Q4

calliditas THERAPEUTICS

CALLIDITAS THERAPEUTICS AB (publ)

Year-End Report January 1 – December 31, 2019

Patient recruitment for Part A of the pivotal Phase 3 study completed on time and on budget

Key figures

October 1 – December 31, 2019

- Net sales for the period amounted to SEK 46.6 (-) million.
- Net income (loss) for the period was SEK -23.1 (-44.2) million.
- Earnings before and after dilution per share totalled SEK -0.60 (-1.26).
- At December 31, 2019, cash and cash equivalents amounted to SEK 753.5 (646.2) million.

January 1 - December 31, 2019

- Net sales for the period amounted to SEK 184.8 (-) million.
- Net income (loss) for the period was SEK -32.6 (-132.0) million.
- Earnings before and after dilution per share totalled SEK -0.88 (-5.09).

Significant events during the period October 1 – December 31, 2019, in summary

- In October 2019, Calliditas obtained positive advice from the European Medicines Agency (EMA) in which the agency expressed support for a conditional marketing authorization (CMA) of Calliditas lead compound Nefecon, subject as usual to the strength of the full data set presented at the time of filing.
- In December 2019, a USD 5 million milestone payment from Everest Medicines was triggered as part of the licensing agreement pursuant to which Everest will develop and commercialize Calliditas leading drug candidate Nefecon in the Greater China and Singapore.
- In December 2019, the recruitment of the 200 patients needed for Part A of Calliditas pivotal Phase 3 study NeflgArd was completed. Topline readout of part A of the study is expected in Q4 2020.

Significant events after the end of reporting period, in summary

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

Investor presentation February 14, 14:00 CET

Audio cast with teleconference, Q4 2019, February 14, 2020, 14:00 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q4-2019

Teleconference: SE +46850558355 UK: +443333009034 US: +18446251570

CEO Statement

An exceptional year

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

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

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

Another key event during the quarter was the acceptance by the Chinese authorities, NMPA, of the IND filed in China by Everest Medicines, with whom we have a collaboration pursuant to which Everest will develop and commercialize Nefecon in the Chinese region and Singapore. We have worked intensely and seamlessly with Everest to bring this about, and we are very excited about the decision which will enable China to join the Phase 3 trial and hence accelerate the market launch of Nefecon into the Chinese market. The collaboration with Everest is proving to be as professional and fruitful as we had hoped when we engaged in negations. The acceptance of the IND triggered one of several milestones under the agreement, resulting in a USD 5 million (approx. SEK 47 million) milestone in Q4, providing additional capital for clinical development programs. As I have previously noted, the Chinese market is very large and truly reflects the significant unmet medical need of this disease. We are very excited about continuing to deliver on the premise in order to be the first approved drug for IgA nephropathy (IgAN) in China, and we applaud Everest in driving this program forward so efficiently.

We also hosted our first Capital markets Day on November 4 in order to provide additional insights and information into the company's lead project as well as our pipeline indications. We were honored to host Professor Jonathan Barratt at the event, who is a leading KOL in the area

of IgAN. We also had an opportunity to provide more information around our US pre-commercial activities and market research, provided by our VP Commercial North America. It was a well-attended event which we hope enabled investors there in person, as well as over the internet, to gain a better insight into our strategy and execution readiness.

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

The trials and tribulations of patient recruitment

I have partially covered this topic previously, however one cannot spend too much time on the issue of recruitment in the area of life sciences. Patient recruitment is widely recognized as key determinant of success for clinical trials. Despite this, a substantial number of trials fail to reach recruitment goals, which has important scientific, financial and ethical implications. There are also implications for investigators, study participants as well as sponsors. A 2015 analysis of registered trials revealed that 19% were closed or terminated early due to the inability to attract enough participants. Secondly, as much as 86% of clinical trials do not reach recruitment targets within their specified time periods. In many instances 50% of sites in a trial enroll 1 or no patients. Data suggests that timelines have often doubled due to low recruitment rates.

Despite decades of focus on ways to enhance recruitment, the issues persist. So, what has been found in these assessments to be related to reasons for recruitment delays? Factors potentially contributing to delays have been identified as: trial design, study staff issues, and recruitment strategies. In addition, issues such as patient contact and convenience, including providing basic financial support for travel expenses and other patient support have proven to be important.

Also, we live in a world where there are often many competing trials. Physicians as well as patients often have a choice as to which trial to participate in and have access to more information about results of previous trials and drug profiles via digital media and social networks.

There is a statement which claims that “it takes a village”, initially used in the context of raising a child. This is not completely out of place in this context. The complexity of the logistics and communication strategies around delivering a large global trial is staggering. It involves an incredibly high number of individual and organizational components, all with their own specific reasons for participating, all which need to be addressed and aligned appropriately in order to achieve a common goal. Within this highly complex and structured process, political, tactical, financial, strategic and personal goals all need to be considered, understood and navigated. No wonder that in 86% of cases, trials fail to deliver in time.

There is obviously a plethora of reasons why recruitment is a real challenge, including patient concerns related to safety, being randomized to placebo and dealing with having invasive tests performed. On the other hand, there still seems to be a lack of communication regarding the availability of clinical trials, with many patients complaining about lack of access and information regarding potential options. Under any circumstance, it feels as if we need to continue to try and improve patient recruitment processes and find strategies to connect more efficiently with both investigators and patients, while controlling the overall costs of conducting clinical trials.

A year of focused value creation and growth

2019 turned out to be an exceptional year for the Company. Having randomized the first patient in the NefIgArd trial in November 2018, the focus in 2019 was firmly on achieving the target of

completing recruitment before the end of the year. Multiple parallel strategies were initiated and pursued in order to ensure success. Engagement with patient organizations, development and launch of a website allowing patients to identify trial centers close to them, interactions with KOLs, establishment of national coordinators and continuous interaction with our CRO, were just a few of the initiatives successfully pursued during the year.

