Q3

calliditas THERAPEUTICS

CALLIDITAS THERAPEUTICS AB (publ)

Interim Report January 1 – September 30, 2019

Positive Regulatory Outcome- Enhanced study design

Key figures

July 1 - September 30, 2019

- Net sales for the period amounted to - (-) million.
- Net income (loss) for the period was SEK -50.1 (-31.4) million.
- Earnings before and after dilution per share totalled SEK -1.30 (-0.91).
- At September 30, 2019, cash and cash equivalents amounted to SEK 805.1 (685.9) million.

January 1 - September 30, 2019

- Net sales for the period amounted to SEK 138.2 (-) million.
- Net income (loss) for the period was SEK -9.5 (-87.8) million.
- Earnings before and after dilution per share totalled SEK -0.26 (-3.88).

Significant events during the period July 1 – September 30, 2019, in summary

- 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.
- In August, Calliditas entered into an exclusive in-licensing agreement of Budenofalk 3mg oral capsule for the US market with Dr Falk Pharma. This enables Calliditas to potentially accelerate its development of the pipeline indication related to the orphan liver disease Autoimmune hepatitis (AIH).
- In September, Calliditas obtained positive feedback from the US Food and Drug Administration (FDA) that has a significant impact on the confirmatory part of the ongoing pivotal Phase 3 study NeflgArd. The FDA accepted a two-year eGFR based end point for the Part B of the study resulting in a reduction from 450 to 360 patients, with significant positive impact on overall costs and recruitment time.

Significant events after the end of reporting period, in summary

- In October, Calliditas obtained positive advice from the European Medicines Agency (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.

Investor presentation November 14, 15:00 CET

Audio cast with teleconference, Q3 2019, November 14, 2019, 15:00 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q3-2019

Teleconference: Dial-in number SE +46850558368 UK: +443333009266 US: +18335268395

CEO Statement

A positive quarter

This third quarter of 2019 saw us move steadily on plan towards full recruitment of the NefIgArd study, despite a slower pace during the summer months. It is exciting that we are able to oversee and manage this very complex global study with a small, highly specialized core team based in Stockholm. When one realizes that this involves more than 150 staff spread across four continents, the logistics of the endeavor is humbling. I am very grateful to all of the staff of the company, but also to all of the investigators and study nurses, national coordinators and CRO staff who make this happen every day across all of the site locations. Everyone is becoming increasingly excited now that the goal of recruiting 200 patients before the year end is within our reach.

A rewarding part of this job is the interaction with patient organizations, which do an amazing job in raising awareness of this orphan disease as well as facilitating connection between patients and clinical trial opportunities. In August, IgA Nephropathy Foundation of America together with Kidney Health Initiative organized an EL-PFDD, an externally led patient focused drug development meeting in Washington D.C. The Patient-Focused Drug Development (PFDD) purpose is to more systematically obtain the patient perspective on specific diseases and their treatments. PFDD meetings give the FDA and other key stakeholders, including medical product developers and health care providers an important opportunity to hear directly from patients, their families and caregivers about the symptoms that matter most to them, the impact the disease has on patients' daily lives, and patients' experiences with currently available treatments. This input can inform FDA's decisions and oversight both during drug development and during our review of a marketing application. At the IgA meeting there were five attendees from the FDA, and issues relating to how patients live with the disease, disease management in lieu of approved drugs, participation in clinical trials and the benefits and limitations of the accelerated approval path were all explored in panels and through polling of patients and caregivers.

The opportunity to interact with patients and hear their stories is extremely valuable, but also heartbreaking. The stories from both elderly and younger patients describing how their lives have been torn apart by this disease and how toxic off label medication is, was a reminder again of why it is so important that we work undeterred at delivering robust clinical data resulting in an approved medication as soon as possible. I found the stories of the younger patients most distressing and unbelievably sad to listen to. My heart also goes out to all parents, partners and carers who live with this on a daily basis, trying to provide support and help in this imperfect and uncertain world.

