Q1

calliditas THERAPEUTICS

CALLIDITAS THERAPEUTICS AB (publ)

Interim Report January 1 – March 31, 2020

NefIgArd proceeding according to plan

Key Figures

January 1 – March 31, 2020

- Net sales for the period amounted to SEK 0.5 (-) million.
- Loss before income tax for the period was SEK 63.7 (42.6) million.
- Loss per share before and after dilution SEK 1.65 (1.21).
- As of March 31, 2020, cash amounts to SEK 728.6 (596.9) million.

Significant events during the period January 1 – March 31, 2020, in summary

- In January 2020, the Company's Board of Directors decided to explore whether there are conditions for a potential offering of the company's securities in the United States and a press release with the title "Calliditas submits draft registration statement for the listing of ADSs in the U.S." was published.
- In January 2020, EMA Paediatric Committee (PDCO) adopted a positive opinion on the Paediatric Investigation Plan (PIP) for Nefecon for the treatment of primary IgA nephropathy (IgAN).
- In March 2020, Calliditas held an Extra General Meeting where authorization for the Board of Directors to issue new shares for a potential equity offering and listing of securities in the United States, adoption of new articles of association and adoption of a new incentive program were approved.

Significant events after the reporting period, in summary

- In April 2020, Calliditas announced that Dr. Richard Philipson had been appointed as Chief Medical Officer (CMO) and would take up the position in early July.

Investor presentation May 14, 15:30 CET

Audio cast with teleconference, Q1 2020, May 14, 2020, 15:30 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q1-2020

Teleconference: SE: +46850558350 UK: +443333009034 US: 18335268347

CEO Statement

Strong performance despite uncertain times

In the first quarter of 2020, the world transformed in front of our eyes in light of a previously unknown virus, Covid-19. The initial reports from Wuhan, China, indicated a highly contagious new corona virus which seemed to affect primarily the respiratory system of infected patients. Quickly the virus spread across the Western world in February and March and developed into the pandemic which now has engulfed the entire world. This has obviously had a significant impact on the entire healthcare system and there has been rapid and significant loss of life, especially amongst those over 70 years of age.

Against this backdrop, much of the activity at the company during the quarter was focused on assessing and mitigating any potential impact Covid-19 might have on NefIgArd, the pivotal Phase 3 study presently ongoing. I am happy to report that, due to the fact that the Part A of the study was fully recruited in December 2019, Nefecon is an oral formulation which patients are able to take at home and that the study doesn't require significant interactions with the healthcare system, the impact to date has been limited and our communicated timelines remain intact. That is not to say that nothing has changed with regards to patients, study nurses and investigators, however. Many of them, like yourselves, are working from home, displaced from their places of work and with limited social interactions as lock downs and distancing rules are implemented across the different countries. This obviously places significant additional pressures on each and every chain of the intricate system which connects patients on a global basis with their clinic, nurses and physician, as well as the subsequent interaction with CROs and us as the global sponsor.

We have put in place a variety of initiatives and solutions designed to ensure patient safety and trial integrity during these extraordinary circumstances. The clinical team has worked tirelessly to increase communication and integration across the board and the results to date have been impressive. Recruitment of the additional patients required for Part B was very strong during the quarter, but we expect to see this rate reduce as lockdowns continue and hospitals shut down non-Covid-19 related activities. In China, however, activities have gradually picked up over the quarter, and we are now seeing significant headway being made in preparing for recruitment into Part B of the trial. Based on information to date, we therefore do not see any significant impact regarding completion of recruitment for Part B. However, the development of the COVID-19 pandemic is uncertain, and future events may alter this timeline.

The team effort required during this quarter has been one step above and beyond what we have achieved before. I am extremely grateful to each and every member of staff who have worked through dislocation, home schooling, digital platforms and general anxiety about the health of friends and family to achieve the exceptional level of excellence produced this quarter. My heartfelt gratitude to all of our patients who bear with us in our endeavors to ensure that the trial continues as much as possible as before in order to read out in Q4 this year and potentially result in an approved medication for IgA nephropathy. Most of all, however, I salute all of the nurses and physicians who everyday focus on curing, helping and supporting patients, many of whom are now fighting at the very front lines of this pandemic.