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

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

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

It has been an exciting year and we have as a company achieved several important milestones during 2019. I look forward to continuing to grow and build on the platform we now have created, and I hope that you will all join us on the continued journey in 2020, which we expect will see the readout of our pivotal Phase 3 trial NefIgArd in Q4

Renée Aguiar-Lucander, CEO

Business overview

Nefecon – An Overview

Nefecon is an oral formulation of a locally acting and potent corticosteroid, budesonide. It is being developed by Calliditas as a potential disease-modifying treatment for patients with IgAN at risk of developing end-stage renal disease (ESRD). Nefecon has obtained orphan designation from both the FDA and EMA.

Calliditas retains all the rights to develop and commercialize Nefecon globally, other than in China and Singapore, where Calliditas has out-licensed development and commercialization to Everest Medicines. The pivotal clinical phase 3 NefIgArd study with Nefecon was initiated in 2018, following the successful completion of the placebo-controlled randomized Phase 2b study, NEFIGAN, where pronounced reduction in proteinuria and a stabilization of eGFR was demonstrated.

Nefecon is a unique formulation, optimized to combine a time lag effect with a concentrated release of the active substance, within a designated target area in the intestine, which down-regulates the disease process in the kidney. Nefecon targets the ileum, the distal part of the small intestine, which is the presumed origin of IgAN due to the ileum being the location of the highest concentration of Peyer's patches, which are responsible for the production of secretory immunoglobulin A, or IgA, antibodies. Nefecon's targeted delivery, showing initially delayed and subsequently concentrated release of the active drug over a specific area in the gut, is what differentiates the product, and which leads to the effect on disease progression.

Nefecon delivers a potent immune suppressant directly to the site in the intestine where the under glycosylated IgA antibodies that precipitate in the kidney are formed. Budesonide has been used for decades to treat patients in other indications, where local treatment is applicable and is rapidly degraded after entering the circulatory system, making it ideal for local delivery, thereby minimizing the systemic effects seen with other corticosteroids.

The NefIgArd study

On November 13, 2018, Calliditas announced that the first patient had been enrolled in the company's pivotal clinical phase 3 study NefIgArd in patients with IgA nephropathy.

The randomized, double-blind and placebo-controlled Phase 3 study for Nefecon has a similar design to the successful Phase 2b study. The study is divided into two parts; a treatment part (Part A) designed to provide efficacy and safety data used for filing for market approval, and an observational part (Part B). Up to 360 patients with biopsy confirmed IgAN and on optimal or highest tolerable blood pressure medication will be randomized across 19 countries in North and South America, Europe, Australia and parts of Asia.

In Part A, the patients will receive either 16 mg Nefecon or placebo, once daily for nine months, on the background of optimized RAS blockade treatment, and will then be followed for three months. The first 200 patients randomized in the study, which were fully recruited by December 2019, will be included in the read-out which will form the basis for accelerated approval/conditional approval by the FDA and EMA respectively. Subsequently, all patients will continue into Part B, which is an observational twelve months follow up period where their renal function as measured by eGFR (estimated glomerular filtration rate) will be followed and measured.

The primary endpoint in Part A is reduction in proteinuriawhich we expect will form the basis for accelerated approval in the United States and conditional approval in the EU. Whilst regulators have typically required eGFR as a primary endpoint for studies of chronic kidney disease, following extensive data analysis by Calliditas in collaboration with Tufts University, the FDA has

agreed to accept proteinuria as the primary endpoint for accelerated approval of Nefecon. The EMA also have accepted reduction in proteinuria as primary endpoint as base for conditional marketing authorization in EU, subject as usual to the strength of the full data set presented at the time of filing.

Based on positive data, we expect to commercialize and market Nefecon in the United States and the EU. Calliditas has licensed the development and commercialization rights of Nefecon in Greater China and Singapore to Everest Medicines.

Calliditas aims to have the necessary data on hand to file for accelerated/conditional FDA and EMA approval in the first half of 2021.

The Part B study analysis design is based on conservative statistical assumptions in order to validate proteinuria as a surrogate marker. No medication will be provided in this follow-up phase, as it is designed to observe changes in eGFR. The top line readout, which could form the basis for a full approval, is expected to happen in 2022.

IgA nephropathy – an orphan disease with great unmet medical need

As is the case for many niche indications, there are few well documented sources related to the prevalence and incidence of IgA nephropathy (IgAN, sometimes referred to as Berger's disease). It is a disease which is not completely understood, both with regards to its initial onset as well as its mode of action. In order to address these shortcomings, Calliditas has been instrumental in supporting research into, and collaboration with other organizations and experts, in order to contribute to the understanding of the disease.

Nephrology environment

Today over 30 million Americans have chronic kidney disease, and over 700,000 Americans have kidney failure, also known as ESRD.

In the last decade, few new drugs have been approved to treat kidney disease. Also, the number of clinical trials in nephrology lag behind most other therapeutic areas. In addition, certain products on the market treating other organs and conditions may have adverse side effects on kidney health.

As the public health implications and economic burdens of kidney disease continue to grow, the care and safety of these patients warrants increased attention. Recent regulatory initiatives such as the acceptance of a surrogate marker by the FDA is an actionable change for companies working in this area hoping to translate R&D into medicines for patients.

Disease profile

IgAN was first described by Berger and Hinglais in 1968[1]. It is characterized by the deposition of IgA antibodies in the kidney, causing inflammation and renal damage which impacts the kidney's ability to filter waste from the blood.

IgAN is the most common cause of glomerulonephritis - kidney inflammation - in the world[2].