This is why I am truly happy to be able to share with you the revised guidance from the FDA which we received in September. The FDA has shown great leadership and commitment to their endeavor to through the review of clinical data as well as statistical frameworks bring new therapeutics to the area of nephrology. Through interactions with the FDA during the year, we have been able to revise the confirmatory part of our study to use a more sensitive endpoint, reduce the number of patients and shorten the confirmatory part of the trial substantially. We have

worked intensively with distinguished KOLs and expert statisticians in order to achieve this result, which truly reflect what collaboration, focus, effort and ingenuity from a dedicated team can accomplish. We are very proud of our accomplishments and our contribution to accelerate the approval of medicines to patients with this disease.

Towards the very end of the quarter we also received positive advice from EMA related to our revised confirmatory Phase 3 study design as well as a confirmed path forward towards conditional approval in Europe. As the first company in the IgA nephropathy space to achieve such supportive advice we see this as a significant and very positive step forward for the company in its endeavor to provide an appropriate risk / reward alternative to the toxic off label treatments as soon as possible.

Finally, we also closed a directed share issue in early July, where we saw BVF, Biotech Value Fund become a shareholder in the company. This is an important validation of our investment thesis by a highly regarded US based specialist healthcare investor.

The Regulatory Pathway of Accelerated Approval

Regulators play an incredibly vital role in the complex web of the life sciences ecosystem. They hold the keys to the acceptance of new endpoints, design of protocols and the clinical development program as a whole. In the evolutionary context of disease management, this is clearly a daunting task. New diseases are continuosly explored, for which there is not always a clear regulatory pathway, or where existing end points are not appropriate or not realistic. New diseases develop as our life styles change and as we continue to live longer. Hence the requirements for novel approaches and advancement of science continues to put pressure on the system.

The main purpose of the FDA is to ensure the safety and efficacy of drugs, medical devices, biologics etc. The approval framework is per definition data driven and dependent mainly on clinical endpoints such as time to organ failure, or patient survival statistics.

However, in the early 1990s saw a turn of events which led to an alternative to the established approval path. This was driven by the AIDS epidemic which was sweeping the country at the time. Young people were tragically dying from a disease for which there seemingly were no remedies. Due to the aggressive nature of the disease, the idea of it taking 10 years or more for a potential drug to make it to the market was met with protests and disbelief. In 1992 the agency proposed the Accelerated Approval / Subpart H pathway which would allow for drugs to get market access based on having shown an effect on a symptom, rather than having proven its efficacy on the underlying clinical endpoint. Firstly, the regulations required that the drug be designed to treat serious or life threatening diseases, defined as illnesses that impact day to day functioning, or are assumed to threaten survival if left untreated. Secondly the drug needs to provide a “meaningful therapeutic benefit over existing therapy,” defined as where “a serious medical need is not met by currently available therapies”. Finally, there were the issues of surrogate endpoints. The FDA defined surrogate endpoint as “a laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and that is expected to predict the effect of the therapy.” The FDA stated its willingness to grant accelerated approval when there is “basis of an adequate and well-controlled trials establishing that the drug has an effect that is reasonably likely (based on epidemiologic, therapeutic, or other evidence) to predict clinical benefit.”

Once the drug was approved to be provided to patients, the drug manufacturer was obliged to carry out a post marketing study in order to provide the agency with additional clinical data in order to ultimately prove the connection between the surrogate marker and the underlying clinical endpoint.

In January 2017, Calliditas was sitting in front of the FDA presenting a statistical framework which had been developed in conjunction with Tufts University and University of Utah. The framework was a meta-analysis of interventional studies in the orphan disease of IgA nephropathy which showed a statistical correlation between reduction of proteinuria and the risk of ending up in end stage renal disease (ESRD). On the basis of this analysis the FDA made the decision to accept a surrogate marker as an approvable endpoint for a nephrology related disease. This was the beginning of the journey that we are now all on together - namely to bring the first approved drug to market for patients, and also possibly the first drug in nephrology to be approved according to the accelerated pathway.

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 ESRD. Nefecon has obtained orphan designation from both the FDA and EMA.

Calliditas has all the rights to develop and commercialize Nefecon globally, however in China and Singapore, Calliditas has 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'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 lead candidate Nefecon have 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 IgA

nephropathy and on optimal or highest tolerable blood pressure medication will be randomized across 19 countries in North and South America, Europe as well as 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 treatment, and will then be followed for three months. The first 200 patients randomized in the study will be included in the read-out which will form the basis for accelerated approval/conditional approval by the FDA and European Medicines Agency (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 proteinuria and will form the basis for accelerated approval in the US 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, this will enable a commercialization and marketing of the drug in the US and the EU. Calliditas have licensed the development and commercialization rights of Nefecon in Greater China and Singapore to Everest Medicines.