During the quarter we have also continued to build our organization, primarily in the US. We welcomed two senior key hires in that region during the quarter, which will enable us to continue our pre-commercial activities and launch medical education initiatives as planned. It seems as if we might just be seeing a slight shimmer of light at the end of the tunnel, and I hope that

over the next couple of months we can get back to a way of life which at least feels somewhat familiar to us all.

Lies, damned lies and statistics…

The statement above probably summarizes the frustration that most of us feel about the quandary we are all facing presently as we immerse ourselves into the never-ending numbers and statistics reported on the corona crisis. It is obviously extremely rare that the vast majority of the world's population is checking the same websites obsessively in order to try to make sense of what is happening around them. Every thesis espoused by a variety of recognized or self-proclaimed experts is double checked, countered, vilified or made fun of. How then are we supposed to make any sense of the information we are provided?

Some of you might have heard of "the fog of war," a term coined by the 19th-century Prussian military writer Carl von Clausewitz. It refers to the idea that war is often conducted in a haze of uncertainty: the military does not necessarily fully understand their enemy's threat or their own capacity to combat it.

It is not unlikely that what we are experiencing now is the fog of pandemic. Anyone trying to track the Covid-19 is swimming in statistics: daily infection rates, mortality rates - inside and outside of hospitals, unemployment rates and testing levels. But at this stage of the fight against the coronavirus, these figures seem to have their own particular limitations. In some countries, health officials seem to call the shots more or less successfully on the basis of reported numbers in some form, in others, this haze of confusing data results in political leaders trying to override the advice of public-health experts.

Other metrics used to try to gauge the speed and scale of the outbreak also have limitations. Countries, or individual states within countries, test for the disease at vastly different rates and in different populations. Even death statistics are a function of case-by-case diagnosis and different approaches as to the cause-of-death methodology. Many deaths due to Covid-19 may have been, and will continue to be, misdiagnosed as the result of pneumonia or another respiratory ailment, resulting in a variety of over – or under – reporting. In brief, everybody seems to be doing the right, or wrong thing depending on where in the room you sit. What we can probably all agree on, however, is that no one seems to have the definitive answer to anything at this time and we are all still fumbling around in a poorly lit room frantically searching for the light button. In summary, it seems as if we all have to be patient about the fact that no single metric is gospel right now. Even many health statistics taken together can offer, at best, an incomplete picture of this crisis.

As extreme as this situation is, this reality of incomplete, contradictory or uncertain data is to some extent the everyday situation of life science companies. We try to control for variations in the population, for the unknown, for placebo effects and for dosing and duration related impacts. The combination of a highly variable presentation of the disease with a poorly understood and defined mode of action generally results in a very difficult equation. We try to study as much data as possible before launching trials and subsequently analyze subgroups and various responses to learn more about how to best proceed. We try to formulate and advance a thesis which we can test and then either adopt or discard. We are now trying to do all of this at the speed of light in "the fog of war".

Let's hope that we can build on some of the experiences we have already gathered in a more controlled environment to shorten the development path of an interim approach, which hopefully can take the edge of the worst consequences of the pandemic. That will hopefully give us breathing room to pursue longer term, well validated and controlled experiments to establish a long term solution to this outbreak, and in the process arrive at agreed definitions at to what the key variables to describe, track and measure the impact of the disease should be. Then perhaps the fog will lift, and we will finally see the light.

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 Greater 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 two-step 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 its 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 proteinuria which we expect will form the basis for us to apply 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 following regulatory approval. 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 – March 31, 2020

- In January 2020, the Company's Board of Directors decided to explore whether there are conditions for a potential offering of the company's securities in the United States and a press release with the title "Calliditas submits draft registration statement for the listing of ADSs in the U.S." was published.
- In January 2020, EMA Paediatric Committee (PDCO) adopted a positive opinion on the Paediatric Investigation Plan (PIP) for Nefecon for the treatment of primary IgA nephropathy (IgAN). With successful completion of the agreed PIP, Nefecon would be eligible for up to an additional two years of marketing exclusivity in the EU, on top of the ten-year EU market exclusivity after market approval.
- In March 2020, Calliditas held an Extra General Meeting where authorization for the Board of Directors to issue up to 11 million new shares for a potential equity offering and listing in the United States was approved. At the meeting the adoption of new articles of association and the adoption of a new incentive program were also approved.