[1] *Berger J, Hinglais N Les Depots Intercapillaires d'IgA – IgG. J Urol Nephrol (Paris) 1968 Sep.*

[2] *Cattran DC, Coppo R, Cook HT, et al. The Oxford classification of IgA nephropathy: rationale, clinicopathological correlations, and classifications. Kidney Int 2009 Jul.*

The disease is highly variable, both clinically and in the pathology. Clinical features range from asymptomatic blood in the urine to rapidly progressive nephritis. The condition often leads to chronic kidney disease and is more common in males than in females. The pathology is not fully understood, but IgAN is increasingly considered as an immune complex deposition disease.

IgAN can occur at any age, but the clinical onset is commonly during a patient's twenties or thirties and is more common in men than in women, especially in the western world. It has been estimated that up to 50% of the patients with IgAN will progress to ESRD within 20 years. The disease is designated as an orphan disease in Europe and the US, with an estimated diagnosed patient population of approximately 200,000 in Europe and between 130,000 and 150,000 in the US.

IgAN is much more common in Asia than in the western world. About 40% of all kidney biopsies performed in China are related to IgAN. Based on this, we estimate that IgAN affects approximately two million people in Greater China.

Liver orphan indications

Beyond IgAN, Calliditas assesses that Nefecon's patented formulation and release technology also offers potential in treatment of other select autoimmune diseases based on the concentrated release in the ilium and the high exposure to the liver, e.g. the liver diseases primary biliary cholangitis (PBC). In order to potentially reduce costs and shorten time for approval and market access, Calliditas has in-licensed Budenofalk for the US market from Dr. Falk Pharma to initially develop autoimmune hepatitis (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 that drain bile from 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[3]. The disease will culminate with end-stage biliary cirrhosis and the need for a liver transplant. There are currently no approved therapies that specifically address the autoimmune response that is believed to drive PBC or the inflammatory consequences of the autoimmune response. UDCA and Ocaliva are the only FDA-approved medical treatments for PBC in the US. Ocaliva has been granted orphan drug designation 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[4]. No targeted steroid therapy is registered for PBC in the United States, 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 have been granted orphan drug designation in the US for the treatment of 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.

[3] *EASL Guidelines, Journal of Hepathology 2017 vol. 67;145-172*

[4] *EASL Guidelines, Journal of Hepathology 2017 vol. 67;145-172*

AIH 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[5].

There are presently no products approved for treatment of AIH in the US. Calliditas believes that its combination of clinical development and regulatory expertise with the in-licensing of Budenofalk, provides an opportunity to potentially reach the market within a relatively short period of time. Calliditas has been granted orphan drug designation in the United States for the treatment of AIH.

Significant events during the period January 1 – December 31, 2019

- Calliditas was granted orphan drug designation (ODD) for the treatment of AIH by the FDA. It is estimated that the patient population in the US amounts to approximately 50,000 – 80,000.
- Calliditas was granted orphan drug designation by the FDA for the treatment ofPBC. 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.
- The Annual General Meeting (AGM) of Calliditas was held in May, and among other things, the AGM resolved on the election of Elmar Schnee (Chairman) and Diane Parks to the Board of Directors.
- In June, Calliditas and Everest Medicines entered into a license agreement to develop and commercialize Calliditas' leading drug candidate Nefecon in Greater China and Singapore for the chronic autoimmune kidney disease IgA Nephropathy (IgAN). Under the terms of the agreement, Calliditas received an initial upfront payment of USD 15 million at signing of the agreement, as well as future payments linked to pre-defined development, regulatory and commercialization milestones up to an additional USD 106 million, including an option worth up to USD 20 million for the development of Nefecon in other potential indications. Everest will also pay typical tiered royalties on future sales.
- In July, Calliditas completed a directed new share issue of 3.5 million shares, raising approximately SEK 210 million with the aim of expanding ongoing research programs and accelerating activities related to the pipeline. The new issue was subscribed by Swedish and international institutional investors, including BVF Partners L.P.
- In August, Calliditas entered into an exclusive in-licensing agreement of Budenofalk 3mg oral capsule for the US market with Dr Falk Pharma. Calliditas will leverage Dr. Falk's clinical trial data and expertise in the liver indication Autoimmune hepatitis (AIH) with a view to accelerate approval and market access. This enables Calliditas to potentially accelerate its development of the pipeline portfolio related to orphan liver disease, such as Autoimmune hepatitis (AIH). The deal has an upfront payment of EUR 1.5 million and foresees additional regulatory related payments, subject to market approval from the FDA. The total deal value amounts to EUR 40 million, including future sales milestones and comes with typical royalties. For additional information see note 9.
- In September, Calliditas obtained positive feedback from the FDA that has a significant impact on the confirmatory part of the ongoing pivotal Phase 3 study, NefIgArd. The FDA accepted a two-year eGFR based end point for the Part B of the study, reducing the overall time from six to under four years, and a reduction from 450 to 360 patients with significant positive impact on overall costs.

[5] *Sahebjam and Vierling, Front Med. 2015 Jun;9(2): 187-219*

- In October, Calliditas obtained positive advice from EMA in which the agency expressed support for a conditional marketing authorization (CMA) of the company's lead compound Nefecon, subject as usual to the strength of the full data set presented at the time of filing.
- In December, a USD 5 million milestone payment from Everest Medicines was triggered as part of the licensing agreement pursuant to which Everest will develop and commercialize Calliditas leading drug candidate Nefecon in the Chinese region and Singapore. The National Medical Products Administration (NMPA, formerly known as CFDA) has approved Everest Medicine's IND (Investigational New Drug application) for Nefecon in China, an important step toward allowing Chinese clinical sites to recruit patients for the ongoing NeflgArd global Phase 3 trial.
- In December, the recruitment of the 200 patients needed for Part A of the company's pivotal Phase 3 study NeflgArd was completed. Topline readout of part A of the study is expected in Q4 2020. On the basis of positive results from Part A, Calliditas thereafter plans to file for market approval with regulatory agencies in the United States and the EU in the first half of 2021.

