

The 15 largest shareholders

Shareholders	Total number of shares	Holding, %	Voting rights, %
Stiftelsen Industrifonden	7,732,538	22.0%	22.0%
Investinor AS	5,530,997	15.7%	15.7%
Bengt Julander	5,276,271	15.0%	15.0%
Gladiator	2,409,000	6.8%	6.8%
AFA Försäkring	1,640,000	4.7%	4.7%
Zaragatero LTD	1,637,317	4.7%	4.7%
Handelsbanken Fonder	1,278,000	3.6%	3.6%
The Fourth Swedish National Pension Fund	1,096,252	3.1%	3.1%
Staffan Rasjö	625,000	1.8%	1.8%
Fidelity Investments (FMR)	517,317	1.5%	1.5%
SEB-Stiftelsen	500,000	1.4%	1.4%
C WorldWide Asset Management	392,247	1.1%	1.1%
Catella Fonder	357,500	1.0%	1.0%
Danica Pension	343,788	1.0%	1.0%
Avanza Pension	284,257	0.8%	0.8%
Total share, 15 largest shareholders	**29,620,484**	**84.1%**	**84.1%**
Other shareholders	5,581,863	15.9%	15.9%
TOTAL	**35,202,347**	**100.0%**	**100.0%**

Share data 2018

Lowest, SEK	39.14
Highest, SEK	59.96
VWAP	47.63
Total number of shares traded	10,663,440
Average shares traded per day	83,308
Number of transactions	29,067
Average number of transactions per day	227
Average value of each transaction, SEK	17,474
Average turnover per day, SEK	3,968,206
Daily turnover rel. to market value, %	0.25%
Percentage over Nasdaq (ordinary), %	83.40%
Block transactions, %	16.20%
Dark pools (Nasdaq), %	0.40%

Analysts

Calliditas is monitored by Carnegie, Stifel and Redeye.

Size classes

Size classes	No. of known shareholders	No. of shares	Holding, %	Voting rights, %	Proportion of known shareholders
1–100	564	25,222	0.1%	0.1%	24.1%
101–200	218	37,783	0.1%	0.1%	9.3%
201–500	755	255,330	0.7%	0.7%	32.2%
501–1,000	322	280,697	0.8%	0.8%	13.7%
1,001–2,000	207	343,908	1.0%	1.0%	8.8%
2,001–5,000	145	512,749	1.5%	1.5%	6.2%
5,001–10,000	48	383,758	1.1%	1.1%	2.0%
10,001–20,000	37	562,997	1.6%	1.6%	1.6%
20,001–50,000	18	554,513	1.6%	1.6%	0.8%
50,001–100,000	6	432,957	1.2%	1.2%	0.3%
100,001–200,000	7	1,022,963	2.9%	2.9%	0.3%
200,001–500,000	8	2,559,774	7.3%	7.3%	0.3%
500,001–1,000,000	2	1,142,317	3.2%	3.2%	0.1%
1,000,001–4,000,000	5	8,060,569	22.9%	22.9%	0.2%
4,000,001–	3	18,539,806	52.7%	52.7%	0.1%
Anonymous shareholders		487,004	1.4%	1.4%	
Total	**2 345**	**35,202,347**	**100.0%**	**100.0%**	**100.0%**

Board of Directors' Report

Multi-year summary, Group

	IFRS 2018	IFRS 2017	IFRS 2016	IFRS 2015	IFRS 2014
Net sales (SEK thousand)	-	-	-	-	-
Net income (loss) for the period (SEK thousand)	-132,049	-86,794	-56,912	-51,014	-48,696
Total assets (SEK thousand)	648,417	62,288	27,298	28,128	20,799
Equity ratio at the end of the period (%)	95%	53%	Neg.	64%	67%
Average number of employees	10	10	9	6	5

Multi-year summary, Parent Company [1)]

	RFR 2 2018	RFR 2 2017	RFR 2 2016	RFR 2 2015	BFNAR 2014
Net sales (SEK thousand)	-	-	-	-	-
Net income (loss) for the period (SEK thousand)	-131,923	-86,848	-58,313	-49,982	-48,288
Total assets (SEK thousand)	651,633	65,366	30,325	32,216	23,974
Equity ratio at the end of the period (%)	95%	55%	Neg.	70%	72%
Average number of employees	10	9	8	5	4

1) Comparative figures for 2014 are not restated as RFR 2.

For definitions of key figures, see Note 27 Definition of key ratios and alternative performance measures on page 44.

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 2018 fiscal year. Figures in parentheses pertain to the preceding year. All amounts are expressed in SEK millions unless otherwise stated.

Operations

Calliditas Therapeutics, a specialist pharmaceutical company with its registered office in Stockholm, is focused on the development of high-quality pharmaceuticals in niched indications with a significant medical need that is not being satisfied and where the company can partially or entirely take part in the commercialization. The company focuses 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.

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. The company intends to take Nefecon through a global Phase 3 trial and onward to commercialization. In 2018, the company mainly focused on the development of Nefecon and preparations for the pivotal Phase 3 trial NefIgArd and in November 2018 announced that the first patients had been enrolled in the trial.

The company has no revenue and until Nefecon begins to generate revenue it is dependent on external financing as a means of ensuring continued operations. During the year, a share issue was conducted yielding proceeds of SEK 739 million before issue costs and the company was listed on Nasdaq Stockholm, Mid Cap (ticker: CALTX).

The Group consists of Parent Company Calliditas Therapeutics AB and the Swedish subsidiaries Nefecon AB, Busulipo AB and Pharmalink Nordic AB, together with the Norwegian subsidiary Pharmalink Oncology AS. During the year, work began to merge Busulipo AB and Pharmalink Nordic AB with the Parent Company, which is expected to be completed in 2019. There are no operating activities in the subsidiaries.

Significant events during the year

New patent application

During the second quarter of 2018, the company filed a new patent application. The application covers method and use for treatment of autoimmune diseases.

New issue and listing on Nasdaq Stockholm

On June 29, 2018, the company was listed on the main list of Nasdaq Stockholm and completed a share issue, which including the overallocation option amounted to SEK 739 million before issue costs. There was considerable interest in the offer, both from institutional investors and the general public in Sweden.

The offer was heavily oversubscribed and all investors from the public were allocated shares in the offer. In conjunction with the IPO, all bridge loans outstanding, in an amount of SEK 95.2 million including accrued interest, were converted to shares at a conversion price of SEK 45 per share, which corresponded to the listing price.

First patient enrolled

In November 2018, the first patient was enrolled in the company's pivotal clinical Phase 3 trial NefIgArd for the treatment of patients with IgA nephropathy (IgAN). The NefIgArd trial will study the effect of Nefecon compared with placebo on proteinuria in patients with IgAN. The randomized, double-blind, placebo-controlled NefIgArd trial will, in all material respects, have a similar design to the successful Phase 2b trial. The trial is divided into two phases: a treatment phase (Part A) and a long-term observation phase (Part B). Up to 450 patients with IgAN, confirmed through biopsies, and who are being treated with optimal or highly tolerable blood pressure medication will be randomized in this study in 19 selected countries in North America, Europe, Asia and Australia.

Extraordinary General Meeting and adoption of long-term incentive program

The Extraordinary General Meeting was held on

Board of Directors' Report

December 14, when the long-term incentive program LTIP 2018/2022 was approved. The Extraordinary General Meeting resolved in accordance with the Board's proposal to adopt a long-term incentive program in the form of up to 1,160,000 warrants for employees and consultants in the Group, consisting of no more than 25 participants. For more information, see Note 9 Warrants.

Sales and earnings

The company reported no revenue during the year. Other operating income amounted to SEK 0.7 million (0.1) and primarily refers to the company's foreign exchange gains on operating liabilities.

Research and development costs

During the year, total costs for research and development rose to SEK 99.3 million (51.7). In 2018, equivalent costs for research and development were 75% (61) of total operating expenses.Of total costs for research and development in 2018, SEK 93.3 million (38.4) was recognized as other external costs in profit or loss, including costs for clinical trials, drug candidate manufacturing and external consultants. The increase is primarily attributable to higher costs for preparations and the start of the company's Phase 3 trial NefIgArd in the form of costs for trial-related activities and manufacturing.

Of total costs for research and development in 2018, SEK 6.0 million (13.3) was recognized as personnel costs in profit or loss, including costs for staff in research and development operations. The decrease in personnel costs relating to research and development operations was largely due to the retroactive reduction of SEK 1.5 million in social security contributions for 2014–2017, which apply solely to research and development operations, and the change in the mix of involvement with the resulting reduction in the percentage of employees in research and development operations and an increase in the number of consultants compared with the full-year 2017.

General and administrative costs

In 2018, total general and administrative costs amounted to SEK 33.9 million (32.9). Of total general and administrative costs in 2018, SEK 20.8 million (25.6) was recognized as other external costs in profit or loss. The decrease in 2018 was primarily attributable to higher costs for preparations for the IPO conducted in 2018, which burdened the full-year 2017.
Of total general and administrative costs in 2018, SEK 13.1 million (7.3) was recognized as personnel costs in profit or loss, which pertain to costs for personnel in management, accounting and business development. The rise in personnel costs relating to general and administrative costs is primarily due to an increase in seniority among employees in this category.

Earnings

Net loss for the year amounted to SEK -132.0 million (-86.8), corresponding to earnings per share before and after dilution on SEK -5.09 (-5.81).

Liquidity and financial position

On December 31, 2018, cash and cash equivalents totaled SEK 646.2 million (57.4). In mid-2018, a new issue was conducted of 16.4 million shares at SEK 45 per share in conjunction with the IPO. The total issue amount was SEK 738.7 million, which yielded proceeds to the company of SEK 684.2 million net after issue costs. In the first quarter of 2018, the company entered into one mandatory convertible bridge loan with a principal amount of SEK 30.0 million from existing shareholders and was converted in its entirety into new shares in conjunction with the IPO in June 2018.

Equity amounted to SEK 618.2 million (33.2) at year-end 2018.

Cash flow and investments

Cash flow from operating activities amounted to SEK -128.2 million (-68.0) in 2018. Cash flow from investing activities amounted to SEK 0 million (-0.1). Cash flow from financing activities amounted to SEK 716.6 million (101.2) and primarily pertains to the new issue in conjunction with the IPO.