The company 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, also known as Berger 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 end-stage renal disease (ESRD).

In the past decades, 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].

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 about 600,000 - 800,000 people have today been diagnosed with IgAN in China.

Liver orphan indications

Beyond IgA nephropathy, 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. 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. 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 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

[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.*

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

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

42,000 patients in the US. 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.

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 60,000-80,000 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. The combination of Calliditas' 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 have been granted orphan drug designation in the US for the treatment of AIH.

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

Significant events during the period January 1 – September 30, 2019

- Calliditas was granted orphan drug designation (ODD) for the treatment of Autoimmune hepatitis (AIH) by the FDA. It is estimated that the patient population in the US amounts to approximately 60,000 – 80,000.
- Calliditas was granted orphan drug status by the FDA for the treatment of primary biliary cholangitis (PBC). 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.
- The Annual General Meeting (AGM) of Calliditas was held in May and the AGM resolved, among other things, on the election of Elmar Schnee (Chairman) and Diane Parks to the Board of Directors.
- Calliditas and Everest Medicines entered into a license agreement in June 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 will receive 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 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.
- 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.

Significant events after the end of reporting period

- In October, Calliditas obtained positive advice from the EMA, in which the agency expressed support for a conditional marketing authorization (CMA) of the company's lead compound Nefecon. The agency provided advice indicating that it could support CMA assessment, subject as usual to the strength of the full data set presented at the time of filing.

Financial overview

Key figures

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	2019	2018	2019	2018	2018
Net sales	-	-	138,243	-	-
Expenses relating to research and development/operating expenses, %[1]	88%	77%	73%	74%	75%
Net income (loss) for the period	(50,139)	(31,403)	(9,528)	(87,825)	(132,049)
Earnings per share before and after dilution, SEK	(1.30)	(0.91)	(0.26)	(3.88)	(5.09)
Cash flow from operating activities	83,109	(15,223)	(25,576)	(85,705)	(128,191)
Total registered shares at the end of period	38,707,638	35,202,347	38,707,638	35,202,347	35,202,347
Equity at the end of the period	809,967	659,568	809,967	659,568	618,175
Equity ratio at the end of the period %[1]	96%	96%	96%	96%	95%
Cash and cash equivalents at the end of the period	805,075	685,871	805,075	685,871	646,175

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

January – September 2019

Revenue

There were no revenues reported (-) in the third quarter of 2019. The revenue for the first nine months of 2019 was SEK 138.2 million (-) and stems from the out-licensing of Nefecon for China to Everest Medicines. For additional information see note 4.

Total operating expenses

Operating expenses for the third quarter of 2019 amounted to SEK 52.6 (31.3) million and SEK 148.2 (87.7) million for the first nine months of 2019.

Research and development expenses

Research and development costs increased by SEK 22.1 million to SEK 46.2 (24.1) million during the third quarter of 2019. Research and development costs for the first nine months of 2019 increased by SEK 43.0 million to SEK 108.1 (65.1) million. The cost increase for both periods are related to the operation of the NefIgArd study for Nefecon where the first patient was included in the study in Q4 2018.

Sales and administration expenses

During the third quarter of 2019, sales and administration expenses increased by SEK 3.0 million to SEK 10.3 (7.3) million. The increase for the third 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. For the first nine months of 2019, the increase was SEK 15.8 million to SEK 39.1 (23.3) million. The increase for the first nine months is also mainly explained by the initiation of commercial preparations for a potential future launch of Nefecon in the US, together with transaction related costs in connection with the out-licensing of Nefecon to Everest Medicines in China.

Other operating revenue/expenses

Other operating income (expenses) were net SEK 3.8 (0.1) million for the third quarter of 2019, respectively, and net SEK -1.0 (0.7) million for the first nine months of 2019 and consist of exchange rate differences on assets and liabilities of an operating nature.

