Q1

calliditas THERAPEUTICS

CALLIDITAS THERAPEUTICS AB (Publ)

Interim Report January 1 – March 31, 2019

Phase 3 study continues according to plan

Key figures

January 1 – March 31, 2019

- Net sales for the period amounted to SEK - (-) million.
- Net income (loss) for the period was SEK -42.6 (-38.2) million.
- Earnings and diluted earnings per share totalled SEK -1.21 (-2.29).
- At March 31, 2019, cash and cash equivalents amounted to SEK 596.9 (53.1) million.

Significant events during the period January 1 – March 31, 2019, in summary

- Calliditas was granted orphan drug designation (ODD) for the treatment of Autoimmune hepatitis (AIH) by the US Food and Drug Administration (FDA).
- Calliditas was also granted orphan drug designation (ODD) for the treatment of Primary biliary cholangitis (PBC) by the FDA.

Investor presentation May 8, 15:00 CET

Audio cast with teleconference, Q1 2019, May 8, 2019, 15:00 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q1-2019

Teleconference: Dial-in number SE: +46856642695 UK: +443333009272 US: 18335268380

CEO Statement

Phase 3 study progresses according to plan

This first quarter of 2019, we were busy ensuring that the recruitment effort for our pivotal phase 3 study NefIgArd remain on track, focusing on site initiation visits and supporting our CRO in its work to ensure that all sites are brought online on a timely manner. We have interacted with patient organizations, as well as with investigators and other clinical staff at our sites, in order to continue to inform and educate them about our trial and its progress.

We were also excited to receive orphan designation (ODD) by the US Food and Drug Administration (FDA) for our pipeline indications, Autoimmune hepatitis (AIH) and Primary biliary cholangitis (PBC), two orphan indications focused on chronic liver disease. In both these indications, we believe that we can leverage our platform and know-how to address a significant unmet medical need. The targeting of the liver is a function of our delivery system, and we believe that the suppression of inflammation using a local, rather than a systemic, approach will have substantial benefits for patients, who are presently offered little, or no, alternative to systemic medications which often wreak havoc with their metabolic system, as well as with their existing immune defense.

We are excited to interact with physicians with expertise in these indications, as well as patients affected by these liver diseases, in order to learn more about how we can best address their needs and develop a medical solution which can be integrated into their daily lives.

In AIH in the US there is a significant unmet medical need and few options for patients today, as there is nothing approved. Pharma driven clinical trials are few and far between, and patients mainly have to resort to systemic steroid treatment for this chronic disease, with significant side effects and large numbers of refractory patients.

Also, in PBC there is a significant unmet need, however there is a significantly higher number of pharma trials underway in this indication partly due to the interest in such diseases as NASH, NAFLD etc. However, in this indication, there are today many patients which do not respond to the existing medications, or who cannot tolerate them as part of a chronic treatment regime. With our focus on a local treatment of the liver focused on the anti-inflammatory pathway, leveraging a known active substance, we believe that there are significant benefits to patients with this approach.

Patient recruitment in the 20th century

As everyone knows who has conducted a clinical trial, irrespective of stage and indication, the issue of patient recruitment is an ever-present concern and warrants continuous focus and effort. As more companies, big and small, enter the race for new and innovative drugs to address unmet medical needs, trials have multiplied in numbers and competition has grown. This has put a growing pressure on hospitals and physicians to recruit patients into multiple trials, leading to escalating costs and reduced yield. In addition, aspects such as patient centricity, digitization of trials and predicative analytics are all making inroads into the clinical trial decision pathway.

Several years after "Eroom's Law"[1] documented the fact that growth in R&D costs has consistently outpaced new drug approvals, it still seems to be a fact that trials are becoming less and less efficient. This is occurring despite better technology and more precise therapies. Or, perhaps it's because of these very things.

The growth of ePRO on mobile devices has led to an explosion of diary assessments. And the more cost-effective tests and imaging becomes, the more numerous and invasive the testing at each visit seems to become.

And of course, the more targeted therapies become, the narrower the slice of the population which is actually eligible for the trial. That most likely translate into smaller sample sizes, which in turn make patients difficult to find. This also brings up the issue of how sites are compensated for screen failures. Based on all of these considerations it should not be surprising that it all seems to net out to longer enrollment periods overall.