Cash flow for the year totaled SEK 588.4 million (33.2).

Personnel

At December 31, the total number of employees in the Parent Company and Group totaled 10 (10), of which 70% are women and 30% are men. The average number of employees was 10 (10) during the year.

Environment

The company works proactively to reduce its adverse environmental impact and to evolve as a sustainable company. Since the company has no sales, the company's products have no impact on the environment. Instead, environmental impact is in the areas of purchasing of products and services, energy consumption and travel. The company aims to contribute to sustainable development and is therefore endeavoring to actively improve environmental performance as far as it is economically viable. Due to the size of the company, no sustainability report for 2018 is established.

Long-term incentive programs

The company has three warrant programs outstanding, issued in 2015, 2017 and 2018. The warrant program issued in 2015 was addressed to employees and consultants and expires in April 2019. The program issued in 2017 was addressed to employees, consultants and Board members and expires in June 2020. The program issued in 2018 was addressed to employees and consultants and expires in March 2022. At the time of issuance, the warrants were priced at market value in accordance with the Black & Scholes pricing model. In the programs issued in 2015 and 2017, option holders may exercise the warrants at any time during the term of the warrant, while participants in the program from 2018 cannot exercise the warrants until the first quarter of 2022. At year-end, the total number of warrants outstanding, if fully subscribed, corresponded to 2,518,086 shares.

For further information about the warrants program, refer to Note 9 Warrants.

Share capital and shareholders

At December 31, 2018, share capital amounted to SEK 1,408,094 distributed between 35,202,347 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). The company's share was admitted to trading on Nasdaq Stockholm, Mid Cap, on June 29, 2018. At the end of 2018, the company had 2,345 shareholders and the ten largest shareholders held 78.8% of all shares outstanding. At December 31, 2018, Stiftelsen Industrifonden, Investinor AS and Linc AB (Bengt Julander) were the largest individual shareholders in the company, with a total of 7,732,538, 5,553,997 and 5,276,271 shares respectively, corresponding to 21.2%, 15.7% and 15.0% of voting rights and capital respectively.

Holdings of treasury shares and warrants

No shares were held in treasury by the company in 2018. The subsidiary Nefecon AB holds 303,414 warrants in the warrant program 2018/2022 pending any distribution to future participants in the program.

Work of the Board of Directors

The company's Board of Directors consists of six Board members including the Chairman, who is elected for the period until the 2019 AGM. The Board of Directors follows a written procedure that is revised on an annual basis and determined at the first regular Board meeting every year. Among other things, the rules of procedure govern the function of the Board of Directors as well as the functions and division of work between the members of the Board of Directors and the CEO. In connection with the Board meeting, the Board of Directors also establishes the instructions for the CEO, including financial reporting.

The Board 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 2018, activity on the Board was higher than normal due to the company's listing and capital procurement. The Board of Directors met 18 times in 2018. Other than the Board meetings, the Chairman of the Board and CEO maintain a continuous dialogue about the company's management.

For further information on corporate governance, see the Corporate Governance Report on page 58.

Guidelines for remuneration of senior executives

Remuneration within the Group is to be based on principles of performance, competitiveness and fairness. Senior executives refer to the CEO and other senior executives. The guidelines are to be applied to employment contracts entered into after the listing on Nasdaq Stockholm, and when changing existing agreements after the listing.

The remuneration to senior executives 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. Senior executives may be offered variable remuneration in cash. Such remuneration may not exceed 40% of the annual fixed remuneration. Variable remuneration shall be connected to predetermined and measurable criteria, designed with the aim of promoting the company's long-term value creation.

Board of Directors' Report

Remuneration and other employment terms for the CEO are determined by the Remuneration Committee and are resolved by the Board of Directors. Remuneration and other employment terms for other senior executives are approved by the CEO, in accordance with the principles adopted by the Board of Directors and Remuneration Committee.

The Board of Directors has the right to deviate from the guidelines if the Board of Directors in a specific case believes there are valid reasons for the deviation. The decision on current remuneration levels and other employment terms for the CEO and other senior executives was approved by the Board of Directors. There is no previous remuneration that is not yet paid.
For 2019, the same guidelines are proposed as for 2018.

Risk management

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

Risks and uncertainties

The company's operations are impacted by a number of factors that affect the company's earnings and financial position and that in certain respects cannot be controlled, in part or in full, by the company. When assessing the company's 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 company's future development are listed below, without any order of precedence.

Operational risks

The company's main operation is research and development of pharmaceuticals, which is a field that is both high-risk and very capital intensive. The company 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.

The company 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 classification in IgA nephropathy. The number of suitable patients for clinical trials is therefore lower than for common diseases and it may be challenging for the company 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 the company may not be approved and approved patents may be cancelled, which may lead to the company 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 US. 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 the company's strategy is to assess the potential to develop products in other indications. However, the company 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 the company's ambition to develop products for the treatment of other indications will be realized.

The company has no revenue and until Nefecon begins to generate revenue it is dependent on external financing as a means of ensuring continued 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. The company is primarily impacted by foreign-currency risk. Most of the company's future costs are in USD and EUR. In compliance with the financial policy, no currency hedging has been conducted as of December 31, 2018. 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 material respects also valid for the Parent Company. Earnings for the Parent Company amounted to a loss of SEK -131.9 million (-86.9).

On December 31, 2018, the Parent Company had cash and cash equivalents of SEK 645.9 million (57.0).

Outlook

The company's 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. Operations are capital intensive and until Nefecon begins to generate revenue, external financing will be required. In 2018, a new issue was conducted in conjunction with an IPO yielding proceeds of SEK 738.7 million before issue costs and conditions are therefore favorable for the company 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	1,069,072,271
Retained earnings	-320,299,629
Net income (loss) for the period	-131,922,968
	616,849,674

The Board of Directors proposes that SEK 616,849,674 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 the company. 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 company's financial position and negative earnings, the company's 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 2018 financial year.

For more information on the company's earnings and financial position, refer the following income statement and balance sheet, changes in equity and cash flow statement with accompanying supplementary disclosure.

Group

Consolidated statement of income

SEK 000	Note	Jan 1, 2018 –Dec 31, 2018	Jan 1, 2017 –Dec 31, 2017
Net sales	3	-	-
Other operating income	4	715	145
Operating expenses			
Other external operating expenses	5.7	-114,056	-63,986
Personnel expenses	8.9	-19,090	-20,617
Depreciation and amortization	14	-51	-51
Total operating expenses	6	**-133,197**	**-84,654**
Operating profit (loss)		**-132,482**	**-84,509**
Financial income	10	441	0
Financial expenses	11	-8	-2,285
Net financial items		**433**	**-2,285**
Profit (loss) before tax		**-132,049**	**-86,794**
Income taxes	12	-	-
Net income (loss) for the period attributable to shareholders of the Parent Company		**-132,049**	**-86,794**
Earnings per share before and after dilution	13	-5.09	-5.81

Consolidated statement of comprehensive income

SEK 000	Note	Jan 1, 2018 –Dec 31, 2018	Jan 1, 2017 –Dec 31, 2017
Net income (loss) for the period		-132,049	-86,794
Other comprehensive income			
Items to be reclassified to profit and loss			
Currency translation effect		6	-4
Total other comprehensive income		**6**	**-4**
Total comprehensive income attributable to shareholders of the Parent Company		**-132,043**	**-86,798**

Group

Consolidiated statement of financial position

SEK 000	Note	2018-12-31	2017-12-31
ASSETS			
Non-current assets			
Equipment	14	107	158
Financial non-current assets	15.16	341	341
Total non-current assets		**448**	**499**
Current assets			
Other current assets	16	1,630	4,272
Prepaid expenses	18	164	165
Cash and cash equivalents	19	646,175	57,352
Total current assets		**647,969**	**61,789**
TOTAL ASSETS		**648,417**	**62,288**
EQUITY AND LIABILITIES			
Shareholders equity	21		
Share capital		1,408	667
Additional paid-in capital		1,072,319	352,959
Reserves		-34	-40
Retained earnings including net loss for the period		-455,518	-320,410
Total equity attributable to shareholders of the Parent Company		**618,175**	**33,176**
Current liabilities			
Accounts payable	16.17	22,643	13,684
Shareholder loans	22	-	470
Other current liabilities		904	683
Accrued expenses	23	6,695	14,275
Total current liabilities		**30,242**	**29,112**
TOTAL EQUITY AND LIABILITIES		**648,417**	**62,288**

Group

Consolidated statement of changes in equity

SEK 000	Note	Share capital	Additional paid-in capital	Translation reserve	Retained earnings including net loss for the year	Total
Opening shareholders equity Jan 1, 2017		**531**	**218,408**	**-36**	**-233,126**	**-14,223**
Net income (loss) for the period		-	-	-	-86,794	-86,794
Other comprehensive income		-	-	-4	-	-4
Total comprehensive income		**-**	**-**	**-4**	**-86,794**	**-86,798**
Transactions with owners:						
New share issue		136	72,069	-	-	72,205
Cost attributable to new share issue		-	-50	-	-	-50
Premiums received from warrants		-	207	-	-	207
Warrants program	9	-	213	-	-	213
Contributions from shareholders	21	-	61,622	-	-	61,622
Interest from capital contributions from shareholders	21	-	490	-	-490	-
Total transactions with owners		**136**	**134,551**	**-**	**-490**	**134,197**
Closing shareholders equity Dec 31, 2017		**667**	**352,959**	**-40**	**-320,410**	**33,176**
Opening shareholders equity Jan 1, 2018		**667**	**352,959**	**-40**	**-320,410**	**33,176**
Net income (loss) for the period		-	-	-	-132,049	-132,049
Other comprehensive income		-	-	6	-	6
Total comprehensive income		**-**	**-**	**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	9	-	2,826	-	-	2,826
Contributions from shareholders	21	-	29,999	-	-	29,999
Interest from capital contributions from shareholders	21	-	3,059	-	-3,059	-
Total transactions with owners		**741**	**719,360**	**-**	**-3,059**	**717,042**
Closing shareholders equity Dec 31, 2018	9,21	**1,408**	**1,072,319**	**-34**	**-455,518**	**618,175**

