CALLIDITAS THERAPEUTICS AB (Publ)

Year-End Report, 2018

A transformational year

Key figures

October 1 - December 31, 2018

- Net sales for the period amounted to SEK - (-) million.
- Net income (loss) for the period was SEK -44.2 (-40.5) million.
- Earnings and diluted earnings per share totalled SEK -1.26 (-2.43).
- At December 31, 2018, cash and cash equivalents amounted to SEK 646.2 (57.4) million.

January 1 - December 31, 2018

- Net sales for the period amounted to SEK - (-) million.
- Net income (loss) for the period was SEK -132.0 (-86.8) million.
- Earnings and diluted earnings per share totalled SEK -5.09 (-5.81).

Significant events during the period October 1 – December 31, 2018, in summary

- On November 13, 2018, the first patient was enrolled in the company's pivotal clinical phase 3 study NefIgArd. The NefIgArd trial will study the effect of lead candidate Nefecon in patients with IgA nephropathy (IgAN).
- At an extraordinary general meeting in Stockholm on December 14, 2018, it was decided to adopt a long-term incentive program in the form of a not more than 1,160,000 warrants to employees and consultants within the Calliditas Therapeutics group. Each warrant entitles to subscription of one share in the company at a subscription price of SEK 74.30.

Significant events after the reporting period

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

Investor presentation February 7, 15:00 CET

Audio cast with teleconference, Q4 2018, February 7, 2019, 15:00 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q4-2018

Teleconference: Dial-in number SE: +46850558353 UK: +443333009034 US: +18335268381

CEO Statement

A transformational year

Events during the year

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

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

IgAN is a large orphan disease

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

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

Looking ahead

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

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

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

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

Renée Aguiar-Lucander, CEO

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 the patients will continue into Part B, which is an observational long-term follow up period where the patients' renal function as measured by eGFR (estimated glomerular filtration rate).

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). Calliditas plan 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). 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

Immunoglobulin A nephropathy or IgA nephropathy (IgAN, also known as Berger disease) was first described by Berger and Hinglais in 1968[1]. IgAN 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.

[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.*

Scientific conferences

Supportive post-hoc results from the clinical Phase 2b study (NEFIGAN) of the company's lead candidate Nefecon were presented by Prof. Bengt Fellström at the *International IgA Nephropathy Network meeting (IIgANN)* in Buenos Aires, Argentina, on September 28, 2018. In addition, recent exploratory data made available at the same conference supports Nefecons' unique mode of action.

Nefecon – An Overview

Calliditas' lead asset 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, such as, 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 patients in the United States, meeting the criteria for an orphan disease[3].

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

There are presently no products approved for treatment of AIH in the United States. Calliditas therefore assesses that budesonide has a promising profile to meet this medical need and therefore believes that this might be an attractive opportunity to reach the market within a relatively short period of time. Calliditas have been granted orphan drug designation in USA 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[4]. The disease will culminate with end-stage biliary cirrhosis and the need for a liver transplant. UDCA and Ocaliva are the only FDA-approved medical treatments for PBC in the USA. Ocaliva has been granted 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[5]. 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 estimates that this segment comprises approximately 42,000 patients in the United States.

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

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

Significant events during the period January 1 – December 31, 2018

- During the second quarter of 2018, the company filed a new patent application. The application covers method of use for treatment of autoimmune diseases.
- On June 29, 2018, Calliditas Therapeutics was listed on Nasdaq Stockholm in the Mid Cap segment and shares worth a value of SEK 650 million were subscribed for. The price per share was SEK 45 and the offering attracted very strong interest from Nordic and international institutional investors as well as the general public in Sweden, and the offering was substantially over-subscribed.
- In connection with the listing in June, 2018, outstanding bridge loans of SEK 95.2 million were converted, including interest, to new shares at a conversion price of SEK 45 per share, which corresponds to the offering price.
- The liquidity from the rights issue of 650 MSEK, before deduction of issue costs, in connection with the listing was received in early July, 2018.
- In July, 2018, the over-allotment option issued in connection with the listing was utilized, which resulted in the company receiving an additional SEK 88.7 million before costs. The price per share was unchanged at SEK 45 per share compared to the Offering price.
- On November 13, 2018, the first patient was enrolled in the company's pivotal clinical phase 3 study NefIgArd. The study is conducted with the leading drug candidate Nefecon for the treatment of patients with IgA nephropathy (IgAN). The NefIgArd trial will study the effect of Nefecon versus placebo on proteinuria in patients with IgAN. Based on positive results from the 200 first-dosed patients, Calliditas plans to seek market approval from the FDA / EMA.
- At an extraordinary general meeting in Stockholm on December 14, 2018, it was decided to adopt a long-term incentive program in the form of a not more than 1,160,000 warrants to employees and consultants within the Calliditas Therapeutics group. Each warrant entitles to subscription of one share in the company at a subscription price of SEK 74.30. See note 7 Warrants program 2018/2022 for additional information.