Earnings

Net income (loss) for the period amounted to SEK -50.1 (-31.4) million for the third quarter of 2019 and SEK -9.5 (-87.8) million for the first nine months of 2019, resulting in earnings per share before and after dilution of SEK -1.30 (-0.91) for the third quarter of 2019, and SEK -0,26 (-3.88) for the first half of 2019. The decline in earnings for the third quarter of 2019 is mainly due to the increased activity in the NefIgArd study compared with the same period 2018, and the improvement in the result for the first nine months of 2019 compared with the same period last year mainly stems from the income of SEK 138.2 million during the second quarter of 2019, from the out-licensing of Nefecon in China to Everest Medicines, far exceeds the increased cost of running the NefIgArd study.

Tax

No tax expenses were reported for the third quarter of 2019 (-) or the first nine months of 2019 (-), as Calliditas has tax losses that is not capitalized since future income is not considered sufficiently secure to enable deferred tax assets to be capitalized.

Cash flow and cash position

The cash flow from operating activities amounted to SEK 83.1 (-15.2) million for the third quarter of 2019 and SEK -25.6 (-85.7) million for the first nine months of 2019. The positive cash flow from operating activities during the third quarter of 2019 is due to the payment of Everest Medicines for the out-licensing of Nefecon in China of USD 15 million received in the third quarter 2019.

Cash flow from investing activities in the third quarter of 2019 was SEK -15.8 (-) million and SEK -17.8 (-) million for the nine-month period 2019 and is mainly due to the in-licensing of Budenofalk 3mg from Dr. Falk Pharma in the third quarter 2019.

Cash flow from financing operations in the third quarter of 2019 was SEK 200.4 (684.2) million and SEK 200.1 (714.3) million for the nine-month period 2019 and is mainly due to the direct share issue of SEK 210.3 million, which was completed in July 2019.

The cash flow amounted to SEK 267.7 (669.0) million for the third quarter of 2019 and SEK -156.7 (628.6) million for the first nine months of 2019. Cash and cash equivalents as of September 30, 2019, amounted to SEK 805.1 (685.9) million.

Changes in equity and number of shares

As of September 30, 2019, equity amounted to SEK 810.0 (659.6) million. The number of shares increased during the third quarter by 3,505,291, as a result of the direct share issue in July 2019, and as of 30 September 2019 it amounted to 38,707,638 (35,202,347).

Employees

As of September 30, 2019, the number of employees in Calliditas Therapeutics was 14 (10). The number of average employees in the third quarter of 2019 was 14 (10) and 13 (10) for the first nine months 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 the warrant program 2019/2022 the allocation continued during the third quarter 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.

Stockholm November 14, 2019

Renée Aguiar-Lucander

CEO

Review report

Calliditas Therapeutics AB, corporate identity number 556659-9766

Introduction

We have reviewed the condensed interim report for Calliditas Therapeutics AB as at September 30, 2019 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 *Review of Interim Financial Statements Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden.

The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm 14 November 2019

Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

Financial statements

Condensed consolidated income statement

		Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**	**2018**
Net sales	4	-	-	138,243	-	-
Total operating income		**-**	**-**	**138,243**	**-**	**-**
Operating expenses						
Research and development expenses		(46,186)	(24,055)	(108,117)	(65,088)	(99,260)
Sales and administration expenses		(10,295)	(7,298)	(39,092)	(23,325)	(33,937)
Other operating revenue		5,590	80	6,643	676	715
Other operating expenses		(1,747)	-	(7,653)	-	-
Total operating expenses		**(52,638)**	**(31,273)**	**(148,219)**	**(87,737)**	**(132,482)**
Operating profit (loss)		**(52,638)**	**(31,273)**	**(9,976)**	**(87,737)**	**(132,482)**
Net financial items		2,499	(130)	448	(88)	433
Profit (loss) before taxes		**(50,139)**	**(31,403)**	**(9,528)**	**(87,825)**	**(132,049)**
Income taxes		-	-	-	-	-
Net income (loss) for the period		**(50,139)**	**(31,403)**	**(9,528)**	**(87,825)**	**(132,049)**
Attributable to:						
Equity holder of the parent company		(50,139)	(31,403)	(9,528)	(87,825)	(132,049)
Earnings per share before and after dilution (SEK)		(1.30)	(0.91)	(0.26)	(3.88)	(5.09)