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

Group

Consolidated statement of cash flow

SEK 000	Note	Jan 1, 2018 –Dec 31, 2018	Jan 1, 2017 –Dec 31, 2017
Operating activities			
Operating profit (loss)		-132,482	-84,509
Adjustments for non-cash items	19	51	332
Interest received		6	0
Interest paid		-8	-11
Cash flow from operating activities before changes in working capital		**-132,433**	**-84,188**
Cash flow from changes in working capital			
Changes in operating receivables		2,642	-1,885
Changes in operating liabilities		1,600	18,066
Cash flow from operating activities		**-128,191**	**-68,007**
Investing activities			
Investments in financial assets	15	-	-50
Cash flow from investing activities		**–**	**-50**
Financing activities			
New share issue		738,650	3,129
Cost attributable to new share issue		-54,433	-50
Loans from related parties		-	36,316
Repayment of loans		-470	-
Premiums received from warrants		2,826	207
Contributions from shareholders		29,999	61,622
Cash flow from financing activities		**716,572**	**101,224**
Net increase (decrease) in cash & cash equivalents		**588,381**	**33,167**
Cash and cash equivalents at beginning of the year		**57,352**	**24,241**
Exchange-rate difference in cash and cash equivalents		442	-56
Cash and cash equivalents at the end of the year	19	**646,175**	**57,352**

Group

Accounting policies and notes

Note 1 Accounting policies

Calliditas Therapeutics AB (556659-9766) and its subsidiaries (collectively, the "Group") conduct development activities in pharmaceuticals. These consolidated financial statements encompass the Swedish Parent Company and its subsidiaries.

The Parent Company is a limited company registered and domiciled in Stockholm, Sweden. The address of the head office is Wallingatan 26 B, Stockholm, Sweden.
The Board of Directors approved this annual report and consolidated financial statements on April 3, 2019 and they will be presented for adoption at the Annual General Meeting on May 8, 2019.

Applied regulations
These consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS), as adopted by the European Union (EU), as well as the recommendation RFR 1 Supplementary Accounting Rules for Corporate 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.

Functional currency and presentation 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 SEK. All amounts, unless otherwise stated, are rounded to the nearest thousand (SEK 000s).

Basis for valuation and classification
Assets, provisions and liabilities are based on cost, unless otherwise stated below.

Fixed assets and non-current liabilities comprise amounts that are expected to be recovered or paid more than twelve months after the closing date. Current assets and current liabilities comprise amounts that are expected to be recovered or paid more within twelve months of the closing date.

New accounting policies applied by the Group
A number of new standards have come into effect during the year, and the IFRS standards that impact the consolidated or Parent Company's financial statements are described below. Other new or amended standards or interpretations were published by the IASB and had no material impact on the Group's or Parent Company's financial statements.

IFRS 9 Financial instruments
The standard concerns the recognition of financial assets and liabilities and replaces IAS 39. Similar to IAS 39, financial assets are classified in different categories, with some measured at amortized cost and others at fair value. To assess the recognition of a financial instrument under IFRS 9, a company must study the contractual cash flows and the business models under which the instrument is held. IFRS 9 also introduced a new model for impairment of financial assets. One of the aims of the new model is that credit losses are to be recognized at an earlier point in time than under IAS 39. As regards financial liabilities, IFRS 9 largely coincides with IAS 39. Changed criteria for hedge accounting could lead to more financial hedging strategies meeting the requirements for hedge accounting under IFRS 9 compared to IAS 39.

IFRS 9 came into effect on January 1, 2018, and was applied by the Group from January 1, 2018. The standard did not have any material impact on the Group's or the Parent Company's earnings or financial position, since all of the Group's and Parent Company's financial instruments continue to fulfill the criteria to be recognized at amortized cost, since the Group's and Parent Company's exposure to credit risk is not material, and since the Group and Parent Company do not apply hedge accounting. The Group applies IFRS 9 forward-looking from 1 January 2018.

IFRS 15 Revenue from Contracts with Customers
This standard replaces all previously issued standards and interpretations that concern revenue with a combined model for revenue recognition. According to IFRS 15, income is reported when a promised good or service is transferred to a customer, which may occur over time or at a time. Revenue is to comprise the amount of consideration to which a company expects to be entitled in exchange for transferring promised goods or services.

IFRS 15 came into effect for fiscal years beginning on or after January 1, 2018. The Group applied the standard from January 1, 2018 using the full retroactive approach. The standard did not have any material impact on the Group's or the Parent Company's earnings or financial position, since the Group and Parent Company as yet do not report any revenue.

New or amended accounting standards that have not yet been applied
A number of new or amended IFRSs have not yet come into effect and were not applied in advance upon the preparation of the financial statements of the Group or Parent Company. The IFRSs that could impact the Group's or Parent Company's financial statements are described below. Other new or amended standards or interpretations published by the IASB are not expected to have any material impact on the Group's or Parent Company's financial statements.

IFRS 16 Leases
IFRS 16 will replace IAS 17. According to the new standard, the lessee must report the obligation to pay lease fees as a lease liability in the balance sheet. The right to use the underlying asset during the lease period is reported as an asset. Depreciation on the asset is reported in the income statement as well as interest on the lease liability. Remaining lease fees are reported partly as payment of interest and partly as amortization of leasing debt. The standard excludes leases with a lease term of less than 12 months (short-term leases) and leases for low value assets. For the lessor, the new standard does not mean any major differences. IFRS 16 enters into force for fiscal years commencing January 1, 2019 or later and was applied by the Group as of January 1, 2019.

The standard means that most of the leases reported in these financial statements as operating leases will be reported as assets and liabilities in the financial statement. This will also cause the cost of these to be reported broken down into interest expense and depreciation. In the Parent Company, the exemption in RFR 2 will be applied for leases. This means the Parent Company's principles for recognition of leases will remain unchanged.
Calliditas is using the simplified transition method, and right-of-use assets and attributable financial liabilities will increase by about SEK 1.8 million as of January 1, 2019.

Revenue
The Group does not currently recognize any income from sales of goods since market approval has not yet been secured for the Group's products.

The Group recognizes revenue when the amount can be measured in a reliable way, when it is likely that there will be future benefits for the company and when specific criteria have been fulfilled for each of the Group's operations. Revenue includes the fair value of what has been paid or will be paid for sold services as part of the Group's ongoing operations. Revenue is recognized excluding VAT, returns and discounts and after elimination of intra-Group sales.

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.

Employee benefits
Current 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 company is unquestionably obligated,
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, a cost for this 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.

Leases
The Group only has leases that are recognized as operating leases, meaning leases whereby the lessor essentially retains all risks and rewards associated with ownership of the asset. Any incentives received when signing leases are included in the calculation of the total cost of the agreement. Lease fees are expensed through profit or loss on a straight-line basis over the contract period.

Financial expenses
Financial expenses mainly consist of interest expenses on loans and foreign exchange losses. Interest expenses on loans are recognized in line with the effective interest method. Interest expenses on loans classified as equity are recognized in equity. Foreign exchange gains and losses are netted.

Tax
Income tax comprises current tax and deferred tax. Income tax is recognized in net profit for the period, 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 tax that is to be paid or received in the current year, with the application of the tax rates that are decided or decided in practice on the closing date. Current tax also includes adjustments of current tax attributable to prior periods.

Deferred tax is calculated on temporary differences between the tax bases 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. Deferred tax is calculated 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 likely that it will be possible to utilize these. The value of deferred tax assets is reduced when it is no longer deemed likely that they can be utilized.

Intangible assets
Development expenditure is capitalized when it meets the criteria for capitalization. The most important criteria for capitalization are that the final product of the development process has a provable future earnings capacity or cost-saving, and that the technical and financial conditions exist for completing the development work. Development expenditure and research expenditure are otherwise expensed 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 expenditure are not met.

Tangible assets
Tangible assets comprise equipment used in the Group's operations. These assets are recognized in the balance sheet at cost less accumulated depreciation and impairment. Maintenance of assets is expensed when the maintenance is carried out, while expenses for improvements are recognized as investments and added to the cost of the assets. Equipment is depreciated on a straight-line basis over the expected useful life. The Group's expected useful lives are:

- Computers – 3 years
- Equipment – 5 years

The useful lives of assets are reviewed and adjusted as necessary. 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.

Financial instruments
Financial instruments are recognized in the balance sheet when the Group becomes a party according to the instrument's contractual terms. A claim is raised when the company has performed and there is a contractual obligation for the counterparty to pay. A liability is raised when the counterparty has performed and there is a contractual obligation to pay. The business model for which the financial asset or liability was acquired or entered into and the nature of the contractual cash flows is crucial for the classification. The Group has financial assets and liabilities classified in the following categories:

- Financial assets at amortized cost
- Financial liabilities at amortized cost

The Group does not conduct any active trading in financial instruments that are not related to the Group's business. Due to this, the financial assets and liabilities reported in the balance sheet are primarily liquid funds, accounts payable and accrued expenses against the Group's suppliers. During the financial year or the comparative year, the Group did not have any financial instruments that are valued at fair value, either through profit or other comprehensive income. During the comparative year, the Group held financial assets classified as loan receivables and accounts receivable according to IAS 39. These have in all material respects been reported in the same way as financial assets at amortized cost according to IFRS 9.

Financial assets classified at amortized cost are initially measured at fair value with the addition of transaction costs. After the first accounting opportunity, the assets are valued according to the effective interest method. Assets classified at amortized cost are held according to the business model to collect contractual cash flows that are only payments of principal amounts and interest on the outstanding capital amount. Expected credit losses have been deemed to be insignificant, since the company's financial assets essentially comprise bank deposits with banks with high credit ratings.

Financial liabilities recognized at amortized cost are initially measured at fair value including transaction costs. After the first accounting date, they are valued at accrued acquisition value according to the effective interest method.

Cash and cash equivalents
Cash and cash equivalents include cash and bank balances.