Significant events after the end of the period

- 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. The company plans to agree the regulatory pathway for this indication in consultation with the FDA later in 2019.

Financial overview

Key figures

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**
Expenses relating to research and development[1]	(34,172)	(27,157)	(99,260)	(51,686)
Expenses relating to research and development/operating expenses, %[1]	76%	67%	75%	61%
Operating profit (loss)[1]	(44,745)	(40,539)	(132,482)	(84,509)
Earnings per share before and after dilution, SEK[1]	(1.26)	(2.43)	(5.09)	(5.81)
Total registered shares at the end of period	35,202,347	16,673 000	35,202,347	16,673,000
Equity at the end of the period	618,175	33,176	618,175	33,176
Equity ratio at the end of the period %[1]	95%	53%	95%	53%
Cash and cash equivalents at the end of the period	646,175	57,352	646,175	57,352

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

October – December 2018

Revenue

No revenue was reported for the quarter (-).

Other operating income was SEK 0.0 (0.0) million.

Operating expenses

Other external operating expenses for the quarter were SEK 37.7 (34.1) million. Out of the other external operating expenses for the quarter, SEK 31.3 (22.9) million was attributable to research and development (R&D) and SEK 6.4 (11.3) million was attributable to general and administration (G&A). The increase of the other external operating expenses attributable to R&D in the quarter was due to the start of the NefIgArd study for Nefecon with accelerated activation of participating clinics and the recruitment of patients to the study. The decrease of the other external operating expenses attributable to G&A in the quarter is mainly due to the fact that costs related to listing preparations were charged to the fourth quarter of 2017.

Personnel expenses amounted to SEK 7.1 (6.4) million. The number of employees as of December 31, 2018 was 10 (10), and the average number of employees in the quarter was 10 (10). Out of the personnel expenses for the quarter, SEK 2.8 (4.3) million was attributable to R&D and SEK 4.2 (2.1) million was attributable to G&A. The decrease in personnel expenses attributable to R&D was mainly due to a change in the mix of engagement form, where expenses from employed personnel decreased, and expenses from consultants increased, compared to the fourth quarter of 2017. The increase in personnel costs attributable to G&A is mainly due to an increase

in seniority among employees in G&A, as well as an increase of variable personnel costs compared with the fourth quarter last year.

Earnings

Loss for the quarter was SEK -44.2 (-40.5) million, resulting in loss per share, before and after dilution of SEK -1.26 (-2.43).

Tax

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

Cash flow, investment and financial position

Cash flow from operating activities for the quarter amounted to SEK -42.5 (-26.7) million and the deterioration in cash flow from operating activities is mainly due to increased costs for operations during the quarter compared with the same period last year.

Cash flow from financing activities amounted to SEK 2.3 (62.1) million for the quarter and derives from paid-in warrant premiums for the warrants program 2018/2022, which was decided by an extraordinary general meeting in December 2018.

Cash flow for the quarter was SEK -40.2 (35.4) million. As of December 31, 2018, cash and cash equivalents amounted to SEK 646.2 (57.4) million.

January – December 2018

Revenue

No revenue was reported for the period (-).

Other operating income of SEK 0.7 (0.1) million consist of the company's foreign exchange profit on operating liabilities

Operating expenses

Other external operating expenses for the period were SEK 114.1 (64.0) million. Out of the other external operating expenses for the period, SEK 93.3 (38.4) million was attributable to research and development (R&D) and SEK 20.8 (25.6) million was attributable to general and administration (G&A). The increase of the other external operating expenses attributable to R&D in the period was due to the preparations and the start for the NeflgArd study for Nefecon. The decrease in costs attributable to G&A is mainly due to the fact that the company had lower costs for listing preparations in 2018 compared with the previous year.

Personnel expenses amounted to SEK 19.1 (20.6) million. The average number of employees in the period was 10 (10). The decrease in personnel expenses are mainly related to the Company has applied for, and been granted, a credit on social security expenses paid for R&D personnel for the years 2014-2017. The credit amounts to SEK 1.5 million. Out of the personnel expenses for the period, SEK 6.0 (13.3) million was attributable to R&D and SEK 13.1 (7.3) million was attributable to G&A. The decrease in personnel expenses attributable to R&D was mainly due the above-mentioned credit on social securities, which was fully attributable to R&D, and a change in the mix of engagement form, where employed personnel decreased, and number of consultants increased, compared to the period 2017. The increase in personnel costs attributable to G&A is mainly due to the fact that seniority among employees in G&A has increased.