Condensed consolidated statement of comprehensive income

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Net income (loss) for the period	(50,139)	(31,403)	(9,528)	(87,825)	(132,049)
Other comprehensive income					
Currency translation effect	42	0	27	(7)	6
Total comprehensive income (loss)	**(50,097)**	**(31,403)**	**(9,501)**	**(87,832)**	**(132,043)**
Attributable to:					
Equity holder of the parent company	(50,097)	(31,403)	(9,501)	(87,832)	(132,043)
Total comprehensive income (loss)	**(50,097)**	**(31,403)**	**(9,501)**	**(87,832)**	**(132,043)**

Condensed consolidated statement of financial position

Amounts in SEK 000s	*Notes*	2019-09-30	2018-09-30	2018-12-31
Non-current assets				
Intangible assets	9	15,775	-	
Other material assets	2	6,697	119	107
Financial non-current assets		1,939	341	341
Total non-current assets		**24,411**	**460**	**448**
Current assets				
Other current assets		11,360	1,502	1,794
Cash and cash equivalents	6	805,075	685,871	646,175
Total current assets		**816,435**	**687,373**	**647,969**
Total assets		**840,846**	**687,833**	**648,417**
Shareholders' equity				
Share capital		1,548	1,408	1,408
Additional paid in capital		1,273,473	1,069,501	1,072,319
Retained earnings, including net loss for the period		(465,054)	(411,341)	(455,552)
Total shareholders' equity attributable to shareholders of the parent company	5,7	**809,967**	**659,568**	**618,175**
Non-current liabilities				
Provision for social security contributions incentive program	8	45	-	**-**
Other non-current liabilities	2	4,210	-	-
Total non-current liabilities		**4,255**	**-**	**-**
Current liabilities				
Accounts payable	6	14,941	19,291	22,643
Other current liabilities	2	3,285	647	904
Accrued expenses	6	8,398	8,327	6,695
Total current liabilities		**26,624**	**28,265**	**30,242**
Total liabilities and shareholders' equity		**840,846**	**687,833**	**648,417**

Condensed consolidation statement of changes in equity

		Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**	**2018**
Opening shareholder equity		659,023	7 332	618,175	33,176	33,176
Profit/loss of the period		(50,139)	(31,403)	(9,528)	(87,825)	(132,049)
Other comprehensive income		42	-	27	(7)	6
Comprehensive income (loss) for the period		**(50,097)**	**(31,403)**	**(9,501)**	**(87,832)**	**(132,043)**
Transaction with owners						
New issue of ordinary shares	7	210,317	738,072	210,317	738,650	738,650
Cost attributable to new share issue		(10,916)	(54,433)	(10,916)	(54,433)	(54,433)
Premiums received from warrants	8	1,533	-	1,750	-	2,826
Share based renumeration	8	107	-	142	8	-
Contribution from shareholders		-	-	-	29,999	29,999
Total transaction with owners		**201,041**	**683,639**	**201,293**	**714,224**	**717,042**
Closing shareholding equity		**809,967**	**659,568**	**809,967**	**659,568**	**618,175**

Condensed consolidated statement of cash flows

		Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**	**2018**
Operating activities						
Operating profit (loss)		(52,638)	(31,273)	(9,976)	(87,737)	(132,482)
Adjustment for non-cash-items		857	12	1,438	38	51
Interest received		-	-	-	6	6
Interest paid		(117)	(2)	(219)	(7)	(8)
Cash flow from operating activities before working capital		**(51,898)**	**(31,263)**	**(8,757)**	**(87,700)**	**(132,433)**
Cash flow from changes in working capital		135,007	16,040	(16,819)	1,995	4,242
Cash flow from operating activities		**83,109**	**(15,223)**	**(25,576)**	**(85,705)**	**(128,191)**
Cash flow from investing activities	9	(15,775)	-	(17,781)	-	-
Cash flow from financing activities	7	200,355	684,198	200,088	714,314	716,572
Cash flow for the period		**267,689**	**668,975**	**156,731**	**628,609**	**588,381**
Cash & cash equivalents, beginning of period		534,863	17,023	646,175	57,352	57,352
Net increase (decrease) in cash & cash equivalents		267,689	668,975	156,731	628,609	588,381
Exchange-rate difference in cash and cash equivalents		2,523	(127)	2,169	(90)	442
Cash & cash equivalents, end of period		**805,075**	**685,871**	**805,075**	**685,871**	**646,175**