Equity
Common shares, other contributed capital and retained earnings are classified as equity. Financial instruments that are deemed to meet the criteria for classification as equity are recognized as equity even if the financial instrument is legally structured as a liability. Calliditas has raised mandatory convertible bridge loans classified as equity in the consolidated financial statements. Interest expenses on the bridge loans is reported in equity as a transfer from additional paid-in capital to retained earnings. Transaction costs that are directly attributable to the issue of new shares or options are recognized net after tax in equity as a deduction from the issue proceeds.

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

Contingent liabilities
A contingent liability is recognized when there is a possible commitment originating from events that have occurred and whose occurrence is confirmed by one or several uncertain future events or when there is a commitment that is not recognized as a liability or provision because it is unlikely that an outflow of resources will be required.

Consolidation
The consolidated financial statements include the Parent Company and all companies that are under the controlling influence of the Parent Company.

Accounting policies and notes – Group

Controlling influence means that 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 financial statements of subsidiaries are included in the consolidated financial statements from the acquisition date until the date on which the controlling influence ceases. Intra-Group receivables and liabilities and income and expenses arising from intra-Group transactions are eliminated in their entirety when the consolidated financial statements are prepared.

Business combinations
Business combination are treated in accordance with the acquisition method. This method entails that the acquisition of a business is considered to be a transaction whereby the Group indirectly acquires the business's assets and assumes its liabilities. The acquisition analysis determines the fair value of the acquired identifiable assets and assumed liabilities, as well as any non-controlling interests, on the acquisition date. Transaction costs attributable to the acquisition are recognized as an expense in net profit for the period. For business combinations whereby consideration transferred exceeds the fair value of the acquired company's net assets, the difference is recognized as goodwill.

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 period. 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.

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' currencies are recognized in other comprehensive income.

Earnings per share
The calculation of earnings per share is based on net profit for the period in the Group attributable to the Parent Company shareholders 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 are 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 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.

Operating segments
An operating segment is a part of the Group that conducts business activities from which it can generate revenue and incur costs, and for which independent financial information is available. Identification of reportable segments is based on internal reporting to the chief operating decision maker, who for the Group is the CEO. The Group comprises one segment for such internal reporting.

Note 2 Judgements and estimates

The preparation of the financial statements in accordance with IFRS requires that management make judgements and estimates, and make assumptions that affect the application of the accounting policies and the recognized amounts of assets, liabilities, income and expenses. The actual outcome may deviate from these estimates.

Estimates and assumptions are reviewed regularly. Changes in estimates are recognized in the period in which the change is made if the change only affects that period, or in the period in which the change is made and future periods if the change affects both current and future periods.

Point in time for capitalization of intangible assets
The Group capitalizes expenditure for the development of pharmaceuticals to the extent that it is expected to meet the criteria in accordance with IAS 38, p. 57. The company's expenditure for the development of pharmaceuticals was not deemed to meet the capitalization criteria for the fiscal years 2018 and 2017 and was thus expensed. Capitalization of expenditure for the development of pharmaceuticals takes place late in Phase 3, 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.

Loss carryforwards
The Group's loss carryforwards has not been measured and is not recognized as a deferred tax asset. This loss carryforwards is measured first when the Group has established a level of earnings that management is likely to judge will result in a tax surplus.

Note 3 Operating segments

Calliditas does not divide its operations into different segments, instead the Group's entire operations are treated as one segment. This division reflects the company's internal organization and reporting system. Calliditas chief operating decision maker is the CEO. The Group's tangible assets are attributable only to Swedish companies.

Note 4 Other operating income

Other operating income of SEK 715 thousand (145) refers mainly to currency exchange differences.

Note 5 Auditors' fee

	2018	2017
Ernst & Young AB		
Audit assignments	509	570
Other audit activities	1,612	2,729
Fees for tax consultations	-	-
Other services	-	-
Total	**2,121**	**3,299**

Note 6 Research and development expenses

	2018	2017
Expenses for research and development	99,260	51,686

Note 7 Leases

Operating lessee
Leasing costs for the year attributable to operating leases primarily comprise rent for premises and leasing fees for office equipment. Leases for premises in the Parent Company extend until March 31, 2022, with the option of extension after the end of the lease period. Future minimum leasing fees are linked to the KPI index, but with restrictions in the event of negative index changes.

Future payment commitments for operating leases as at December 31 are specified as follows:

Future minimum lease fees

	2018	2017
Within 1 year	610	580
Between 1 and 5 years	1,373	145
More than 5 years	-	-
Total	**1,983**	**725**
Lease costs for the year in respect of operating leases amount to:	723	777

Note 8 Employees and personnel costs

Average number of employees

	2018		2017	
Parent Company	No. of employees	Of whom, men	No. of employees	Of whom, men
Sweden	10	30%	9	33%
	10	**30%**	**9**	**33%**
Subsidiaries				
Norway	-	-	1	100%
	-	**-**	**1**	**100%**
Group, total	**10**	**30%**	**10**	**40%**

Salaries and other remuneration, pension costs and social security expenses to the Board, senior executives and other employees

Salaries and other remuneration

	2018	2017
Parent Company		
Board and senior executives[1)]	9,875	9,420
Other employees	3,789	3,123
Subsidiaries		
Board and senior executives	-	-
Other employees	-	852
Total	**13,664**	**13,395**

Social security expenses and pension costs

	2018	2017
Parent Company		
Pension costs for the Board and senior executives	1,429	1,203
Pension costs to other employees	699	611
Social security expenses	2,843	4,260
Subsidiaries		
Pension costs to other employees	-	68
Social security expenses	-	130
Total	**4,971**	**6,272**

Senior executives include the Board, CEO and other senior executives.

Gender distribution among senior executives

	Dec 31, 2018	Dec 31, 2017
Percentage of women on the Board	33%	33%
Percentage of men on the Board	67%	67%
Percentage of women among other senior executives	43%	38%
Percentage of men among other senior executives	57%	62%

Note 8, cont. →

Accounting policies and notes – Group

Note 8 Employees and personnel costs, cont.

Disclosures regarding remuneration of the Board and senior executives

	Basic salary, Board fee	Pension costs	Variable remuneration	Other remuneration	Share-based payments	Total
2018						
Board Chairman 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
of which, subsidiaries	-	-	-	-	-	-
Total	**8,509**	**1,429**	**1,366**	**6,001**	**0**	**17,305**
2017						
Board Chairman Maria Carell (until July 2017)	197	-	-	-	-	197
Thomas Eklund (from Aug 2017)	150	-	-	-	-	150
Board members						
Olav Hellebø	185	-	-	-	-	185
Hilde Furberg	211	-	-	-	-	211
Senior executives						
CEO (Johan Häggblad until April 2017)	520	93	-	-	-	613
CEO (Renée Lucander from May 2017)	1,531	269	410	-	61	2,271
Other senior executives (6 people)	5,406	840	652	5,047	97	12,042
of which, subsidiaries	-	-	-	-	-	-
Total	**8,200**	**1,202**	**1,062**	**5,047**	**158**	**15,669**

[1] *Bengt Julander, Lennart Hansson and Ann-Tove Kongsnes received no reimbursement for 2017 and 2018.*

Other remuneration
Other remuneration comprises fees for services rendered to the Parent Company. Services purchased from Jedako Consult AB amounted to SEK 3,424 thousand (2,432) and refer to the Chief Medical Officer in management. Services purchased from Cordcom Consultants KB amounted to SEK 951 thousand and refer to the Head of Communications and IR in management. Services purchased from Skepparhagen AB amounted to SEK 1,625 thousand (2,615) and refer to the Finance Director in management up to and including September 2018.

Remuneration of senior executives
Remuneration of the CEO and other senior executives comprises basic salary, pension benefits, variable remuneration and remuneration in the form as consultancy fees. Other senior executives comprise the seven (six) individuals who, together with the CEO, comprise Executive Management. Other senior executives are: Chief Financial Officer, Chief Medical Officer, VP Head of Clinical Development & Project Management, VP Pharmaceutical Development, VP Licensing, IP and Legal, Head of Communications and IR and Finance Director (until Sep 2018).

Pensions
All pension commitments are defined-contribution. The age of retirement for the CEO is 65 and the pension premium is 20% of basic salary. Pension commitments for other Swedish senior executives are between 15% and 20% of basic 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 basic 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 is 30% of basic salary and for other senior executives is up to 25% of basic salary.

Warrants
Premiums received for warrants granted to acquire shares in companies within the Group are reported as an addition to equity, based on the warrant premium, at the date when the warrant was transferred to the counterparty. For warrants programs issued in 2017, employee benefits are included in staff costs for 2017, on the basis that the fair value of the warrants exceeded the paid premium.

For further information about the warrants program, refer to Note 9 Warrants.

Severance pay
A notice period of six months applies if employment is terminated by the CEO. A notice period of 12 months applies if employment is terminated by the company. The CEO is not entitled to separate severance pay, but receives a salary during the period of notice. A mutual notice period of 3–12 months, with salary paid, applies between the company and senior executives. No severance pay is paid to Board members.

Note 9 Warrants

Calliditas Therapeutics AB has three warrants programs, whereby personnel and certain other employees have purchased warrants with rights to acquire shares in the Parent Company. The exercised warrants entail that the holder pays a subscription price and then receives one common share in the Parent Company. For the programs initiated in 2015 and 2017, the warrants can be exercised at any time until their expiry date without having to fulfil any conditions, while the program initiated in 2018 can be exercised between January 1 and March 31, 2022.

The warrants have been valued according to the Black & Scholes model, which means the value of the warrant depends on factors including the value of the underlying share, which in this case is the common share. For the programs initiated in 2015 and 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 program initiated in 2018, the observation period was short for the underlying share. 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 expiry.

Allotted warrants	Accumulated no. of outstanding	Average exercise price, SEK
On Dec 31, 2017	1,661,500	46
On Dec 31, 2018	2,518,086	56

The allocated average exercise price for warrants that are outstanding on the closing date amounts to SEK 56. No warrants were forfeited, expired or redeemed in 2018. In 2017, 452,500 warrants issued in 2015 were terminated.