Earnings

Loss for the period was SEK -132.0 (-86.8) million, resulting in loss per share, before and after dilution of SEK -5.09 (-5.81).

Tax

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

Cash flow and investment

Cash flow from operating activities for the period amounted to SEK -128.2 (-68.0) million, and the decreased in cash flow from operating activities was due to the preparations and start for the NeflgArd study for Nefecon.

Cash flow from financing activities amounted to SEK 716.6 (101.2) million for the period. The increase in cash flow from financing activities stems mainly from the rights issue in conjunction with the listing in June 2018, which resulted in a cash flow of SEK 684.2 million, as well as a bridge loan of SEK 30.0 million with mandatory conversion from existing shareholders in the first quarter of 2018. The bridge loan was in its entirety converted to new shares in connection with the listing in June 2018.

Cash flow for the period was SEK 588.4 (33.2) million.

Changes in equity and number of shares

As of December 31, 2018, equity amounted to SEK 618.2 (33.2) million. The number of registered shares amounted to 35,202,347 (16,673,000), and the total number of shares increase in the period was 18,529,347 whereof 16,414,444 new shares originated from the IPO offering, and 2,114,903 new shares originated from the conversion of the outstanding bridge loans.

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 February 7, 2019

Calliditas Therapeutics AB

Renée Aguiar-Lucander, CEO

Financial statements

Condensed Consolidated Income Statement

		Oct-Dec		Jan-Dec	
Amounts in SEK 000s	*Notes*	**2018**	**2017**	**2018**	**2017**
Net sales		-	-	-	-
Other operating income		39	48	715	145
Total operating income		**39**	**48**	**715**	**145**
Operating expenses					
Other external operating expenses		(37,713)	(34,133)	(114,056)	(63,986)
Personnel expenses		(7,058)	(6,441)	(19,090)	(20,617)
Depreciation and amortization		(13)	(13)	(51)	(51)
Total operating expenses		**(44,784)**	**(40,587)**	**(133,197)**	**(84,654)**
Operating profit (loss)		**(44,745)**	**(40,539)**	**(132,482)**	**(84,509)**
Net financial items		521	(5)	433	(2,285)
Profit (loss) before taxes		**(44,224)**	**(40,544)**	**(132,049)**	**(86,794)**
Income taxes		-	-	-	-
Net income (loss) for the period		**(44,224)**	**(40,544)**	**(132,049)**	**(86,794)**
Attributable to:					
Equity holder of the parent company		(44,224)	(40,544)	(132,049)	(86,794)
Earnings and diluted earnings per share (SEK)		(1.26)	(2.43)	(5.09)	(5.81)

Condensed Consolidated Statement of Comprehensive Income

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**
Net income (loss) for the period	(44,224)	(40,544)	(132,049)	(86,794)
Other comprehensive income				
Currency translation effect	13	-	6	(4)
Total comprehensive income (loss)	**(44,211)**	**(40,544)**	**(132,043)**	**(86,798)**
Attributable to:				
Equity holder of the parent company	(44,211)	(40,544)	(132,043)	(86,798)
Total comprehensive income (loss)	**(44,211)**	**(40,544)**	**(132,043)**	**(86,798)**

Condensed Consolidated Statement of Financial Position

		As of	
Amounts in SEK 000s	*Notes*	**31.12.2018**	**31.12.2017**
Non-current assets			
Property, plant and equipment		107	158
Financial non-current assets		341	341
Total non-current assets		**448**	**499**
Current assets			
Other current assets		1,794	4,437
Cash and cash equivalents	5	646,175	57,352
Total current assets		**647,969**	**61,789**
Total assets		**648,417**	**62,288**
Shareholders' equity			
Share capital		1,408	667
Additional paid in capital		1,072,319	352,959
Retained earnings, including net loss for the period		(455,552)	(320,450)
Total shareholders' equity attributable to shareholders of the parent company	4,6	**618,175**	**33,176**
Current liabilities			
Accounts payable	5	22,643	13,684
Shareholder loans		-	470
Other current liabilities		904	683
Accrued expenses	5	6,695	14,275
Total current liabilities		**30,242**	**29,112**
Total liabilities and shareholders' equity		**648,417**	**62,288**