Significant events after the end of reporting period

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

Financial overview

Key figures

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**
Net sales	46,586	-	184,829	-
Expenses relating to research and development/operating expenses, %[1]	65%	76%	70%	75%
Net income (loss) for the period	(23,050)	(44,224)	(32,578)	(132,049)
Earnings per share before and after dilution, SEK	(0,60)	(1,26)	(0,88)	(5,09)
Cash flow from operating activities	(45,435)	(42,486)	(71,011)	(128,191)
Total registered shares at the end of period	38,707,638	35,202,347	38,707,638	35,202,347
Equity at the end of the period	788,071	618,175	788,071	618,175
Equity ratio at the end of the period %[1]	93%	95%	93%	95%
Cash and cash equivalents at the end of the period	753,540	646,175	753,540	646,175

[1] Non-IFRS performance measure, see definitions page.

January – December 2019

Revenue

Revenues of SEK 46.6 million (-) were reported in the fourth quarter of 2019 and stem from the fact that approval of the application for IND in China triggered a milestone payment in the licensing agreement with Everest Medicines for Nefecon in China. The revenues for the full year of 2019 were SEK 184.8 million (-) and stem from the out-licensing of Nefecon for China to Everest Medicines. For additional information see note 4.

Total operating expenses

Operating expenses for the fourth quarter of 2019 amounted to SEK 64.6 (44.7) million and SEK 212.8 (132.5) million for the full year of 2019.

Research and development expenses

Research and development costs increased by SEK 7.5 million to SEK 41.7 (34.2) million during the fourth quarter of 2019. Research and development costs for the full year of 2019 increased by SEK 50.6 million to SEK 149.8 (99.3) million. The cost increase for both periods is related to the operation of the NefIgArd study for Nefecon, where the first patient was included in the study in Q4 2018 and 200 patients recruited were announced in December 2019.

Sales and administration expenses

During the fourth quarter of 2019, sales and administration expenses increased by SEK 14.9 million to SEK 23.8 (8.9) million. The increase for the fourth quarter is explained by the initiation of commercial preparations for a potential future launch of Nefecon in the US and a general increase in administration costs due to increased level of activity and growth of the organization. For the full year of 2019, the increase was SEK 31.8 million to SEK 62.9 (31.1) million. The increase for the full year is also mainly explained by the initiation of commercial preparations for a potential future launch of Nefecon in the US, transaction related costs in connection with the out-licensing of Nefecon to Everest Medicines in China and the growth of operations.

Other operating incomes/expenses

Other operating incomes were SEK 0.9 (-) million for the fourth quarter of 2019 and SEK 4.4 (-) million for the full year of 2019 and consist of exchange rate differences on assets of operating nature.

Other operating expenses were SEK - (1.7) million for the fourth quarter of 2019 and SEK 4.5 (2.1) million for the full year of 2019 and consist of exchange rate differences on liabilities of operating nature.

Tax

Tax expenses of SEK 0.1 (-) million were reported for both the fourth quarter of 2019 and the full year 2019 and are attributable to income tax for the American subsidiary Calliditas Therapeutics Inc. No tax costs are reported in the Parent Company since Calliditas has tax losses that is not capitalized since future income is not considered sufficiently secure to enable deferred tax assets to be capitalized.

Earnings

Net income (loss) for the period amounted to SEK -23.1 (-44.2) million for the fourth quarter of 2019 and SEK -32.6 (-132.0) million for the full year of 2019, resulting in earnings per share before and after dilution of SEK -0.60 (-1.26) for the fourth quarter of 2019, and SEK -0.88 (-5.09) for the full year of 2019. The decline in earnings for the fourth quarter of 2019 and the full year of 2019 compared with the same period last year is mainly due to the fact that revenues from the Nefecon out-licensing in China to Everest Medicines exceed the increased cost of running the NefIgArd study and the increased costs for commercial preparations.

Cash flow and cash position

The cash flow from operating activities amounted to SEK -45.4 (-42.5) million for the fourth quarter of 2019 and SEK -71.0 (-128.2) million for the full year of 2019. The negative cash flow from operating activities during the fourth quarter of 2019 is according to plan and is explained by the company's increased clinical activities as well as work within the company's administrative and commercial functions.

Cash flow from investing activities were SEK -0.3 (-) million for the fourth quarter and SEK -18.1 (-) million for the full year of 2019 and is mainly due to the in-licensing of Budenofalk 3mg from Dr. Falk Pharma.

Cash flow from financing operations in the fourth quarter of 2019 was SEK -1.3 (2.3) million and SEK 198.8 (716.6) million for the full year 2019, which is mainly due to the direct share issue of net SEK 199.4 million, which was completed in July 2019.

The cash flow amounted to SEK -47.0 (-42.2) million for the fourth quarter of 2019 and SEK -109.8 (588.4) million for the full year of 2019. Cash and cash equivalents as of December 31, 2019, amounted to SEK 753.5 (646.2) million.

Changes in equity and number of shares

As of December 31, 2019, equity amounted to SEK 788.1 (618.2) million. The number of shares increased during the full year of 2019 by 3,505,291, as a result of the direct share issue in July 2019, and as of 31 December 2019 it amounted to 38,707,638 (35,202,347).

Employees

As of December 31, 2019, the number of employees in Calliditas Therapeutics was 16 (10). The number of average employees in the fourth quarter of 2019 was 16 (10) and 14 (10) for the full year of 2019.

Incentive programs

During the second quarter of 2019, the implementation began of the warrants program 2019/2022 for Calliditas staff and the LTIP 2019 stock option program for the Board of Directors, which both was decided by the Annual General Meeting in May 2019. For more information, see Note 8.

Parent Company

Since the operations for the Parent Company are consistent with those of the Group in all material respects, the comments for the Group are also relevant for the Parent Company.