Significant Events After the Reporting Period

- In April 2020, Calliditas announced that Dr. Richard Philipson had been appointed as Chief Medical Officer (CMO) of Calliditas and would take up the position in early July. Richard Philipson has 24 years of experience in the pharmaceutical industry. Having worked in both large pharmaceutical companies such as GlaxoSmithKline and smaller biotechs, he has extensive experience in rare diseases, having brought several products from early development to the market. Dr. Krassimir Mitchev, our acting CMO, will return to his position as our Head of Medical Affairs.

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

Financial Overview

Key Figures

(SEK in thousands, except share amounts or as otherwise indicated)	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019	Year Ended December 31, 2019
Net sales	474	-	184,829
Research and development expenses	(54,106)	(30,740)	(149,826)
Research and development expenses/Total operating expenses in %[1]	74%	72%	70%
Loss before income tax for the period	(63,677)	(42,556)	(32,501)
Loss per share before and after dilution	(1.65)	(1.21)	(0.88)
Cash flow used in operating activities	(18,775)	(49,382)	(71,011)

(SEK in thousands, except share amounts or as otherwise indicated)	March 31, 2020	March 31, 2019	December 31, 2019
Total registered shares at the end of period	38,707,638	35,202,347	38,707,638
Equity at the end of the period	724,514	575,608	788,071
Equity ratio at the end of the period in %[1]	92%	95%	93%
Cash at the end of the period	728,574	596,850	753,540

[1] Alternative performance measure, see definitions on page 20.

January – March 2020

Revenue

Net sales for the three months ended March 31, 2020 amounted to SEK 0.5 million and derived from the delivery of Nefecon to China as part of the license agreement with Everest Medicines. For additional information see Note 4. No net sales were recognized for the three months ended March 31, 2019.

Total Operating Expenses

Operating expenses amounted to SEK 72.8 and SEK 42.7 million for the three months ended March 31, 2020 and 2019, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 54.1 million and SEK 30.7 million for the three months ended March 31, 2020 and 2019, respectively. The increase by SEK 23.4 million is primarily due to the increased activity of the NefIgArd study and increased expenses for product development compared to the same period last year.

Administrative and Selling Expenses

Administrative and selling expenses amounted to SEK 18.0 million and SEK 9.8 million for the three months ended March 31, 2020 and 2019, respectively. The increase by SEK 8.2 million compared to the previous period is mainly due to the increased activity and increase of head-count in the pre-commercial organization.

Other Operating Incomes/Expenses

Other operating income amounted to SEK 0.8 million for the three months ended March 31, 2020. This was primarily relating to favourable exchange rates on accounts receivables. No other operating income were recognized for the three months ended March 31, 2019.

Other operating expenses amounted to SEK 1.5 million and SEK 2.2 million for the three months ended March 31, 2020 and 2019, respectively. The decrease by SEK 0.7 million primarily relates to a more favourable exchange rate development on operating liabilities.

Net Financial Income and Expenses

Net financial income and expenses amounted to SEK 8.6 million and SEK 0.2 for the three months ended March 31, 2020 and 2019, respectively. The increase by SEK 8.4 million is primarily derived by unrealized foreign currency transaction gains on cash accounts and realized and unrealized gain on derivative instruments.

Tax

Income tax expenses are consistent period over period and primarily relates to the US subsidiary Calliditas Therapeutics Inc. The Groups tax losses carried forward have not been recognized as deferred tax assets. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

Result for The Period

For the three months ended March 31, 2020 and 2019 the Group had a net loss of SEK 63.7 million and SEK 42.6 million, respectively and corresponding loss per share before and after dilution amounted to SEK 1.65 and SEK 1.21 for the three months ended, respectively. The decrease in the result for the period is mainly due to the increased activities in R&D and pre-commercial activities.

Cash Flow and Cash Position

The cash flow used in operating activities amounted to SEK 18.8 million and SEK 49.4 million for the three months ended March 31, 2020 and 2019, respectively. The cash flow used in operating activities during this period is according to plan and is explained by the Group's increased clinical activities as well as work within the Group's administrative and commercial functions.