Condensed parent company income statement

		Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**	**2018**
Net sales	4	-	-	138,243	-	-
Gross profit		**-**	**-**	**138,243**	**-**	**-**
Operating expenses						
Research and development expenses		(46,186)	(24,055)	(108,117)	(65,088)	(99,260)
Sales and administration expenses		(10,248)	(7,236)	(39,389)	(23,192)	-
Other operating revenue		5,590	80	6,628	676	(33,805)
Other operating expenses		(1,747)	-	(7,653)	-	715
Total operating expenses		**(52,591)**	**(31,211)**	**(148,531)**	**(87,604)**	**(132,350)**
Operating profit (loss)		**(52,591)**	**(31,211)**	**(10,288)**	**(87,604)**	**(132,350)**
Net financial items		2,614	(125)	635	(113)	427
Profit (loss) before taxes		**(49,977)**	**(31,336)**	**(9,653)**	**(87,717)**	**(131,923)**
Income taxes		-	-	-	-	-
Net income (loss) for the period		**(49,977)**	**(31,336)**	**(9,653)**	**(87,717)**	**(131,923)**

Condensed parent company statement of other comprehensive income

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Net income (loss) for the period	(49,977)	(31,336)	(9,653)	(87,717)	(131,923)
Other comprehensive income	-	-	-	-	-
Total comprehensive income	**(49,977)**	**(31,336)**	**(9,653)**	**(87,717)**	**(131,923)**

Condensed parent company balance sheet

Amounts in SEK 000s	*Notes*	2019-09-30	2018-09-30	2018-12-31
Non-current assets				
Intangible assets	9	15,775	-	-
Property, plant and equipment		110	119	107
Financial non-current assets		5,428	3,830	3,830
Total non-current assets		**21,313**	**3,949**	**3,937**
Current assets				
Other current assets		11,540	1,486	1,793
Cash and cash equivalents	6	804,146	685,592	645,903
Total current assets		**815,686**	**687,078**	**647,696**
Total assets		**836,999**	**691,027**	**651,633**
Shareholders' equity				
Share capital		1,548	1,408	1,408
Statutory reserve		3,092	3,092	3,092
Restricted equity		**4,640**	**4,500**	**4,500**
Additional paid in capital		1,268,334	1,069,072	1,069,072
Retained earnings, including net loss for the period		(459,834)	(410,834)	(452,222)
Non-restricted equity		**808,500**	**658,238**	**616,850**
Total shareholders' equity	5,8	**813,140**	**662,738**	**621,350**
Non-current liabilities				
Provision for social security contributions incentive program	8	45	-	-
Other non-current liabilities		-	77	77
Total non-current liabilities		**45**	**77**	**77**
Current liabilities				
Accounts payable	6	14,876	19,269	22,628
Other current liabilities		836	647	904
Accrued expenses	6	8,102	8,296	6,674
Total current liabilities		**23,814**	**28,212**	**30,206**
Total liabilities and shareholders' equity		**836,999**	**691,027**	**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 interim report for January – September 2019, has been approved for publication on November 14, 2019, 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.

Calliditas applies International Financial Reporting standards (IFRS) as adopted by the European Union. 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, Jul-Sep, 2018			
Research and development expenses	-	(24,055)	(24,055)
Sales and administration expenses	-	(7,298)	(7,298)
Other operating revenue	80	-	80
Other external operating expenses	(26,644)	26,644	-
Personnel expenses	(4,696)	4,696	-
Depreciation and amortization	(13)	13	-
Total operating expenses	**(31,273)**	**-**	**(31,273)**