Auditor's review

This report has not been reviewed by the company's auditor.

Stockholm February 14, 2020

Renée Aguiar-Lucander

CEO

Financial statements

Condensed consolidated income statement

		Oct-Dec		Jan-Dec	
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**
Net sales	4	46,586	-	184,829	-
Total operating income		**46,586**	**-**	**184,829**	**-**
Operating expenses					
Research and development expenses		(41,709)	(34,172)	(149,826)	(99,260)
Sales and administration expenses		(23,790)	(8,896)	(62,882)	(31,132)
Other operating revenue		870	-	4,385	-
Other operating expenses		-	(1,677)	(4,525)	(2,090)
Total operating expenses		**(64,629)**	**(44,745)**	**(212,848)**	**(132,482)**
Operating profit (loss)		**(18,043)**	**(44,745)**	**(28,019)**	**(132,482)**
Net financial items		(4,930)	521	(4,482)	433
Profit (loss) before taxes		**(22,973)**	**(44,224)**	**(32,501)**	**(132,049)**
Income taxes		(77)	-	(77)	-
Net income (loss) for the period		**(23,050)**	**(44,224)**	**(32,578)**	**(132,049)**
Attributable to:					
Equity holder of the parent company		(23, 050)	(44,224)	(32,578)	(132,049)
Earnings per share before and after dilution (SEK)		(0.60)	(1.26)	(0.88)	(5.09)

Condensed consolidated statement of comprehensive income

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**
Net income (loss) for the period	(23,050)	(44,224)	(32,578)	(132,049)
Other comprehensive income				
Currency translation effect	(38)	13	(11)	6
Total comprehensive income (loss)	**(23,088)**	**(44,211)**	**(3,589)**	**(132,043)**
Attributable to:				
Equity holder of the parent company	(23,088)	(44,211)	(32,589)	(132,043)
Total comprehensive income (loss)	**(23,088)**	**(44,211)**	**(32,589)**	**(132,043)**

Condensed consolidated statement of financial position

Amounts in SEK 000s	*Notes*	2019-12-31	2018-12-31
Non-current assets			
Intangible assets	9	16,066	-
Tangible assets	2	6,063	107
Financial non-current assets		1,939	341
Total non-current assets		**24,068**	**448**
Current assets			
Accounts receivable		46,586	-
Other current assets		21,006	1,794
Cash and cash equivalents	6	753,540	646,175
Total current assets		**821,132**	**647,969**
Total assets		**845,200**	**648,417**
Shareholders' equity			
Share capital		1,548	1,408
Additional paid in capital		1,274,664	1,072,319
Retained earnings, including net loss for the period		(488,141)	(455,552)
Total shareholders' equity attributable to shareholders of the parent company	5,7	**788,071**	**618,175**
Non-current liabilities			
Provision for social security contributions incentive program	8	175	-
Other non-current liabilities	2	3,584	-
Total non-current liabilities		**3,759**	**-**
Current liabilities			
Accounts payable	6	24,384	22,643
Other current liabilities	2	3,471	904
Accrued expenses and prepaid income	6	25,515	6,695
Total current liabilities		**53,370**	**30,242**
Total liabilities and shareholders' equity		**845,200**	**648,417**

Condensed consolidation statement of changes in equity

		Oct-Dec		Jan-Dec	
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**
Opening shareholder equity		809,967	659,568	618,175	33,176
Profit/loss of the period		(23,050)	(44,224)	(32,578)	(132,049)
Other comprehensive income		(38)	13	(11)	6
Comprehensive income (loss) for the period		**(23,088)**	**(44,211)**	**(32,589)**	**(132,043)**
Transaction with owners					
New issue of ordinary shares	7	-	-	210,317	738,650
Cost attributable to new share issue		-	-	(10,916)	(54,433)
Premiums received from warrants	8	1,084	2,818	2,834	2,826
Share based payments	8	107	-	249	-
Contribution from shareholders		-	-	-	29,999
Total transaction with owners		**1,191**	**2,818**	**202,485**	**717,042**
Closing shareholding equity		**788,071**	**618,175**	**788,071**	**618,175**

Condensed consolidated statement of cash flows

		Oct-Dec		Jan-Dec	
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**
Operating activities					
Operating profit (loss)		(18,043)	(44,745)	(28,019)	(132,482)
Adjustment for non-cash-items		870	13	2 308	51
Interest received		926	-	926	6
Interest paid		(106)	(1)	(325)	(8)
Cash flow from operating activities before working capital		**(16,353)**	**(44,733)**	**(25,110)**	**(132,433)**
Cash flow from changes in working capital		(29,082)	2,247	(45,901)	4,242
Cash flow from operating activities		**(45,435)**	**(42,486)**	**(71,011)**	**(128,191)**
Cash flow from investing activities	9	(291)	-	(18,072)	-
Cash flow from financing activities	7	(1,253)	2,258	198,835	716,572
Cash flow for the period		**(46,979)**	**(40,228)**	**109,752**	**588,381**
Cash & cash equivalents, beginning of period		805,075	685,871	646,175	57,352
Net increase (decrease) in cash & cash equivalents		(46,979)	(40,228)	109,752	588,381
Exchange-rate difference in cash and cash equivalents		(4,556)	532	(2,387)	442
Cash & cash equivalents, end of period		**753,540**	**646,175**	**753,540**	**646,175**