The Group had no cash flows from investing activities for the three months ended March 31, 2020 and 2019, respectively. Cash flow used in financing activities amounted to SEK 13.5 million and SEK 0.1 million for the three months ended March 31, 2020 and 2019, respectively. The increase is mainly due to transaction costs for a potential offering of the Parent Company's securities in the United States and the change of lease agreement when Calliditas moved to the new headquarters.

Net decrease in cash amounted to SEK 32.3 million and SEK 49.5 million for the three months ended March 31, 2020 and 2019, respectively. Cash amounted to SEK 728.6 million and SEK 596.9 million as of March 31, 2020 and 2019, respectively.

Changes in Shareholders' Equity and Number of Shares

Shareholders' equity amounted to SEK 724.5 million and SEK 575.6 million as of March 31, 2020 and 2019, respectively. The number of shares amounted to 38,707,638 and 35,202,347 as of March 31, 2020 and 2019, respectively. The increase in the number of shares between the periods is due to a directed new share issuance of 3.5 million shares in July 2019.

Employees

The number of employees in the Group was 17 and 13 employees as of March 31, 2020 and 2019, respectively. The average number of employees was 17 and 12 employees for the three months ended March 31, 2020 and 2019, respectively.

Incentive Programs

For the three months ended March 31, 2020, there has been no additional allocation within incentive programs. For more information on incentive programs, 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 May 14, 2020

Renée Aguiar-Lucander

CEO

Financial Statements

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019	Year Ended December 31, 2019
Net sales	4	474	-	184,829
Research and development expenses		(54,106)	(30,740)	(149,826)
Administrative and selling expenses		(18,009)	(9,801)	(62,882)
Other operating income		782	-	4,385
Other operating expenses		(1,467)	(2,183)	(4,525)
Operating loss		**(72,326)**	**(42,724)**	**(28,019)**
Net financial income and expenses		8,649	168	(4,482)
Loss before income tax		**(63,677)**	**(42,556)**	**(32,501)**
Income tax expense		(38)	-	(77)
Loss for the period attributable to shareholders of the Parent Company		**(63,715)**	**(42,556)**	**(32,578)**
Loss per share before and after dilution		(1.65)	(1.21)	(0.88)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Notes	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019	Year Ended December 31, 2019
Loss for the period		(63,715)	(42,556)	(32,578)
Other comprehensive income				
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations		51	(11)	(11)
Total other comprehensive income/(loss)		**(63,664)**	**(42,567)**	**(32,589)**
Total comprehensive loss attributable to shareholders of the Parent Company		**(63,664)**	**(42,567)**	**(32,589)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	March 31, 2020	March 31, 2019	December 31, 2019
ASSETS				
Non-current assets				
Intangible assets		16,066	-	16,066
Equipment		98	94	104
Right-of-use assets		5,419	297	5,959
Non-current financial assets		1,939	341	1,939
Total non-current assets		**23,522**	**732**	**24,068**
Current assets				
Accounts receivable		-	-	46,586
Other current assets	6	32,150	7,615	21,006
Cash		728,574	596,850	753,540
Total current assets		**760,724**	**604,465**	**821,132**
TOTAL ASSETS		**784,246**	**605,197**	**845,200**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Share capital		1,548	1,408	1,548
Additional paid-in capital		1,274,771	1,072,319	1,274,664
Retained earnings, including net loss for the period		(551,805)	(498,119)	(488,141)
Total equity attributable to shareholders of the Parent Company	7,8	**724,514**	**575,608**	**788,071**
Non-current liabilities				
Provisions	8	250	-	175
Other non-current liabilities		2,338	-	3,584
Total non-current liabilities		**2,588**	**-**	**3,759**
Current liabilities				
Accounts payable		28,363	20,803	24,384
Other current liabilities		3,818	2,730	3,471
Accrued expenses and deferred revenue		24,963	6,056	25,515
Total current liabilities		**57,144**	**29,589**	**53,370**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**784,246**	**605,197**	**845,200**