In orphan diseases the issue of patient recruitment has always been an issue, as patients per definition are harder to either identify or to enroll, due to very limited numbers to start with. However, as the general demand for patients in areas such as oncology has grown, many institutions have increased the cost per patient significantly, driven by simple demand and supply factors. For orphan trials, this becomes particularly challenging as the cost of development cannot be distributed amongst a large and growing patient population. This requires smaller companies to be even more creative and innovative in order to find ways to ensure that recruitment stays on track, without simply resorting to throwing more money at the problem. One way in which companies are trying to address this is to work more closely with patient organizations and to leverage social media and digital platforms to complement the traditional CRO routes.

Here at Calliditas, we have also looked into how we might partner with patient organizations and industry groups to help patients become aware of ongoing trials and enable them to connect with centers providing access to clinical trials. It is clear from these interactions that there is an interest in, and a need for, providing better information about trials which are being conducted. We are therefore very excited to have launched our dedicated webpage – www.treatigan.com – initially in the US, to provide information, education and connectivity for patients interested in identifying and connecting directly with sites participating in the NefIgArd study. We hope that this initiative will prove helpful to patients and will facilitate transparency and connectivity related to patient recruitment efforts in this orphan indication.

We look forward to continue to report timely progress with regards to our global Phase 3 trial and to leverage both direct and indirect paths in order to facilitate for patients to become connected to ongoing trials.

Renée Aguiar-Lucander, CEO

[1] *https://blogs.sciencemag.org/pipeline/archives/2012/03/08/erooms_law*

Business overview

The NefIgArd study

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

The randomized, double-blind and placebo-controlled Phase 3 study for lead candidate Nefecon will 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 a long-term observational part ("Part B"). Up to 450 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 the first part of the study ("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 long-term 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.

Based on positive data, this will enable a commercialization and marketing of the drug in the US and the EU.

The company aims to have the necessary data on hand to file for accelerated FDA 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 and related events, (where an event is defined as a relevant reduction in eGFR from baseline). The company plans to conduct an interim analysis during Part B, after 50 such events have occurred, estimated to take place approximately 18 months after the top line readout, which would form the basis for a full approval.

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[2]. 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[3].

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.

Scientific conferences

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

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

Supportive post-hoc results from the clinical Phase 2b study (NEFIGAN) of the company's lead candidate Nefecon were presented in September 2018 by Professor Bengt Fellström at the *International IgA Nephropathy Network meeting (IIgANN)* in Buenos Aires, Argentina. In addition, recent exploratory data made available at the same conference supports Nefecon's unique mode of action.

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.

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.

Potential in additional 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 autoimmune hepatitis (AIH) and primary biliary cholangitis (PBC).

Autoimmune hepatitis (AIH)

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

It is an orphan disease and population-based epidemiology studies are limited. Prevalence rates of 17 per 100,000 have been reported, suggesting there may be approximately 50,000-80,000 patients in the US, meeting the criteria for an orphan disease[4].

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

There are presently no products approved for treatment of AIH in the US. Calliditas therefore assesses that budesonide has a promising profile to meet this medical need and believes that this might be an attractive opportunity to 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.

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[5]. 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[6]. No targeted steroid therapy is registered for PBC in the US, nor in Europe. Calliditas assesses that there is a significant unmet medical need to improve outcomes as second-line therapy to the approved therapies with UDCA and Ocaliva. Calliditas estimates that this segment comprises approximately 42,000 patients in the US. Calliditas have been granted orphan drug designation in the US for the treatment of PBC.

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

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

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

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

Financial overview

Key figures

	Jan-Mar		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2018**
Expenses relating to research and development/operating expenses, %[1]	72%	81%	75%
Net income (loss) for the period	(42,556)	(38,237)	(132,049)
Earnings per share before and after dilution, SEK[1]	(1.21)	(2.29)	(5.09)
Cash flow from operating activities	(49,382)	(33,835)	(128,191)
Total registered shares at the end of period	35,202,347	16,673,000	35,202,347
Equity at the end of the period	575,608	24,941	618,175
Equity ratio at the end of the period %[1]	95%	44%	95%
Cash and cash equivalents at the end of the period	596,850	53,074	646,175

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

January – March, 2019

Revenue

No revenue was reported for the period (-).

Total operating expenses

Total operating expenses for the quarter amounted to SEK 42.7 (38.3) million.

Research and development expenses

The costs for research and development costs during the quarter were virtually unchanged at SEK 30.7 (31.0) million. Most of the research and development expenses are related to clinical activities in the NeflgArd study for Nefecon, and the manufacture of drugs for the same.