Outstanding per year, warrants	No. of outstanding, Dec 31, 2018	No. of outstanding, Dec 31, 2017	Subscription price, SEK	Price per warrant, SEK	Value per share, SEK	Volatility	Expiry date
Warrant program 2015/2019	365,000	365,000	60.00	0.08	21.2	30%	Apr 30, 2019
Warrant program 2017/2020	1,296,500	1,296,500	42.36	0.28	21.2	27%	Jun 30, 2020
Warrant program 2018/2022	856,586	-	74.30	3.29	46.5	33%	Mar 31, 2022
Total	**2,518,086**	**1,661,500**					

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

Holder	No. of outstanding Jan 1, 2017	Change	No. of outstanding Dec 31, 2017	Change	No. of outstanding Dec 31, 2018
CEO Renée Lucander (from May 2017)	-	369,500	369,500	350,000	719,500
Board Chairman Thomas Eklund	-	111,250	111,250	-	111,250
Board member Hilde Furberg	47,500	-17,875	29,625	-	29,625
Board member Olav Hellebø	47,500	-28,125	19,375	-	19,375
Other senior executives	302,500	287,500	590,000	188,586	778,586
Other employees, consultants and external parties	420,000	121,750	541,750	318,000	859,750
Total	**817,500**	**844,000**	**1,661,500**	**856,586**	**2,518,086**

Note 10 Financial income

	2018	2017
Interest income	6	0
Exchange rate differences	435	-
Total	**441**	**0**

Note 11 Financial expenses

	2018	2017
Interest expense on loans to shareholders	-	-2,233
Other interest expenses	-8	-11
Exchange rate differences	-	-41
Total	**-8**	**-2,285**

Accounting policies and notes – Group

Note 12 Income tax

	2018	2017
Aktuell skatt	-	-
Reported tax expense	**-**	**-**
Reconciliation of effective tax rate		
Loss before tax	-132,049	-86,794
Tax in accordance with applicable tax rate for Parent Company (22%)	29,051	19,095
Tax attributable to unrecognized deferred tax assets	-29,069	-19,231
Non-deductible expenses	-35	-186
Non-taxable income	53	322
Reported tax expense	**-**	**-**

The Group has tax items pertaining to issue costs that are recognized directly against equity. There are loss carryforwards for which deferred tax assets have not been recognized in the balance sheet amounting to SEK 535,802 thousand (349,398), and these loss carryforwards have no time limit.

Deferred tax assets were not recognized for these items since it is not yet probable that the Group will utilize them to settle against future taxable profits.

Note 13 Earnings per share

	2018	2017
Earnings per share before and after dilution		
Net profit for the year (SEK 000s) attributable to Parent Company shareholders	-132,049	-86,794
Average number of common shares outstanding	25,948,037	14,927,736
Earnings per share before dilution (SEK)	**-5.09**	**-5.81**

There is no dilution effect for issued warrants with entitlement to subscribe to 2,518,086 shares, since the earnings for the years presented above have been negative.

For disclosures regarding the number of outstanding shares, refer to Note 21 Equity.

Note 14 Equipment

	Dec 31, 2018	Dec 31, 2017
Opening cost	813	813
Closing accumulated cost	**813**	**813**
Opening depreciation	-655	-604
Depreciation for the year	-51	-51
Closing accumulated depreciation	**-706**	**-655**
Closing carrying amount	**107**	**158**

Note 15 Financial non-current assets

	Dec 31, 2018	Dec 31, 2017
Opening cost	341	291
Bank guarantees granted	-	50
Closing carrying amount	**341**	**341**

Other financial assets comprise deposits paid for rent of premises SEK 340 thousand (340) and SEK 1 thousand (1) that pertains to 1,000 shares in LFF Service AB, whose holdings are linked to insurance in connection with the company's wholesale license.

Note 16 Financial assets and liabilities

Financial assets and liabilities at December 31, 2018

	Financial assets measured amortized cost	Non-financial assets	Total carrying amount
Assets			
Equipment	-	107	107
Financial non-current assets	341	-	341
Other current receivables	-	1,630	1,630
Prepaid expenses	-	164	164
Cash and cash equivalents	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	944	5,751	6,695
	23,587	**6,655**	**30,242**

Financial assets and liabilities at December 31, 2017

	Accounts receivable and loan receivables	Non-financial assets	Total carrying amount
Assets			
Equipment	-	158	158
Financial non-current assets	341	-	341
Other current receivables	-	4,272	4,272
Prepaid expenses	-	165	165
Cash and cash equivalents	57,352	-	57,352
	57,693	**4,595**	**62,288**

	Financial liabilities measured at amortized cost	Non-financial assets	Total carrying amount
Liabilities			
Accounts payable	13,684	-	13,684
Shareholder loans	470	-	470
Other current liabilities	-	683	683
Accrued expenses	9,780	4,495	14,275
	23,934	**5,178**	**29,112**

The carrying amount for all items above is an approximation of the fair value. The Group's financial assets comprise in all material respects deposits with banks with high credit ratings, which means the company is of the opinion that there is no material credit risk, and accordingly no provision for credit risk is recognized.

Note 17 Financial risks

Through its operations, the Group is exposed to a variety of financial risks: credit risk, market risks (currency risk, interest rate risk and other price 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 by the Parent Company 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. The Group does not currently hedge any currencies.

Credit risk
Credit risk is the risk that the Group's counterparty in a financial instrument is unable to meet its obligations and thereby causes a financial loss for the Group. The Group's exposure to credit risk is limited to deposits with banks with AA credit ratings.

Market risks
Market risk is the risk that the fair value of, or future cash flows from, a financial instrument will vary due to 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.

Currency risk
Currency risk is the risk that the fair value of, or future cash flows from, a financial instrument will vary due to fluctuations 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 2018 (%)	Operating income	Operating expenses
USD	-	10%
EUR	-	52%
GBP	-	2%
SEK	-	36%

As presented in the table above, the Group's primary transaction exposure is in EUR and USD. A 10% stronger EUR against SEK would have a negative impact on profit after tax and equity of approximately SEK -6,006 thousand. A 10% stronger USD against SEK would have a negative impact on profit after tax and equity of approximately SEK -1,115 thousand.

Translation exposure
The Group also has translation exposure that arises on the translation of earnings and net assets of foreign subsidiaries to SEK. This translation exposure exists against the NOK and amounted to a loss of SEK -213 thousand on the closing date (-54). A 10% stronger SEK against NOK would impact equity by a gain of approximately SEK 21 thousand (5).

The Group also has a translation exposure arising from the translation of foreign trade debt to SEK. This exposure amounted to SEK 3,202 thousand (4,600) at the closing date in USD and SEK 15,701 thousand (1,160) in EUR. A 10% stronger USD against SEK would have a negative impact on profit after tax and equity of approximately SEK -320 thousand (-460). A 10% stronger EUR against SEK would have a negative impact on profit after tax and equity of approximately SEK -1,570 thousand (-116).

Refinancing risk
Refinancing risk refers to the risk that cash and cash equivalents are not available and that financing can only partly, or even not at all, be secured or alternatively at a higher cost.

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 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 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 calculated at the rate on the closing date. Liabilities were included in the earliest period when repayment is required.

Maturity analysis

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

	Dec 31, 2017		
	<6 months	6-12 months	>12 months
Accounts payable	13,684	-	-
Shareholder loans	470	-	-
Other current liabilities	683	-	-
Accrued expenses	12,333	1,942	-

Accounting policies and notes – Group

Note 18 Prepaid expenses

	Dec 31, 2018	Dec 31, 2017
Prepaid rental charges	164	165
Total	**164**	**165**

Note 19 Cash and cash equivalents

	Dec 31, 2018	Dec 31, 2017
Available balances	646,175	57,352
Total	**646,175**	**57,352**

Cash and cash equivalents refer to bank balances and are primarily in SEK.

Cash flow, items that do not affect liquidity

	Dec 31, 2018	Dec 31, 2017
Depreciation/amortization	51	51
Warrants	-	213
Other	-	68
Total	**51**	**332**

Reconciliation of liabilities from financing activities

		Cash flow	Non-cash-items		
	Jan 1, 2018		Interest on loan	Offsetting of new shares	Dec 31, 2018
Shareholder loans	470	-470	–	–	–
	470	**-470**	**–**	**–**	**–**

		Cash flow	Non-cash-items		
	Jan 1, 2017		Interest on loan	Offsetting of new shares	Dec 31, 2017
Shareholder loans	30,000	36,316	–	-65,846	470
Accrued interest	996	–	2,233	-3,229	–
	30,996	**36,316**	**2,233**	**-69,075**	**470**

Note 20 Group companies

Company	Main activity	Participating interest 2018	Participating interest 2017
Parent Company			
Calliditas Therapeutics AB	Research and development of pharmaceuticals		
Nefecon AB	Holding of intellectual property rights and administration of incentive programs issued by the Parent Company	100%	100%
Pharmalink Nordic AB	Currently no activities	100%	100%
Pharmalink Oncology AS, Norway	Currently no activities	100%	100%
Busulipo AB	Currently no activities	100%	100%

The composition of the Group was unchanged during the fiscal year. The Pharmalink Nordic AB and Busulipo AB subsidiaries will be discontinued through a merger with the Parent Company Calliditas Therapeutics AB. The mergers are expected to be completed in 2019.

Note 21 Shareholders equity

Share capital and other contributed capital

	No. of shares	Share capital	Additional paid-in capital
At January 1, 2017	13,262,500	531	218,408
Warrants program and premiums received from warrants			421
Offset issue approved in April 2017	1,512,500	60	31,975
New share issue approved in June 2017	141,500	6	2,961
Offset issue approved in September 2017	1,756,500	70	37,082
Contributions from shareholder			61,622
Interest from capital contributions from shareholders			490
At December 31, 2017	**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
IPO new share issue June, 2018	16,414,444	657	683,560
At December 31, 2018	**35,202,347**	**1,408**	**1,072,319**

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. No shares are held in treasury by the company or its subsidiaries.

Additional paid-in capital
Other contributed capital comprises capital contributed by the 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 2017 and 2018, the company entered into mandatory convertible bridge loans with a principal amount of SEK 91.6 million from existing shareholders with an annual interest of 8% and maturity of 12 months. In conjunction with the IPO on June 29, 2018, all bridge loans outstanding, in an amount of SEK 95.2 million including accrued interest, were converted to shares at a conversion price of SEK 45 per share, which corresponded to the market price when listing the company's share on Nasdaq Stockholm.