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Notes	March 31, 2020	March 31, 2019	December 31, 2019
Opening shareholders' equity		**788,071**	**618,175**	**618,175**
Loss for the period		(63,715)	(42,556)	(32,578)
Other comprehensive income/(loss)		51	(11)	(11)
Total comprehensive income/(loss) for the period		**(63,664)**	**(42,567)**	**(32,589)**
Transactions with owners:				
New share issue		-	-	210,317
Cost attributable to new share issue		-	-	(10,915)
Premiums received from warrants		-	-	2,834
Share-based payments	8	107	-	249
Total transactions with owners		**107**	**-**	**202,485**
Closing shareholders' equity		**724,514**	**575,608**	**788,071**

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Notes	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019	Year Ended December 31, 2019
Operating activities				
Operating loss		(72,326)	(42,724)	(28,019)
Adjustment for non-cash-items		825	144	2 308
Interest received		-	-	926
Interest paid		(183)	(24)	(325)
Cash flow used in operating activities before changes in working capital		**(71,684)**	**(42,604)**	**(25,110)**
Cash flow used in/(from) changes in working capital		52,909	(6,778)	(45,901)
Cash flow used in/(from) operating activities		**(18,775)**	**(49,382)**	**(71,011)**
Cash flow used in investing activities		-	-	(18,072)
Cash flow used in investing activities		**-**	**-**	**(18,072)**
Cash flow used in/(from) financing activities		(13,477)	(129)	198,835
Cash flow used in/(from) financing activities		**(13,477)**	**(129)**	**198,835**
Net increase/(decrease) in cash		**(32,252)**	**(49,511)**	**109,752**
Cash at the beginning of the period		**753,540**	**646,175**	**646,175**
Net foreign exchange gains/(loss) on cash		7,286	186	(2,387)
Cash at the end of the period		**728,574**	**596,850**	**753,540**

Condensed Parent Company Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019	Year Ended December 31, 2019
Net sales	4	474	-	184,829
Research and development expenses		(54,106)	(30,740)	(149,826)
Administrative and selling expenses		(18,220)	(9,800)	(63,410)
Other operating income		782	-	4,385
Other operating expenses		(1,467)	(2,192)	(4,540)
Operating loss		**(72,537)**	**(42,732)**	**(28,562)**
Net financial income and expenses		8,854	176	(7,624)
Loss before income tax		**(63,683)**	**(42,556)**	**(36,186)**
Income tax expense		-	-	-
Loss for the period		**(63,683)**	**(42,556)**	**(36,186)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Notes	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019	Year Ended December 31, 2019
Loss for the period		(63,683)	(42,556)	(36,186)
Other comprehensive income/(loss)		-	-	-
Total comprehensive loss		**(63,683)**	**(42,556)**	**(36,186)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	March 31, 2020	March 31, 2019	December 31, 2019
ASSETS				
Non-current assets				
Intangible assets		16,066	-	16,066
Equipment		98	94	104
Non-current financial assets		2,040	3,830	2,040
Total non-current assets		**18,204**	**3,924**	**18,210**
Current assets				
Accounts receivable		-	-	46,586
Other current assets	6	32,715	7,610	21,005
Cash		727,753	596,470	752,448
Total current assets		**760,468**	**604,080**	**820,039**
TOTAL ASSETS		**778,672**	**608,004**	**838,249**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Restricted Shareholders' equity				
Share capital		1,548	1,408	1,548
Statutory reserve		3,092	3,092	3,092
		4,640	**4,500**	**4,640**
Non-restricted shareholders' equity				
Share premium reserve		1,268,334	1,069,072	1,268,334
Retained earnings		(485,068)	(452,222)	(448,989)
Net loss for the period		(63,683)	(42,556)	(36,186)
		719,583	**574,294**	**783,159**
Total shareholders' equity	7,8	**724,223**	**578,794**	**787,799**
Non-current liabilities				
Provisions	8	250	-	175
Other non-current liabilities		50	77	50
Total non-current liabilities		**300**	**77**	**225**
Current liabilities				
Accounts payable		27,769	20,730	24,362
Other current liabilities		1,924	2,430	1,332
Accrued expenses and deferred revenue		24,456	5,973	24,531
Total current liabilities		**54,149**	**29,133**	**50,225**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**778,672**	**608,004**	**838,249**

Notes to Condensed Consolidated Financial Statements

Note 1 Description of Business

Calliditas Therapeutics AB (publ) ("Calliditas" or the "Parent Company"), with corporate registration number 556659-9766, and its subsidiaries (collectively, the "Group") conduct development activities in pharmaceuticals. These interim condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the three months ended March 31, 2020 and March 31, 2019. All the Group's significant business operations are conducted in the Parent Company.