	Before adjustment	Adjustment	After adjustment
Group, Jan-Sep, 2018			
Research and development expenses	-	(65,088)	(65,088)
Sales and administration expenses	-	(23,325)	(23,325)
Other operating revenue	676	-	676
Other external operating expenses	(76,539)	76,539	-
Personnel expenses	(11,836)	11,836	-
Depreciation and amortization	(38)	38	-
Total operating expenses	**(87,737)**	**-**	**(87,737)**
Group, Jan-Dec, 2018			
Research and development expenses	-	(99,260)	(99,260)
Sales and administration expenses	-	(33,937)	(33,937)
Other operating revenue	715	-	715
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, Jul-Sep, 2018			
Research and development expenses	-	(24,055)	(24,055)
Sales and administration expenses	-	(7,236)	(7,236)
Other operating revenue	80	-	80
Other external operating expenses	(26,778)	26,778	-
Personnel expenses	(4,500)	4,500	-
Depreciation and amortization	(13)	13	-
Total operating expenses	**(31,211)**	**-**	**(31,211)**
Parent Company, Jan-Sep, 2018			
Research and development expenses	-	(65,088)	(65,088)
Sales and administration expenses	-	(23,192)	(23,192)
Other operating revenue	676	-	676
Other external operating expenses	(76,409)	76,409	-
Personnel expenses	(11,833)	11,833	-
Depreciation and amortization	(38)	38	-
Total operating expenses	**(87,604)**	**-**	**(87,604)**
Parent Company, Jan-Dec, 2018			
Research and development expenses	-	(99,260)	(99,260)
Sales and administration expenses	-	(33,805)	(33,805)
Other operating revenue	715	-	715
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. 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 first nine months 2019 improved by SEK 131 thousand, and that the result for the period decreased by SEK 73 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	-1,609	-1,624
Depreciation	-1,151	-
Amortization	-	-1,063
Outgoing balance on September 30, 2019	**6,586**	**6,659**

During the period, a revaluation of the agreement has taken place, as a result of changed assessments regarding whether a lease agreement for premises will be extended. Utility rights assets are reported in the line of other material assets and long-term portion of leasing liabilities are reported in the line of other non-current liabilities. The short-term part of leasing liabilities is reported in the line of other current liabilities in the Group's consolidated statement of financial position.

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. Variable remuneration (for example, attributable to future regulatory or sales-based milestones) is not recognized until there is no longer any significant uncertainty as to whether these will occur. Compensation attributable to royalties is not recognized until the sale that results in the right to royalty 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 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.

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

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
By type of revenue					
Licensing	-	-	138,243	-	-
Net sales	**-**	**-**	**138,243**	**-**	**-**
By geographic area					
Asia	-		138,243	-	-
Net sales	**-**	**-**	**138,243**	**-**	**-**

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 1,590 thousand and have been valued according to level 2 in the fair value hierarchy. 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

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Total registered shares at the beginning of period	35,202,347	33,232,347	35,202,347	16,673,000	16,673,000
New issue of shares during the period	3,505,291	1,970,000	3,505,291	18,529,347	18,529,347
Total registered shares at the end of period[1]	38,707,638	35,202,347	38,707,638	35,202,347	**35,202,347**
Share capital at the end of period	1,548	1,408	1,548	1,408	1,408
Equity at the end of period	809,967	659,568	809,967	659,568	618,175
Earnings per share before and after dilution, SEK	(1.30)	(0.91)	(0.26)	(3.88)	(5.09)
Average number of shares for the period[1]	38,593,335	34,581,369	36,345,098	22,647,398	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 -8 (-47) thousand are included in equity as of September 30, 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 2019-06-30
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 June 30 2019	**2,575,586**	**57,032**	**2,632,618**

Note 9 Intangible assets

During the third quarter, Calliditas Therapeutics licensed Budenofalk 3 mg oral capsule from the German pharmaceutical company Dr Falk Pharma GmbH, for development in the US market. The agreement covers all indications for the US market, excluding orphan indications who are not liver related. During the third quarter, 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 15.8 million) has been reported as an intangible asset in the third quarter 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 no 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 unlimited 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 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

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Expenses relating to research and development/operating expenses, %					
Research and development expenses	(46,186)	(24,055)	(108,117)	(65,088)	(99,260)
Sales and administration expenses	(10,295)	(7,298)	(39,092)	(23,325)	(33,937)
Other operating revenue/expenses	3,843	80	(1,010)	676	715
Total operating expenses	**(52,638)**	**(31,273)**	**(148,219)**	**(87,737)**	**(132,482)**
Expenses relating to research and development/operating expenses, %	88%	77%	73%	74%	75%
Equity ratio at the end of the period %					
Total shareholders' equity at the end of the period	809,967	659,568	809,967	659,568	618,175
Total assets at the end of the period	840,846	687,833	840,846	687,833	648,417
Equity ratio at the end of the period %	**96%**	**96%**	**96%**	**96%**	**95%**

Financial calendar

Year-end report for the period January 1 – December 31, 2019	February 14, 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

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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.