Translation reserve
The reserves pertains 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.

	2018	2017
Opening carrying amount	-40	-36
Change for the year	6	-4
Closing carrying amount	**-34**	**-40**

Note 22 Loan from shareholders

	Dec 31, 2018	Dec 31, 2017
Opening balance	470	30,000
Borrowing for the year	-	36,316
Offsetting of loan	-	-65,846
Amortization for the year	-470	-
Total	**–**	**470**

No interest was paid on the loan amounting to SEK 470 thousand.

Note 23 Accrued expenses

	Dec 31, 2018	Dec 31, 2017
Accrued salaries and Board fees	2,286	1,684
Vacation pay liability	1,347	1,143
Social security contributions	2,098	1,560
Accrued expenses for research and development	944	7,271
Other accrued expenses	20	2,617
Total	**6,695**	**14,275**

Note 24 Related-party transactions

For information regarding remuneration of senior executives, refer to Note 8 Employees and personnel costs.

There are no additional agreements or transactions with related parties, other than those described in Notes 8, 9 and 22.

Note 25 Pledged assets, contingent liabilities and other obligations

The company has a licensing agreement with Archimedes Development Ltd (UK). Under this agreement, the company has an exclusive global right to use a certain formulation for Nefecon.

The company has exclusive rights to use, develop and market the formulation under the agreement, and Archimedes Development Ltd only has rights to royalties when the product is sold in the future. The company will then have an obligation to pay royalties of 3% of net sales until the exclusive license for the patent expires in 2029.

The company has pledged assets amounting to SEK 340 thousand (340) in restricted bank accounts. The Group has no other obligations.

Accounting policies and notes – Group

Note 26 Events after the closing date

Calliditas was granted orphan designation by the US Food and Drug Administration (FDA) for the treatment of autoimmune hepatitis (AIH) and the company is planning to reach an agreement with the FDA concerning the regulatory path moving forward for this indication in 2019.

Calliditas was also granted orphan designation by the FDA for the treatment of primary biliary cholangitis (PBC). The company is planning to discuss the regulatory path forward with the FDA as a means of deciding on the most appropriate clinical trials for this indication.

Not 27 Definition of key ratios and alternative performance measures

Equity ratio at the end of the period %	The ratio at the end of respective period 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.

SEK 000	Jan 1, 2018 – Dec 31, 2018	Jan 1, 2017 – Dec 31, 2017
Expenses relating to research and development/operating expenses, %		
Personnel expenses related to R&D[1]	-5,961	-13,324
Other external operating expenses related to R&D	-93,299	-38,362
Expenses related to research and development	**-99,260**	**-51,686**
Personnel expenses related to G&A[2]	-13,129	-7,293
Other external operating expenses related to G&A	-20,757	-25,624
Expenses related to general and administration	**-33,886**	**-32,917**
Depreciation and amortization	-51	-51
Total operating expenses	**-133,197**	**-84,654**
Expenses relating to research and development/ operating expenses, %	75%	61%
Expenses relating to general and administration/ operating expenses, %	25%	39%

	Dec 31, 2018	Dec 31, 2017
Equity ratio at the end of the period %		
Total shareholders' equity at the end of the period	618,175	33,176
Total assets at the end of the period	648,417	62,288
Equity ratio at the end of the period %	**95%**	**53%**

[1] Research and development costs (R&D).
[2] General and administrative costs (G&A).

Parent Company

Income statement

SEK 000	Note	Jan 1, 2018 –Dec 31, 2018	Jan 1, 2017 –Dec 31, 2017
Net sales		-	-
Other operating income	2	715	151
Operating expenses			
Other external operating expenses	3.4	-113,927	-64,422
Personnel expenses	5	-19,087	-19,568
Depreciation and amortization	10	-51	-51
Total operating expenses		**-133,065**	**-84,041**
Operating profit (loss)		**-132,350**	**-83,890**
Result from financial items			
Result from participations in Group companies	6	-20	-677
Other interest income and similar income statement items	7	454	5
Interest expense and similar income statement items	8	-7	-2,286
		427	**-2,958**
Result after financial items		**-131,923**	**-86,848**
Tax on net income (loss) for the period	9	-	-
Net income (loss) for the period		**-131,923**	**-86,848**

Statement of comprehensive income

SEK 000	Note	Jan 1, 2018 –Dec 31, 2018	Jan 1, 2017 –Dec 31, 2017
Net income (loss) for the period		-131,923	-86,848
Other comprehensive income		-	-
Total comprehensive income		**-131,923**	**-86,848**

Parent Company

Balance sheet

SEK 000	Note	Dec 31, 2018	Dec 31, 2017
ASSETS			
Non-current assets			
Tangible assets			
Equipment	10	107	158
		107	**158**
Non-current financial assets			
Participations in Group companies	11	3,489	3,489
Other long-term receivables	12	341	341
		3,830	**3,830**
Total fixed assets		**3,937**	**3,988**
Current assets			
Current receivables			
Other current receivables		1,629	4,229
Prepaid expenses	13	164	165
		1,793	**4,394**
Cash and bank balances	14	645,903	56,984
Total non-current assets		**647,696**	**61,378**
TOTAL ASSETS		**651,633**	**65,366**

SEK 000	Note	Dec 31, 2018	Dec 31, 2017
EQUITY AND LIABILITIES			
Shareholders equity	15		
Restricted equity			
Share capital		1,408	667
Statutory reserve		3,092	3,092
		4,500	**3,759**
Non-restricted equity			
Share premium reserve		1,069,072	290,426
Retained earnings		-320,299	-171,106
Net income (loss) for the period		-131,923	-86,848
		616,850	**32,472**
Total shareholders equity		**621,350**	**36,231**
Long-term liabilities			
Liabilities to Group companies	18	77	-
		77	**–**
Current liabilities			
Accounts payable		22,628	13,672
Liabilities to Group companies		-	77
Shareholder loans		-	470
Other current liabilities		903	675
Accrued expenses	16	6,675	14,241
Total liabilities		**30,206**	**29,135**
TOTAL SHAREHOLDERS EQUITY AND LIABILITIES		**651,633**	**65,366**

Parent Company

Statement of changes in equity

SEK 000	Restricted equity		Non-restricted equity			
	Share capital	Statutory reserve	Share premium reserve	Retained earnings	Net income (loss) for the period	Total
Opening shareholders equity Jan 1, 2017	**531**	**3,092**	**218,408**	**-174,836**	**-58,313**	**-11,119**
Transfer of earnings from preceding year				-58,313	58,313	-
Net income (loss) for the period					-86,848	-86,848
Other comprehensive income	-	-	-	-	-	-
Total comprehensive income	**-**	**-**	**-**	**-**	**-86,848**	**-86,848**
Transactions with owners:						
New share issue	136	-	72,069	-		72,205
Cost attributable to new share issue	-	-	-50	-		-50
Premiums received from warrants	-	-	-	207		207
Warrants program	-	-	-	213		213
Contributions from shareholders	-	-	-	61,622		61,622
Total transactions with owners	**136**	**-**	**72,018**	**62,043**		**134,197**
Closing shareholders equity Dec 31, 2017	**667**	**3,092**	**290,426**	**-171,106**	**-86,848**	**36,231**
Opening shareholders equity Jan 1, 2018	**667**	**3,092**	**290,426**	**-171,106**	**-86,848**	**36,231**
Transfer of earnings from preceding year				-86,848	86,848	-
Net income (loss) for the period					-131,923	-131,923
Other comprehensive income	-	-	-	-	-	-
Total comprehensive income	**-**	**-**	**-**	**-**	**-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 Dec 31, 2018	**1,408**	**3,092**	**1,069,072**	**-320,299**	**-131,923**	**621,350**

Parent Company

Statement of cash flow

SEK 000	Note	Jan 1, 2018 –Dec 31, 2018	Jan 1, 2017 –Dec 31, 2017
Operating activities			
Operating profit (loss)		-132,350	-83,890
Adjustments for non-cash items	14	51	332
Interest received		6	0
Interest paid		-7	-11
Cash flow from operating activities before changes in working capital		**-132,300**	**-83,569**
Changes in working capital			
Changes in operating receivables		2,600	-1,931
Changes in operating liabilities		1,618	18,073
Cash flow from operating activities		**-128,082**	**-67,427**
Investing activities			
Investments in financial assets[1]	12	-	-646
Cash flow from investing activities		**–**	**-646**
Financing activities			
New share issue		738,650	3,129
Cost attributable to new share issue		-54,433	-50
Loans from related parties		-	36,316
Repayment of loans		-470	-
Premiums received from warrants		2,826	207
Contributions from shareholders		29,999	61,622
Cash flow from financing activities		**716,572**	**101,224**
Net increase (decrease) in cash & cash equivalents		**588,490**	**33,151**
Cash and cash equivalents at beginning of the year		**56,984**	**23,874**
Exchange-rate difference in cash and cash equivalents		429	-41
Cash and cash equivalents at the end of the year	14	**645,903**	**56,984**

1) Investments in financial assets pertain to bank guarantees granted of SEK 0 thousand (50) and receivables with the Group SEK 0 thousand (595).

Parent Company

Accounting policies and notes

Note 1 Accounting policies

The Parent Company prepares its annual accounts in accordance with the Annual Accounts Act and the Swedish Financial Accounting Standards Council's recommendation RFR 2 Accounting for legal entities.

The differences between the accounting policies of the Group and the Parent Company are stated below. The accounting policies for the Parent Company stated below have been consistently applied over all periods presented in the financial statements of the Parent Company, unless otherwise stated.

Subsidiaries
Shares in subsidiaries and associated companies are recognized in the Parent Company according to the cost method. This means that transaction charges are included in the carrying amount for holdings in subsidiaries.

Financial assets and liabilities
In view of the connection 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, rather the Parent Company applies the cost method in accordance with the Swedish Annual Accounts Act. However, financial assets are measured in the Parent Company at cost less any impairment and financial current assets according to the lowest value principle.