Calliditas is a Swedish public limited company registered in and with its registered office in Stockholm. The registered address of the corporate headquarters is Kungsbron 1, C8, Stockholm, Sweden. Calliditas is listed at Nasdaq Stockholm in the Mid Cap segment with ticker CALTX.

These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on May 14, 2020.

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 the Group's results.

Note 2 Accounting Policies

These interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard No. 34 (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, 2020, have had a significant impact on the Group's financial reporting. Relevant accounting principles can be found on pages 38-42 of the Annual Report for 2019.

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 on page 20.

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 insufficient 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 profiles, 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.

COVID-19

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

The pandemic may negatively impact our trial as a result of disruptions, such as travel bans, quarantines, and inability of patients to access the trial sites and provide samples as well as interruptions in the supply chain, which could result in delays and impact on the data integrity of the trial.

It is too early to assess the full impact of the coronavirus outbreak for Calliditas, but the continued spread of the coronavirus globally, may negatively impact our operations, including our trials. It could also negatively affect the operations of key governmental agencies, such as the FDA and EMA, which may delay the development of our product candidates, or could result in the inability of our suppliers to deliver components or raw materials on a timely basis, each of which in turn could have a negative impact on our business and results of operations.

Financial risks

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 Group is primarily affected by foreign exchange risk, since the development costs for Nefecon are mainly paid in USD and EUR. Regarding the Group and the Parent Company's financial risk management, the risks are essentially unchanged compared with the description in the Annual Report for 2019.

For more information regarding the operational- and financial risks, reference is made to the Annual Report for 2019.

Note 4 Revenue from Contracts with Customers

The Group's revenues during the period consisted of revenues for the delivery of study-related drugs within the framework of the out-licensing of Nefecon in connection with the agreement with Everest Medicines to Greater China and Singapore.

Revenue for the provision of drug for conducting clinical trials was recognized at a point in time, which occurred when control over the drug was transferred to Everest Medicines. Calliditas has not completed all performance obligations within the agreement as of the delivery of study-related drugs to Everest Medicines. The remaining performance obligations are expected to be completed during 2020 – 2021.

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

	Three Months Ended March 31,		Year Ended December 31,
(SEK in thousands)	2020	2019	2019
Type of good or service			
Out-licensing	-	-	184,829
Provision of drugs	474	-	-
Total	**474**	**-**	**184,829**
Geographical markets			
China, Hong Kong, Macau, Taiwan and Singapore	474	-	184,829
Total	**474**	**-**	**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

The Groups' financial assets comprise of long-term receivables, derivatives, other current receivables and cash, all of which, except derivatives, are recognized at amortized cost. Derivatives are recognized at fair value through profit or loss, which consist of currency options amounting to SEK 1,691 thousand as of March 31, 2020. No currency options existed as of March 31, 2019. Currency options are presented as Other current assets and valued at fair value based on calculation using the Black-Scholes option pricing model (Level 2) for the three months ended March 31, 2020. Further, presented as Other current assets the Group has transaction costs for a potential offering of the Parent Company's securities in the United States amounted to SEK 26,062 thousand as of March 31, 2020. The Group had transaction costs amounted to SEK 14 662 thousand as of December 31, 2019. The Group's financial liabilities comprise of accounts payable and other current liabilities, which are recognized at amortized cost. The carrying amount is an approximation of the fair value.

Note 7 Shareholders' Equity

	March 31,		December 31,
(SEK in thousands, except per share amounts and number of shares)	2020	2019	2019
Total registered shares at the beginning of period	38,707,638	35,202,347	35,202,347
New issue of shares during the period	-	-	3,505,291
Total registered shares at the end of period[1]	**38,707,638**	**35,202,347**	**38,707,638**
Share capital at the end of period	1,548	1,408	1,548
Equity at the end of period	724,514	575,608	788,071
Loss per share before and after dilution	(1.65)	(1.21)	(0.88)
Weighted-average number of shares outstanding for the period[1]	38,707,638	35,202,347	36,940,587

[1] When calculating loss 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 warrants outstanding in Warrant Programs 2017/2020, 2018/2022 and 2019/2022. If the result of the period is negative, the warrants are not considered dilutive. No dilution effect exists for the warrant programs as the result for the period is negative.