Sales and administration expenses

During the quarter, administration and sales expenses increased to SEK 9.8 (7.5) million. The increase is mainly due to costs for initiating commercial preparations for a potential future launch of Nefecon in the US.

Earnings

Loss for the quarter was SEK -42.6 (-38.2) million, resulting in loss per share, before and after dilution of SEK -1,21 (-2,29).

Tax

No tax expenses were reported for the period (-).

Cash flow and cash position

Cash flow from operating activities for the quarter amounted to SEK -49.4 (-33.8) million. The continued negative cash flow is according to plan and is mainly explained by the company's increased clinical activities in connection with the operation of the NeflgArd study for Nefecon.

Cash flow for the quarter amounted to SEK -49.5 (-4.3) million and the cash position at the end of the quarter was SEK 596,9 (53,1) million.

Changes in equity and number of shares

As of March 31, 2019, equity amounted to SEK 575.6 (24.9) million. The number of shares at the end of the period was 35,202,347 (16,673,000).

Employees

As of March 31, 2019, the number of employees in Calliditas Therapeutics was 13 (10). The average number of employees during the period was 12 (10).

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 auditors.

Stockholm May 8, 2019

Calliditas Therapeutics AB

Renée Aguiar-Lucander, CEO

Financial statements

Condensed Consolidated Income Statement

		Jan-Mar		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2018**
Net sales		-	-	-
Total operating income		**-**	**-**	**-**
Operating expenses				
Research and development expenses		(30,740)	(31,033)	(99,260)
Sales and administration expenses		(9,801)	(7,469)	(33,937)
Other operating revenue[1]		486	245	715
Other operating expenses[1]		(2,669)	-	-
Total operating expenses		**(42,724)**	**(38,257)**	**(132,482)**
Operating profit (loss)		**(42,724)**	**(38,257)**	**(132,482)**
Net financial items		168	20	433
Profit (loss) before taxes		**(42,556)**	**(38,237)**	**(132,049)**
Income taxes		-	-	-
Net income (loss) for the period		**(42,556)**	**(38,237)**	**(132,049)**
Attributable to:				
Equity holder of the parent company		(42,556)	(38,237)	(132,049)
Earnings and diluted earnings per share (SEK)		(1.21)	(2.29)	(5.09)

[1)] Exchange rate differences on assets and liabilities of an operating nature

Condensed Consolidated Statement of Comprehensive Income

	Jan-Mar		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2018**
Net income (loss) for the period	(42,556)	(38,237)	(132,049)
Other comprehensive income			
Currency translation effect	(11)	(5)	6
Total comprehensive income (loss)	**(42,567)**	**(38,242)**	**(132,043)**
Attributable to:			
Equity holder of the parent company	(42,567)	(38,242)	(132,043)
Total comprehensive income (loss)	**(42,567)**	**(38,242)**	**(132,043)**

Condensed Consolidated Statement of Financial Position

		As of		As of
Amounts in SEK 000s	*Notes*	**31.03.2019**	**31.03.2018**	**31.12.2018**
Non-current assets				
Other material assets		391	145	107
Financial non-current assets		341	341	341
Total non-current assets		**732**	**486**	**448**
Current assets				
Other current assets		7,615	3,470	1,794
Cash and cash equivalents	5	596,850	53,074	646,175
Total current assets		**604,465**	**56,544**	**647,969**
Total assets		**605,197**	**57,030**	**648,417**
Shareholders' equity				
Share capital		1,408	667	1,408
Additional paid in capital		1,072,319	384,223	1,072,319
Retained earnings, including net loss for the period		(498,119)	(359,949)	(455,552)
Total shareholders' equity attributable to shareholders of the parent company	4,6	**575,608**	**24,941**	**618,175**
Current liabilities				
Accounts payable	5	20,803	8,597	22,643
Other current liabilities		2,730	646	904
Accrued expenses	5	6,056	22,846	6,695
Total current liabilities		**29,589**	**32,089**	**30,242**
Total liabilities and shareholders' equity		**605,197**	**57,030**	**648,417**