Condensed Parent Company income statement

		Oct-Dec		Jan-Dec	
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**
Net sales	4	46,586	-	184,829	-
Gross profit		**46,586**	**-**	**184,829**	**-**
Operating expenses					
Research and development expenses		(41,709)	(34,172)	(149,826)	(99,260)
Sales and administration expenses		(24,021)	(8,897)	(63,410)	(31,000)
Other operating revenue		870	-	4,385	-
Other operating expenses		-	(1,677)	(4,540)	(2,090)
Total operating expenses		**(64,860)**	**(44,746)**	**(213,391)**	**(132,350)**
Operating profit (loss)		**(18,274)**	**(44,746)**	**(28,562)**	**(132,350)**
Net financial items		(8,259)	540	(7,624)	427
Profit (loss) before taxes		**(26,533)**	**(44,206)**	**(36,186)**	**(131,923)**
Income taxes		-	-	-	-
Net income (loss) for the period		**(26,533)**	**(44,206)**	**(36,186)**	**(131,923)**

Condensed Parent Company statement of other comprehensive income

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**
Net income (loss) for the period	(26,533)	(44,206)	(36,186)	(131,923)
Other comprehensive income	-	-	-	-
Total comprehensive income	**(26,533)**	**(44,206)**	**(36,186)**	**(131,923)**

Condensed Parent Company balance sheet

Amounts in SEK 000s	*Notes*	2019-12-31	2018-12-31
Non-current assets			
Intangible assets	9	16,066	-
Equipment		104	107
Financial non-current assets		2,040	3,830
Total non-current assets		**18,210**	**3,937**
Current assets			
Accounts receivable		46,586	-
Other current assets		21,005	1,793
Cash and cash equivalents	6	752,448	645,903
Total current assets		**820,039**	**647,696**
Total assets		**838,249**	**651,633**
Shareholders' equity			
Share capital		1,548	1,408
Statutory reserve		3,092	3,092
Restricted equity		**4,640**	**4,500**
Additional paid in capital		1,268,334	1,069,072
Retained earnings, including net loss for the period		(485,175)	(452,222)
Non-restricted equity		**783,159**	**616,850**
Total shareholders' equity	5,8	**787,799**	**621,350**
Non-current liabilities			
Provision for social security contributions incentive program	8	50	-
Other non-current liabilities		175	77
Total non-current liabilities		**225**	**77**
Current liabilities			
Accounts payable	6	24,362	22,628
Other current liabilities		1,332	904
Accrued expenses	6	24,531	6,674
Total current liabilities		**50,225**	**30,206**
Total liabilities and shareholders' equity		**838,249**	**651,633**

Notes

Note 1 General information

This report covers the Swedish parent company Calliditas Therapeutics AB (publ), Swedish corporate identity no. 556659-9766 and its subsidiaries. All the Group's significant business operations are conducted in the parent company.

The parent company is a Swedish public limited company registered in and with its registered office in Stockholm. The head office is located at Kungsbron 1, Stockholm, Sweden. Calliditas Therapeutics AB is listed at Nasdaq Stockholm in the Mid Cap segment with ticker CALTX.

The full year report for 2019 has been approved for publication on February 14, 2020, according to the Board of Director's decision.

This report may include forward looking statements. Actual outcomes may deviate from what has been stated. Internal factors such as successful management of research projects, and intellectual property rights may affect future results. There are also external conditions, e.g. the economic climate, political changes and competing research projects that may affect Calliditas results.

Note 2 Accounting policies

The interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting. The Parent Company applies the Swedish Financial Reporting Board recommendation RFR2, Accounting for legal entities. None of the new or amended standards and interpretations that became effective January 1, 2019, have had a significant impact on the company's financial reporting, otherwise what is stated below. Relevant accounting principles can be found on pages 34-36 of the Annual Report for 2018.

The ESMA (European Securities and Markets Authority) guidelines on alternative key performance ratios are applied, which means disclosure requirements regarding financial measures that are not defined in accordance with IFRS. For key ratios not defined by IFRS, see the Definitions and reconciliations of alternative performance measures.

Change of accounting principle

From January 1, 2019, Calliditas has switched to presenting costs in the income statement based on function instead of on the basis of cost type. The purpose of the change is to provide more relevant information about the Group's and the parent company's financial results, as a function-divided presentation better reflects the practice in the industry in which the company operates. The change constitutes a voluntary change of accounting principle and is applied with full retroactivity. The effects of the change in the income statements for the preceding periods are shown below:

	Before adjustment	Adjustment	After adjustment
Group, Oct-Dec, 2018			
Research and development expenses	-	(34,172)	(34,172)
Sales and administration expenses	-	(8,896)	(8,896)
Other operating revenue	39	(39)	-
Other operating expenses	-	(1,677)	(1,677)
Other external operating expenses	(37,713)	37,713	-
Personnel expenses	(7,058)	7,058	-
Depreciation and amortization	(13)	13	-
Total operating expenses	**(44,745)**	**-**	**(44,745)**

	Before adjustment	Adjustment	After adjustment
Group, Jan-Dec, 2018			
Research and development expenses	-	(99,260)	(99,260)
Sales and administration expenses	-	(31,132)	(31,132)
Other operating revenues	715	(715)	-
Other operating expenses	-	(2,090)	(2,090)
Other external operating expenses	(114,056)	114,056	-
Personnel expenses	(19,090)	19,090	-
Depreciation and amortization	(51)	51	-
Total operating expenses	**(132,482)**	**-**	**(132,482)**
Parent Company, Oct-Dec, 2018			
Research and development expenses	-	(34,172)	(34,172)
Sales and administration expenses	-	(8,897)	(8,897)
Other operating revenue	39	(39)	-
Other operating expenses	-	(1,677)	(1,677)
Other external operating expenses	(37,518)	37,518	-
Personnel expenses	(7,254)	7,254	-
Depreciation and amortization	(13)	13	-
Total operating expenses	**(44,746)**	**-**	**(44,746)**
Parent Company, Jan-Dec, 2018			
Research and development expenses	-	(99,260)	(99,260)
Sales and administration expenses	-	(31,000)	(31,000)
Other operating revenue	715	(715)	-
Other operating expenses	-	(2,090)	(2,090)
Other external operating expenses	(113,927)	113,927	-
Personnel expenses	(19,087)	19,087	-
Depreciation and amortization	(51)	51	-
Total operating expenses	**(132,350)**	**-**	**(132,350)**

The change has not had any effect on the Group's or the Parent Company's financial position, cash flows, or earnings per share, for any of the periods.