Reserves for translation from foreign operations amounted to SEK 51 thousand and (SEK 11 thousand), which are included in equity as of March 31, 2020 and 2019, respectively.

Note 8 Incentive Programs

Warrant Program 2017/2020

The warrants in Warrant Program 2017/2020 may be exercised up until June 30, 2020, and August 30, 2020, and the subscription price per share is SEK 42.36. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model.

Warrant Program 2018/2022

The warrants in Warrant Program 2018/2022 may be exercised from January 1, 2022 until March 31, 2022 and each warrant will entitle the participant to subscribe for one new share in

the Parent Company at a subscription price of SEK 74.30 per share. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model.

Warrant Program 2019/2022

The warrants in the Warrant 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 Parent Company at a subscription price of SEK 74.50 per share. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model.

Board LTIP 2019

This is a performance-based long-term incentive program for some members of Calliditas' board. A total of 57,032 share awards were granted under the program during the second quarter of 2019. The share awards are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2019 Annual General Meeting ("AGM") to June 1, 2022.

Summary of Outstanding Incentive Programs

	Warrants Outstanding	Share Awards Outstanding	Total Outstanding as of March 31, 2020
Incentive Programs			
Warrant program 2017/2020	1,296 500		1,296,500
Warrant program 2018/2022	856,586		856,586
Warrant program 2019/2022	422,500		422,500
Board LTIP 2019		57,032	57,032
Total Outstanding as of March 31, 2020	**2,575,586**	**57,032**	**2,632,618**

Definitions of Performance Measures and Reconciliations of Alternative Performance Measures

Definitions of Performance Measures

Performance Measures	Definitions
Earnings (loss) per share before/after dilution	Earnings (loss) 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, which is in accordance with IAS 33 Earnings Per Share.
Share capital at the end of the period	Share capital at the end of respective period. The measure is extracted from the statements of financial position.
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 ratio at the end of the period	Equity position at the end of respective period. The measure is extracted from the statements of financial position.
Cash at the end of the period	Cash at the end of respective period. The measure is extracted from the statements of financial position.

Definitions of Alternative Performance Measures

Alternative Key Performance Indicator	Definitions	Reason for Inclusion
Research and development expenses/Total operating expenses in %	Research and development expenses, divided by total operating expenses, which is the sum of research and development expenses, administrative and selling expenses, other operating income and expenses.	The key performance indicator helps the reader of the interim financial statements to analyse the portion of the Groups expenses that are attributable to the Group's research and development activities.
Equity ratio at the end of the period in %	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 shareholders.

Reconciliations of Alternative Performance Measures

	Three Months Ended March 31,		Year Ended December 31,
(SEK in thousands or as otherwise indicated)	2020	2019	2019
Research and development expenses/Total operating expenses in %			
Research and development expenses	(54,106)	(30,740)	(149,826)
Administrative and selling expenses	(18,009)	(9,801)	(62,882)
Other operating income/expenses	(685)	(2,183)	(140)
Total operating expenses	**(72,800)**	**(42,724)**	**(212,848)**
Research and development expenses/Total operating expenses in %	**74%**	**72%**	**70%**

	March 31,		December 31,
(SEK in thousands or as otherwise indicated)	2020	2019	2019
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	724,514	575,608	788,071
Total assets at the end of the period	784,246	605,197	845,200
Equity ratio at the end of the period in %	**92%**	**95%**	**93%**

Financial Calendar

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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Contact:

Renée Aguiar-Lucander
Chief Executive Officer

Calliditas Therapeutics AB
Kungsbron 1, SE-111 22 Stockholm, Sweden
Phone: +46 (0)8 411 3005
Mobile: +46 (0)72 252 1006
Email: renee.lucander@calliditas.com

www.calliditas.com

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.