Leases
In the Parent Company, all lease agreements are recognized according to the rules for operational leases. The parent company will apply the possibility according to RFR 2 to continue to report lease agreements according to these rules, and therefore will not have any effects from the transition to IFRS 16.

Group and shareholder contributions
Both Group contributions received and paid are to be recognized as appropriations in accordance with the alternative rule. Shareholders' contributions are transferred directly against equity by the recipient and capitalized in shares and participations by the giver, where impairment is not required.

Note 2 Other operating income

Other operating income of SEK 715 thousand (151) refers mainly to currency exchange differences.

Note 3 Auditors' fee

	2018	2017
Ernst & Young AB		
Audit assignments	509	570
Other audit activities	1,612	2,729
Fees for tax consultations	-	-
Other services	-	-
Total	**2,121**	**3,299**

Note 4 Leases

Leasing costs for the year in respect to operating leases amounted to SEK 713 thousand (748). Future payment commitments for operating leases as at December 31 are specified as follows:

	2018	2017
Future minimum lease fees		
Within 1 year	610	580
Between 1 and 5 years	1,373	145
More than 5 years	-	-
Total	**1,983**	**725**

Note 5 Employees and personnel costs

For salaries and benefits to employees and senior executives and information about the number of employees, refer to Note 8 for the Group. For information about warrants, see Note 9 Warrants for the Group.

Note 6 Result from participations in Group companies

	2018	2017
Impairment of participations in Group companies	-	-807
Impairment of receivables with the Group	-20	-600
Reversal of impairment of receivables with the Group	-	730
Total	**-20**	**-677**

Impairment of receivables with the Group takes place where repayment capacity is lacking.

Note 7 Other interest revenue and similar income statement items

	2018	2017
Interest income	19	5
Exchange rate differences	435	-
Total	**454**	**5**

Note 8 Interest expense and similar income statement items

	2018	2017
Interest expense on loans to shareholders	-	-2,233
Interest expense	-7	-12
Exchange rate differences	-	-41
Total	**-7**	**-2,286**

Note 9 Tax on net income (loss) for the period

	2018	2017
Current tax	-	-
Reported tax expense	**-**	**-**
Reconciliation of effective tax rate		
Loss before tax	-131,923	-86,848
Tax in accordance with applicable tax rate for Parent Company (22%)	29,023	19,107
Tax attributable to unrecognized deferred tax assets	-28,989	-18,921
Non-deductible expenses	-35	-186
Non-taxable income	1	0
Reported tax expense	**-**	**-**

The Parent Company has tax items pertaining to issue costs that are recognized directly against equity.

There are loss carryforwards for which deferred tax assets have not been recognized in the balance sheet amounting to SEK 532,976 thousand (346,753), and these loss carryforwards have no time limit. Deferred tax assets were not recognized for these items since it is not probable that the Group will utilize them to settle against future taxable profits.

Note 10 Equipments

Equipment

	Dec 31, 2018	Dec 31, 2017
Opening cost	813	813
Closing accumulated cost	**813**	**813**
Opening depreciation	-655	-604
Depreciation for the year	-51	-51
Closing accumulated depreciation	**-706**	**-655**
Closing carrying amount	**107**	**158**

Note 11 Participations in Group companies

	Dec 31, 2018	Dec 31, 2017
Opening cost	5,924	5,117
Shareholders' contributions	-	807
Closing accumulated cost	**5,924**	**5,924**
Opening impairment	-2,435	-1,628
Impairment for the year	-	-807
Closing accumulated impairment	**-2,435**	**-2,435**
Closing carrying amount	**3,489**	**3,489**

Company / Corporate Registration Number / Registered office	**Dec 31, 2018**	**Dec 31, 2017**
Nefecon AB, 556604-9069, Stockholm		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	1,000	1,000
Carrying amount	**3,489**	**3,489**
Pharmalink Nordic AB, 556957-5235, Stockholm		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	500	500
Carrying amount	**0**	**0**
Pharmalink Oncology AS, 913317904, Oslo		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	30	30
Carrying amount	**0**	**0**
Busulipo AB, 556697-2179, Stockholm		
Share of equity	100%	100%
Share of voting power	100%	100%
Number of participation rights	100,000	100,000
Carrying amount	**0**	**0**

Note 12 Other long-term receivables

	Dec 31, 2018	Dec 31, 2017
Opening cost	341	291
Bank guarantees granted	-	50
Closing carrying amount	**341**	**341**

Note 13 Prepaid expenses

	Dec 31, 2018	Dec 31, 2017
Prepaid rental charges	164	165
Total	**164**	**165**

Accounting policies and notes – Parent Company

Note 14 Cash and bank balances

	Dec 31, 2018	Dec 31, 2017
Available balances	645,903	56,984
Total	**645,903**	**56,984**

Available balances refers to bank deposits and are primarily in SEK.

Cash flow, items that do not affect liquidity:

	Dec 31, 2018	Dec 31, 2017
Depreciation/amortization	51	51
Warrants program	-	213
Other	-	68
Total	**51**	**332**

AReconciliation of liabilities from financing activities

		Cash flow	Non-cash-items		
	Jan 1, 2018		Interest on loan	Offsetting of new shares	Dec 31, 2018
Shareholder loans	470	-470	–	–	–
	470	**-470**	**–**	**–**	**–**

		Cash flow	Non-cash-items		
	Jan 1, 2017		Interest on loan	Offsetting of new shares	Dec 31, 2017
Shareholder loans	30,000	36,316	3,229	-69,075	470
	30,000	**36,316**	**3,229**	**-69,075**	**470**

Note 15 Shareholders equity

At December 31, 2018
Share capital consists of 35,202,347 (16,673,000) shares with a quotient value of SEK 0.04 (0.04). All shares hold the same entitlement to the company's profits. See also information in the Group's Note 21 Equity.

The share premium reserve refers to capital from new shares that were issued at a price that exceeded the quotient value and less expenses for the new issue.

Proposed appropriation of earnings
The following earnings (SEK thousand) are at the disposal of the Annual General Meeting:

Share premium reserve	1,069,072
Retained earnings	-320,299
Net income (loss) for the period	-131,923
	616,850

The Board of Directors and CEO propose that SEK 616,850 thousand be carried forward.

Note 16 Accrued expenses

	Dec 31, 2018	Dec 31, 2017
Accrued salaries and Board fees	2,286	1,684
Vacation pay liability	1,347	1,143
Social security contributions	2,098	1,560
Accrued expenses for research and development	944	7,271
Other accrued expenses	-	2,583
Total	**6,675**	**14,241**

Note 17 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 25 Assets pledged, contingent liabilities and other obligations.

Note 18 Related-party transactions

	Sales of goods/ services	Purchase of goods/ services	Other	Receivables on closing date	Debt on closing date
Subsidiaries					
2018	-	-	-	-	77
2017	-	1,058	-	-	77

For information regarding remuneration of senior executives, refer to the Group's Note 8 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. he 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 3, 2019.

Thomas Eklund
Board Chairman

Hilde Furberg
Board member

Olav Hellebø
Board member

Ann-Tove Kongsnes
Board member

Lenart Hansson
Board member

Bengt Julander
Board member

Renée Aguiar-Lucander
CEO

Our audit report was submitted in April 3, 2019

Ernst & Young AB

Anna Svanberg
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 2018. The annual accounts and consolidated accounts of the company are included on pages 24-53 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 1-23 and 58-71. 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, 3 April 2019

Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

Corporate governance report

Introduction

Calliditas Therapeutics AB 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 2018 financial year 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 Therapeutics' (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 2018, the total number of shares and voting rights amounted to 35,202,347, distributed between 2,345 shareholders. The ten largest shareholders held 78.8% of shares outstanding and other shareholders 22.2%. On December 31, 2018, three shareholders owned shares that each represented 10% or more of the total number of shares and voting rights in the company: Stiftelsen Industrifonden, 21.2%, Investinor AS 15.7% and Linc AB (Bengt Julander) 15.0%.

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 the company. 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 company's 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 2019

Calliditas' 2019 AGM will be held on Wednesday, May 8, 2019, at 4:00 p.m. in Apotekarsocieteten premises on Wallingatan 26, SE-111 24 Stockholm, Sweden. The minutes from the AGM will be made available at www.calliditas.com.

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", Wallingatan 26B, SE-111 24 Stockholm, Sweden. The notification must state the shareholder's name, personal identity number/registration number, shareholding, address, day time telephone number and information about the attendance of any assistants (maximum two) and, if applicable, information about any proxies.

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 the company 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 the company as of the expiry of the third quarter of the fiscal year. The Nomination Committee in 2019 consists of:

- Patrik Sobocki, appointed by Stiftelsen Industrifonden (Chairman)
- Jon Öyvind Eriksen, appointed by Investinor AS
- Karl Tobieson, appointed by Linc AB
- Thomas Eklund, 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 the company. 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 2019 AGM and its proposals will be presented in the convening notice of the AGM and on the company's 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 2018 AGM elected the registered firm of accountants Ernst & Young AB as auditor, up to the 2019 AGM. The Auditor-in-Charge is Anna Svanberg. The auditor examines the Parent Company's and the Group's accounts and administration on behalf of the AGM. The external audit of the Parent Company's and the Group's accounts and the Board's and CEO's administration is conducted using generally

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accepted auditing standards in Sweden. The company entrusted the auditor to review two interim reports in 2018, which satisfies the requirements of the Code. For information about remuneration of the auditor, refer to Note 5 Auditors' fee.

Board of Directors

The Board of Directors is the second-highest decision making body of the company after the AGM. According to the Swedish Companies Act, the Board of Directors is responsible for the organization of the company 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 the company's 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 on the date on which this report was published.

Work of the Board in 2018

During the 2018, the Board of Directors held a total of 18 meetings, of which 6 were ordinary and 12 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 the IPO.

Board remuneration

The 2018 AGM resolved on fees to be paid to the Board of Directors for the time until the close of the next AGM. The Chairman of the Board, who does not represent a principal shareholder, is to receive SEK 400,000 per year. Other members who do not represent principal shareholders, are thus to each receive SEK 160,000 per year. The AGM also resolved, in accordance with the Board's motion, that reimbursement for committee work, for the period until the end of the next AGM, be paid in the amount of SEK 40,000 to the Chairman of the Audit Committee and SEK 20,000 to each of the other members of the Audit Committee and that no remuneration be paid for work on the Remuneration Committee. Total fees to be paid to the Board of Directors for the time until the close of the next AGM will therefore amount to SEK 800,000.