Condensed Consolidation Statement of Changes in Equity

		Jan-Mar		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2018**
Opening balance		618,175	33,176	**33,176**
Profit/loss of the period		(42,556)	(38,237)	(132,049)
Other comprehensive income		(11)	(5)	6
Comprehensive income (loss) for the period		**(42,567)**	**(38,242)**	**(132,043)**
Transaction with owners				
New issue of ordinary shares	6	-	-	738,650
Cost attributable to new share issue		-	-	(54,433)
Premiums received from warrants		-	8	2,826
Contribution from shareholders	4	-	29,999	29,999
Total transaction with owners		**-**	**30,007**	**717,042**
Closing balance		**575,608**	**24,941**	**618,175**

Condensed Consolidated Statement of Cash Flows

		Jan-Mar		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2018**
Operating activities				
Operating profit (loss)		(42,724)	(38,257)	(132,482)
Adjustment for non-cash-items		144	13	51
Interest received		-	-	6
Interest paid		(24)	(3)	(8)
Cash flow from operating activities before working capital		**(42,604)**	**(38,247)**	**(132,433)**
Cash flow from changes in working capital		(6,778)	4,412	4,242
Cash flow from operating activities		**(49,382)**	**(33,835)**	**(128,191)**
Cash flow from investing activities		-	-	-
Cash flow from financing activities	6	(129)	29,538	716,572
Cash flow for the period		**(49,511)**	**(4,297)**	**588,381**
Cash & cash equivalents, beginning of period		646,175	57,352	57,352
Net increase (decrease) in cash & cash equivalents		(49,511)	(4,297)	588,381
Exchange-rate difference in cash and cash equivalents		186	19	442
Cash & cash equivalents, end of period		**596,850**	**53,074**	**646,175**

Condensed Parent Company Income Statement

		Jan-Mar		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2018**
Net sales		-	-	-
Gross profit		**-**	**-**	**-**
Operating expenses				
Research and development expenses		(30,740)	(31,033)	(99,260)
Sales and administration expenses		(9,800)	(7,429)	(33,805)
Other operating revenue[1]		478	245	715
Other operating expenses[1]		(2,670)	-	-
Total operating expenses		**(42,732)**	**(38,217)**	**(132,350)**
Operating profit (loss)		**(42,732)**	**(38,217)**	**(132,350)**
Net financial items		176	1	427
Profit (loss) before taxes		**(42,556)**	**(38,216)**	**(131,923)**
Income taxes		-	-	-
Net income (loss) for the period		**(42,556)**	**(38,216)**	**(131,923)**

Condensed Parent Company Statement of Other Comprehensive Income

	Jan-Mar		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2018**
Net income (loss) for the period	(42,556)	(38,216)	(131,923)
Other comprehensive income			
Total comprehensive income	**(42,556)**	**(38,216)**	**(131,923)**

Condensed Parent Company Balance Sheet

Amounts in SEK 000s	*Notes*	As of 31.03.2019	As of 31.03.2018	As of 31.12.2018
Non-current assets				
Property, plant and equipment		94	145	107
Financial non-current assets		3,830	3,830	3,830
Total non-current assets		**3 924**	**3 975**	**3 937**
Current assets				
Other current assets		7,610	3,459	1,793
Cash and cash equivalents	5	596,470	52,692	645,903
Total current assets		**604,080**	**56,151**	**647,696**
Total assets		**608,004**	**60,126**	**651,633**
Shareholders' equity				
Share capital		1,408	667	1,408
Statutory reserve		3,092	3,092	3,092
Restricted equity		**4,500**	**3,759**	**4,500**
Additional paid in capital		1,069,072	290,426	1,069,072
Retained earnings, including net loss for the period		(494,778)	(266,163)	(452,222)
Non-restricted equity		**574,294**	**24,263**	**616,850**
Total shareholders' equity	4	**578,794**	**28,022**	**621,350**
Non-current liabilities				
Other liabilities	5	77	77	77
Total non-current liabilities		**77**	**77**	**77**
Current liabilities				
Accounts payable	5	20,730	8,555	22,628
Other current liabilities		2,430	646	904
Accrued expenses	5	5,973	22,826	6,674
Total current liabilities		**29,133**	**32,027**	**30,206**
Total liabilities and shareholders' equity		**608,004**	**60,126**	**651,633**

Notes

Note 1 General information

This report covers the Swedish parent company Calliditas Therapeutics AB, 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 Wallingatan 26B, Stockholm, Sweden. Calliditas Therapeutics AB is listed at Nasdaq Stockholm in the Mid Cap segment with ticker CALTX.

The interim report for January - March of 2019 has been approved for publication on May 8, 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

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.