IFRS 16 Leasing

IFRS 16 is applied by the Group as of January 1, 2019. IFSR 16 replaces IAS 17, and according to the new standard, lessees must report the obligation to pay lease payments as a lease debt in the balance sheet. The right to use the underlying asset during the leasing period is reported as an asset. Depreciation of the asset is recognized in the income statement as well as an interest on the lease debt. Paid leasing fees are reported partly as interest payment and partly as amortization of the lease liability. The standard gives the possibility to exclude leasing agreements with a lease term of less than 12 months (short-term leases) and leasing agreements for assets that have a low value.

The standard means that the majority of existing leases are reported as assets and liabilities in the balance sheet. This means that the cost for these is reported divided into interest expenses and depreciation. In the parent company, the exception is applied in RFR 2 regarding leasing agreements. This means that the parent company's principles for reporting leases are unchanged. Calliditas applies the simplified transition method, meaning numbers for previous periods are not presented. The transition to IFRS 16 meant that the Group had the right to use assets and leasing liabilities of SEK 1,819 thousand as of January 1, 2019. The transition to IFRS 16 also meant that the operating profit for the Group for the full year 2019 improved by SEK 196 thousand, and that the result for the same period decreased by SEK 111 thousand compared with the corresponding accounting principles applied in the previous year.

Reconciliation of operational leasing commitments, *Amounts in SEK 000s*	
Commitments for operational leasing agreements December 31, 2018	**1,983**
Discounting effects	(164)
Reported leasing liabilities as of January 1, 2019	**1,819**

Leasing agreements, Amounts in SEK 000s	**Right of use assets**	**Lease liabilities**
Opening balance January 1, 2019	1,819	1,819
Additional agreements	7,527	7,527
Revaluation of agreements	-1,819	-1,624
Depreciation	-1,568	-
Amortization	-	-1,652
Outgoing balance on December 31, 2019	**5,959**	**6,070**

During the period, a revaluation of the agreement was made when the lease was terminated prematurely. Additional agreements pertain to leases for an office with an agreement period until May 2022. The lease can be extended by three years unless either of the parties terminates the lease at least nine months before. Calliditas cannot determine with reasonable certainty whether the extension will take place in view of the company's development and has therefore not expected utilization after May 2022.

Right-of-use assets are reported in the line of tangible assets, long-term portion of leasing liabilities are reported in the line of other non-current liabilities and short-term portion of leasing liabilities is reported in the line of other current liabilities in the consolidated report on financial position.

In the Parent Company, the exception is applied in RFR 2 regarding leasing agreements. This means that the parent company's principles for accounting for leases are unchanged.

Note 3 Risks and uncertainties in the Group and the Parent Company

Operational risks

Research and drug development up to approved registration is subject to considerable risk and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to the technological risk such as the risk for insufficiency efficacy, intolerable side effects or manufacturing problems. Competing pharmaceuticals can capture market share or reach the market faster, or if competing research projects achieve better product profile, the future value of the product portfolio may be lower than expected. The operations may also be impacted negatively by regulatory decisions, such as approvals and price changes.

Financial risk management

Calliditas' financial policy governing the management of financial risks has been designed by the Board of Directors and represents the framework of guidelines and rules in the form of risk mandated and limits for financial activities.

The Company is primarily affected by foreign exchange risk, since the development costs for Nefecon are mainly paid in USD and EUR. Regarding the Group and parent company's financial risk management, the risks are essentially unchanged compared with the description in the annual report for 2018.

For more information regarding the operational- and financial risks, reference is made to the listing prospectus published in connection with IPO on Nasdaq Stockholm in 2018, pages 12-20, and page 28 in the Annual Report of 2018.

Note 4 Revenue

Revenue is reported when a promised product or service is transferred to the counterparty, which can be done over time or at a specific time. Revenue is the amount that the Group / Parent Company expects to receive as compensation for transferred goods or services.

The Group's and Parent Company's revenues during the period consisted of revenues for the out-licensing of Nefecon within the framework of the agreement with Everest Medicines on the out-licensing of Nefecon to China.

Revenue for out-licensing is reported at a time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreement with Everest Medicines was signed. Variable remuneration (for example, attributable to future regulatory milestones) is recognized when there is no longer any significant uncertainty as to whether these will occur. Compensation attributable to sales-based milestones or royalties are not recognized until the sale that results in the right to milestones or royalties arises. Revenue attributable to the supply of drug is recognized at a time when the control of the goods is transferred to the counterparty.

The Group and the Parent Company have identified two performance commitments under the agreement: 1) Out-licensing of the product candidate Nefecon as is at the time of signing and 2) Provision of drugs for conducting clinical trials. The share of the transaction amount attributable to the supply of drug for clinical trial has not been recognized as revenue and has been calculated by the acquisition price based on the cost of the goods, plus a fair market margin. The proportion attributable to out-licensing has been calculated as a residual of the remaining transaction price after deduction of other performance commitments, since the product candidate has not been approved for market by the regulatory authorities and no commercial pricing occur.

A breakdown of the Group's revenue looks as follows:

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**
By type of revenue				
Licensing	46,586	-	184,829	-
Net sales	**46 586**	**-**	**184 829**	**-**
By geographic area				
Asia	46,586		184,829	-
Net sales	**46,586**	**-**	**184,829**	**-**

Note 5 Related-party transactions

During the reporting period, no significant related-party transactions have taken place. For information about incentive programs please see note 8.