For more information regarding remuneration of Board members, refer to Note 8 Employees and personnel costs, and the table below.

Board members' independence, attendance and remuneration in 2018

			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
Thomas Eklund	Board Chairman	2017	Yes	Yes	17/18	6/6	3/3	413
Lennart Hansson	Board member	2009	Yes	No	17/18		2/3	-
Ann-Tove Kongsnes	Board member	2013	Yes	No	17/18	6/6		-
Bengt Julander	Board member	2004	Yes	No	18/18		3/3	-
Hilde Furberg	Board member	2014	Yes	Yes	16/18	6/6		173
Olav Hellebö	Board member	2014	Yes	Yes	18/18			160

Board committees

Audit Committee

Calliditas has an Audit Committee consisting of three members: Ann-Tove Kongsnes (Chairman), Thomas Eklund 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 six meetings in 2018. The company's auditors took part in four of the meetings, where discussions included the auditors' planning of the audit, their observations and examination of the company and the company's financial statements.

Remuneration Committee

Calliditas has a Remuneration Committee consisting of three members: Lennart Hansson (Chairman), Bengt Julander and Thomas Eklund. The Remuneration Committee shall prepare matters concerning remuneration principles, remuneration and other employment terms for the CEO and the executive management.

The Committee held three meetings in 2018. 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 Extraordinary General Meeting on December 14, 2018.

Remuneration of the CEO and senior executives

Calliditas shall offer remuneration in accordance with market practice to enable the recruitment and retention of qualified senior executives. Remunerations within Calliditas shall be based on principles of performance, competitiveness and fairness. Senior executives refer to the CEO and the other members of the executive management. The remuneration to senior executives 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. Senior executives 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 senior executives, the premium may, in situations where premium-based pension is applicable, amount to a maximum of 30 per cent of the fixed salary. Notwithstanding the above, the Board of Directors is entitled to offer other solutions which, in terms of cost, are equivalent to the above.

Evaluation of the Board and CEO

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

CEO and management team

The role of the CEO is subordinate to the Board of Directors, and his or her primary task is to attend to the company's daily management and operations in the company. The Rules of Procedure for Decision-making

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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 Head of Clinical Development & Project Management, Chief Medical Officer, Vice President of Licensing, IP and Legal, 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 66–68 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.

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.

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.

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 2018 on pages 58–63 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, 3 April 2019

Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

Board of Directors

Thomas Eklund

Board of Directors

Born 1967.
Chair of the Board of Directors since 2017.

Education: MBA from Stockholm School of Economics.

Experience: 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 21,250 shares in the company and 445 warrants of Class C*.

Hilde Furberg

Board member

Born 1958.
Board member since 2014.

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

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 and Chairman of Blueprint Genetic.

Holdings in the company: Hilde Furberg holds 15,250 shares in the company and 118 warrants of Class B*.

Lennart Hansson

Board member

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 9,000 shares in the company.

Olav Hellebø

Board member

Born 1965.
Board member since 2014.

Education: Bachelor of Business Administration from Hofstra University. MBA from IESE Business School.

Experience: Olav Hellebø is CEO of the UK-listed ReNeuron Group plc and the Chairman of the Board of Directors and co-founder of Palma Biotech S.L. in Spain. He is an experienced pharmaceutical executive who has held senior positions in the pharmaceutical industry in both Europe and the US. Previously, Olav Hellebø was CEO of Clavis Pharma ASA and before that he was Senior Vice President of UCB Pharma and President of Immunology Operations. In this position, he built and led the global organization responsible for the successful registration and launch of Cimzia®, UCB's antibody drug for the treatment of rheumatoid arthritis and Crohn's disease.

Other current assignments:
Chairman of the Board of Directors of Barcelona Bioscience. Member of the Board of Directors and CEO of ReNeuron.

Holdings in the company: Olav Hellebø holds 8,000 shares in the company and 78 warrants of Class B*

Bengt Julander

Board member

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) 4,116,250 shares in the company.

Ann-Tove Kongsnes

Board member

Born 1967.
Board member since 2013.

Education: Master of Science in Economics and Business Administration from Bodø Graduate School of Business. Advanced Program in Corporate Finance at Norwegian School of Economics.

Experience: Ann-Tove Kongsnes has 18 years' experience of active ownership and investments, development, transactions, divestments and IPO of technology companies. Ann-Tove Kongsnes is an Investment Director at Investinor, Norway's largest investor in venture and expansion capital and an investor in Calliditas. Before this, she worked 7 years in international marketing, as the Director of Marketing and Operations. Ann-Tove Kongsnes has many years of experience as an investor and a broad experience in board activities.

Other current assignments: Member of the board of directors and deputy Chairman of the board of Vitux AS (Ayanda) and poLight AS. Member of the board of directors of Numascale AS, Spinchip Diagnostics AS and Curida AS. Deputy member of the board of directors of Boost AS, Boostcom Group AS, Data-Consult AS, Fondstiftelsen ved St. Olavs Hospital and Orientekspressen AS. Employed by Investinor AS. Observer in Phoenix AS.

Holdings in the company: Ann-Tove Kongsnes does not hold any shares in the company.

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, mainly in the media, technology and pharmaceuticals sectors. 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 and 1,478 warrants from the warrant program 2017/2020* and 350,000 warrants from the warrant program 2018/2022

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 tasks, was in charge of the acquisition and reversed listing of Teki Solutions. Previous CFO positions also include Phone Family and Teligent Telecom.

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 and 325 warrants from the warrants program 2017/2020* and 90,000 warrants from the warrants program 2018/2022

Jens Kristensen

Chief Medical Officer

Born 1958.
Chief Medical Officer since 2016.

Education: Doctor of Medicine from Odense University, Denmark. PhD in Neuroscience from Uppsala University. Board certified specialist in anesthesia and intensive care from Uppsala University Hospital, and Pharmaceutical Medicine from Basel University.

Experience: Jens Kristensen has broad experience in the drug development sector, having spent 20 years in the pharmaceutical industry and 15 years as a clinician before that. At AstraZeneca, Jens Kristensen served as Disease Area Expert and Global Product Team Physician for neuroscience programs from Phase 2 and Phase 3. Jens Kristensen also served as Chief Medical Officer and Head of Development at a number of smaller pharmaceutical companies, including Karo Bio and Medivir. He is a specialist in anesthesia, intensive care and drug development.

Other current assignments: Member of the Board of Directors of Jedako Consult AB.

Holdings in the company: Jens Kristensen holds no shares in the company but holds 500 warrants from the warrant program 2017/2020* and 50,000 warrants from the warrant program 2018/2022

Johan Häggblad

Vice President of Licensing, IP and Legal

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

E**ducation:** 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 of Calliditas between 2007 and 2017.

Other current assignments: Member of the Board of Directors of Pharmalink Oncology AS Deputy member of the Board of Directors of Busulipo AB, Nefecon AB and Pharmalink Nordic AB.

Holdings in the company: Johan Häggblad holds 14,250 shares in the company, 739 warrants from the warrant program 2017/2020* and 45,000 warrants from the 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 no shares in the company but holds 295 warrants from the warrant program 2017/2020* and 11,798 warrants from the warrant program 2018/2022

Kari Sandvold

Vice President of Pharmaceutical Development

VP Pharmaceutical Development and Manufacturing since 2016.

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

Experience: Kari Sandvold joined Calliditas in May 2016. She has more than 25 years of extensive experience working in pharmaceutical development and manufacturing of new products, including technology transfer, CMC regulatory and clinical supply. Her experience comprises of developing new products intended for the global market, all the way from pharmaceutical development to tech transfer and filing for market approval. Previous positions have been in both big pharmaceutical companies and in small and medium-sized pharmaceutical companies and her most recent position was as Head of Pharmaceutical Development at Orexo AB.

Holdings in the company: Kari Sandvold holds no shares in the company but holds 295 warrants from the warrant program 2017/2020*

** 1 warrants in warrants program 2017/2020 entitles to subscription of 250 shares.*

Management team

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 in financial media, for example, at the Swedish business daily Dagens Industri, and has held different in-house corporate communications positions at such companies as AstraZeneca, Biovitrum (Sobi) and Nordic Capital. He has also worked in strategy as a communications advisor within financial PR and IR. Mikael Widell 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.

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' commercial experience in the pharmaceutical industry. Before Andrew joined Calliditas, he worked as Vice President North America Commercial at NeuroDerm. Andrew began his career in the pharmaceuticals industry at Purdue Pharma and held several sales and marketing positions, including responsibility for the company's brands and headed a cross-functional team for a multibillion USD pain pharmaceutical.

Holdings in the company: Andrew Udell holds no shares in the company but holds 200,000 warrants from the warrant program 2018/2022.

Frank Bringstrup

Vice President Regulatory Affairs

Born 1959.
VP Regulatory Affairs since 2019.

Education: Doctor of Medicine from Copenhagen University. He holds a diploma in Managing Medical Product Innovation (MMPI) from the Copenhagen School of Economics, a diploma in Business Administration from Warwick University, a post graduate specialist course in public health from the Danish Health Authority.

Experience: Frank Bringstrup has more than 17 years' experience in the pharmaceutical industry in regulatory issues and interactions with national medicines agencies. Before he joined Calliditas, he worked in various positions at Novo Nordic A/S. He launched his professional career initially as a clinical doctor and then became Frederiksborg County Medical Advisor.

Holdings in the company: Frank Bringstrup holds no shares in the company but holds 5,000 warrants from the warrant program 2018/2022.

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, 2019	May 8, 2019
Annual General Meeting 2019	May 8, 2019
Interim report for the period January 1–June 30, 2019	August 15, 2019
Interim report for the period January 1–September 30, 2019	November 14, 2019
Year-end report for the period January 1–December 31, 2019	February 14, 2020

PHOTO: ROBERT HARDING/JOHNÉR BILDBYRÅ

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