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.

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:

Amounts in SEK 000s	**Before adjustment**	**Adjustment**	**After adjustment**
Group, Jan-Mar 2018			
Research and development expenses	0	(31,033)	(31,033)
Sales and administration expenses	0	(7,469)	(7,469)
Other operating revenue	245	0	245
Other external operating expenses	(35,711)	35,711	0
Personnel expenses	(2,778)	2,778	0
Depreciation and amortization	(13)	13	0
Total operating expenses	**(38,257)**	**0**	**(38,257)**

Group, Jan-Dec 2018			
Research and development expenses	0	(99,260)	(99,260)
Sales and administration expenses	0	(33,937)	(33,937)
Other operating revenue	715	0	715
Other external operating expenses	(114,056)	114,056	0
Personnel expenses	(19,090)	19,090	0
Depreciation and amortization	(51)	51	0
Total operating expenses	**(132,482)**	**0**	**(132,482)**
Parent Company, Jan-Mar 2018			
Research and development expenses	0	(31,033)	(31,033)
Sales and administration expenses	0	(7,429)	(7,429)
Other operating revenue	245	0	245
Other external operating expenses	(35,671)	35,671	0
Personnel expenses	(2,778)	2,778	0
Depreciation and amortization	(13)	13	0
Total operating expenses	**(38,217)**	**0**	**(38,217)**
Parent Company, Jan-Dec 2018			
Research and development expenses	0	(99,260)	(99,260)
Sales and administration expenses	0	(33,805)	(33,805)
Other operating revenue	715	0	715
Other external operating expenses	(113,927)	113,927	0
Personnel expenses	(19,087)	19,087	0
Depreciation and amortization	(51)	51	0
Total operating expenses	**(132,350)**	**0**	**(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 profit or loss as well as an interest on the lease debt. Leasing fees paid are reported partly as interest payment and partly as amortization of the lease liability. The standard excludes 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 period ended March 31, 2019 improved by SEK 21 thousand, and that the result for the period for the same period was SEK 21 thousand. period decreased by SEK 2,000, 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**
Revaluation of agreements	(1,381)	(1,390)
Depreciation	(140)	-
Amortization	-	(130)
Outgoing balance on March 31, 2019	**298**	**299**

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. Useful assets are reported in the real tangible fixed assets, and leasing liabilities are reported in the line Other current liabilities, in the Group's financial position report.

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, pages 12-20, and page 28 in the Annual Report for 2018.

Note 4 Related-party transactions

During the reporting period, no significant related-party transactions have taken place.

Note 5 Financial instruments

Calliditas financial assets and liabilities comprise of cash and cash equivalents, financial non-current assets, other current assets, accrued expenses, shareholder loans and accounts payable. The fair value of all financial instruments is materially equal to their carrying amounts.

Note 6 Equity

	Jan-Mar		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2018**
Total registered shares at the beginning of period	35,202,347	16,673,000	16,673,000
New issue of shares during the period	-	-	18,529,347
Total registered shares at the end of period[1]	**35,202,347**	**16,673,000**	**35,202,347**
Share capital at the end of period, SEK thousand	1,408	667	1,408
Equity at the end of period, SEK thousand	575,608	24,941	618,175
Earnings per share before and after dilution, SEK[1]	(1,21)	(2,29)	(5.09)
Average number of shares during the period[1]	35,202,347	16,673,000	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 2,153,086 options outstanding in option programs 2017 and 2018. If the result of the period is negative, the options are not considered dilutive. No dilution effect exists for the option programs as the result for the period is negative.

Reserves for translation difference of SEK -45 (-46) thousand are included in equity as of March 31, 2019.

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

	Jan-Mar		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2018**
Expenses relating to research and development/operating expenses, %			
Research and development expenses	(30,740)	(31,033)	(99,260)
Sales and administration expenses	(9,801)	(7,469)	(33,937)
Other operating revenue/expenses	(2,183)	245	715
Total operating expenses	**(42,724)**	**(38,257)**	**(132,482)**
Expenses relating to research and development/operating expenses, %	72%	81%	75%
Equity ratio at the end of the period %			
Total shareholders' equity at the end of the period	575,608	24,941	618,175
Total assets at the end of the period	605,197	57,030	648,417
Equity ratio at the end of the period %	**95%**	**44%**	**95%**

Financial calendar

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

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THERAPEUTICS

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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.