Note 6 Financial instruments

Calliditas financial assets and liabilities comprise of cash and cash equivalents, non-current assets, other current assets, accrued expenses and accounts payable. The Company has financial assets recognized at fair value in respect of currency options. These are entered at a value of SEK 399 thousand per December 31, 2019 and have been valued according to quoted prices in active markets for identical assets or liabilities. Other financial assets and liabilities have been valued based on amortized cost. The fair value of all financial instruments is materially equal to their carrying amounts.

Note 7 Equity

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**
Total registered shares at the beginning of period	38,707,638	35,202,347	35,202,347	16,673,000
New issue of shares during the period	-	-	3,505,291	18,529,347
Total registered shares at the end of period[1]	**38,707,638**	**35,202,347**	**38,707,638**	**35,202,347**
Share capital at the end of period	1,548	1,408	1,548	1,408
Equity at the end of period	788,071	618,175	788,071	618,175
Earnings per share before and after dilution, SEK	(0.60)	(1.26)	(0.88)	(5.09)
Average number of shares for the period[1]	38,707,638	35,202,347	36,998,208	25,948,037

[1] When calculating earnings per share after dilution, the weighted average is adjusted by the number of outstanding common shares for the dilution effect of all potential common shares. These potential common shares are attributable to a total of 2,575,586 options outstanding in option programs 2017, 2018 and 2019. If the result of the period is negative, the options are not considered dilutive. No dilution effect exists for the option programs as the result for the period is negative.

Reserves for translation difference of SEK -45 (-34) thousand are included in equity as of December 31, 2019.

Note 8 Incentive programs

Warrants Program 2019/2022

During 2019, a total of 422,500 warrants have been issued to employees and consultants in the Group. The reason is the company's need to recruit and retain key employees. The warrants in the Warrants Program 2019/2022 can be exercised between October 1, 2022 and December 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the company at a subscription price of SEK 74.50 per share. At the time of the grant, the warrants were valued at market value according to Black & Scholes valuation model.

Board LTIP 2019

This is a performance-based long-term incentive program for some members of Calliditas. A total of 57,032 share rights have been granted under the program during the second quarter of

2019. The share rights are subject to performance-based earnings based on the development of Calliditas share price during the period from the date of the 2019 AGM to June 1, 2022.

Summary of outstanding incentive programs

	Warrants allocated	Granted share rights	Total allocation 2019-12-31
Incentive program			
Warrants program 2017/2020	1,296 500		1,296,500
Warrants program 2018/2022	856,586		856,586
Warrants program 2019/2022	422,500		422,500
Board LTIP 2019		57,032	57,032
Total allocation December 31 2019	**2,575,586**	**57,032**	**2,632,618**

Note 9 Intangible assets

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

The initial payment of EUR 1.5 million (SEK 16.1 million) has been reported as an intangible asset according to IAS 38. Calliditas will include future one-off payments in the acquisition cost if and when a decision has been made to take the measures that triggers additional payment. This means only payments Calliditas has control over if they will occur, are included in the acquisition cost of intangible assets.

Until market approval from the FDA has been granted, the asset will be treated as if it has indefinite useful life. Since market approval has not yet been obtained, no other costs are capitalized until after market approval. Until a market approval of the product has been obtained, the asset is tested at least once a year, or one when there is an indication that a need for impairment may exist, to determine a potential impairment requirement.

Definitions of performance measures and reconciliations of alternative performance measures

Definitions of performance measures

Earnings per share before/after dilution	Earnings for the period divided by the average number of share before and after dilution. Diluted earnings per share is calculated by adjusting the weighted average number of common share outstanding to assume conversion of all dilutive potential common shares.
Share capital at the end of the period	Share capital at the end of respective period. The measure is extracted from the balance sheet.
Total outstanding shares at the beginning of period	Total outstanding shares at the beginning of respective period.
Total outstanding shares at the end of period	Total outstanding shares at the end of respective period.

Average number of outstanding shares during the period	Average number of outstanding shares of respective period.
Equity at the end of the period	Equity position at the end of respective period. The measure is extracted from the balance sheet.
Cash and cash equivalents at the end of the period	Cash and cash equivalents at the end of respective period. The measure is extracted from the balance sheet.

Definitions of alternative performance measures

Alternative key performance indicator	Definition	Reason for inclusion
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.
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.

Reconciliations of alternative performance measures

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**
Expenses relating to research and development/operating expenses, %				
Research and development expenses	(41,709)	(34,172)	(149,826)	(99,260)
Sales and administration expenses	(23,790)	(8,896)	(62,882)	(31,132)
Other operating income	870	-	4,385	-
Other operating expenses	-	(1,677)	(4,525)	(2,090)
Total operating expenses	**(64,629)**	**(44,745)**	**(212,848)**	**(132,482)**
Expenses relating to research and development/operating expenses, %	65%	76%	70%	75%
Equity ratio at the end of the period %				
Total shareholders' equity at the end of the period	788,071	618,175	788,071	618,175
Total assets at the end of the period	845,200	648,417	845,200	648,417
Equity ratio at the end of the period %	**93%**	**95%**	**93%**	**95%**

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Annual General Meeting 2020

Calliditas Therapeutics Annual General Meeting will be held on Thursday, May 14, at 16:30 CET at Freys Hotel, Bryggaregatan 12, Stockholm.

In accordance with the dividend policy adopted by the Board, no dividend is proposed for the financial year 2019.

Financial calendar

Publication of the annual report 2019	Week of March 30, 2020
Interim report for the period January 1 – March 31, 2020	May 14, 2020
Interim report for the period January 1 – June 30, 2020	August 13, 2020
Interim report for the period January 1 – September 30, 2020	November 12, 2020
Year-end report for the period January 1 – December 31, 2020	February 18, 2021

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This report has been prepared in a Swedish original and has been translated into English. In case of differences between the two, the Swedish version shall apply.