Condensed Consolidation Statement of Changes in Equity

		Oct-Dec		Jan-Dec	
Amounts in SEK 000s	*Notes*	**2018**	**2017**	**2018**	**2017**
Opening balance		**659,568**	**12,067**	**33,176**	**(14,223)**
Profit/loss of the period		(44,224)	(40,544)	(132,049)	(86,794)
Other comprehensive income		13	-	6	(4)
Comprehensive income (loss) for the period		**(44,211)**	**(40,544)**	**(132,043)**	**(86,798)**
Transaction with owners					
New issue of ordinary shares	6	-	-	738,650	72,205
Cost attributable to new share issue		-	-	(54,433)	(50)
Premiums received from warrants	7	2,818	-	2,826	207
Warrants		-	31	-	213
Contribution from shareholders	4	-	61,622	29,999	61,622
Total transaction with owners		**2,818**	**61,653**	**717,042**	**134,197**
Closing balance		**618,175**	**33,176**	**618,175**	**33,176**

Condensed Consolidated Statement of Cash Flows

		Oct-Dec		Jan-Dec	
Amounts in SEK 000s	*Notes*	**2018**	**2017**	**2018**	**2017**
Operating activities					
Operating profit (loss)		(44,745)	(40,539)	(132,482)	(84,509)
Adjustment for non-cash-items		13	13	51	332
Interest received		-	-	6	-
Interest paid		(1)	(5)	(8)	(11)
Cash flow from operating activities before working capital		**(44,733)**	**(40,531)**	**(132,433)**	**(84,188)**
Cash flow from changes in working capital		2,247	13,881	4,242	16,181
Cash flow from operating activities		**(42,486)**	**(26,650)**	**(128,191)**	**(68,007)**
Cash flow from investing activities		-	(50)	-	(50)
Cash flow from financing activities	6,7	2,258	62,106	716,572	101,224
Cash flow for the period		**(40,228)**	**35,406**	**588,381**	**33,167**
Cash & cash equivalents, beginning of period		685,871	21,952	57,352	24,241
Net increase (decrease) in cash & cash equivalents		(40,228)	35,406	588,381	33,167
Exchange-rate difference in cash and cash equivalents		532	(6)	442	(56)
Cash & cash equivalents, end of period		**646,175**	**57,352**	**646,175**	**57,352**

Condensed Parent Company Income Statement

		Oct-Dec		Jan-Dec	
Amounts in SEK 000s	*Notes*	**2018**	**2017**	**2018**	**2017**
Net sales		-	-	-	-
Other operating income		39	48	715	151
Gross profit		**39**	**48**	**715**	**151**
Operating expenses					
Other external operating expenses		(37,518)	(34,135)	(113,927)	(64,422)
Personnel expenses		(7,254)	(6,450)	(19,087)	(19,568)
Depreciation and amortization		(13)	(13)	(51)	(51)
Total operating expenses		**(44,785)**	**(40,598)**	**(133,065)**	**(84,041)**
Operating profit (loss)		**(44,746)**	**(40,550)**	**(132,350)**	**(83,890)**
Net financial items		540	(678)	427	(2,958)
Profit (loss) before taxes		**(44,206)**	**(41,228)**	**(131,923)**	**(86,848)**
Income taxes		-	-	-	-
Net income (loss) for the period		**(44,206)**	**(41,228)**	**(131,923)**	**(86,848)**

Condensed Parent Company Statement of Other Comprehensive Income

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**
Net income (loss) for the period	(44,206)	(41,228)	(131,923)	(86,848)
Other comprehensive income				
Total comprehensive income	**(44,206)**	**(41,228)**	**(131,923)**	**(86,848)**

Condensed Parent Company Balance Sheet

		As of	
Amounts in SEK 000s	*Notes*	**31.12.2018**	**31.12.2017**
Non-current assets			
Property, plant and equipment		107	158
Financial non-current assets		3,830	3,830
Total non-current assets		**3 937**	**3 988**
Current assets			
Other current assets		1,793	4,394
Cash and cash equivalents	5	645,903	56,984
Total current assets		**647,696**	**61,378**
Total assets		**651,633**	**65,366**
Shareholders' equity			
Share capital		1,408	667
Statutory reserve		3,092	3,092
Restricted equity		**4,500**	**3,759**
Additional paid in capital		1,069,072	290,426
Retained earnings, including net loss for the period		(452,222)	(257,954)
Non-restricted equity		**616,850**	**32,472**
Total shareholders' equity	4,6,7	**621,350**	**36,231**
Non-current liabilities			
Other liabilities		77	-
Total non-current liabilities		**77**	**-**
Current liabilities			
Accounts payable	5	22,628	13,672
Shareholder loans		-	470
Other current liabilities		904	752
Accrued expenses	5	6,674	14,241
Total current liabilities		**30,206**	**29,135**
Total liabilities and shareholders' equity		**651,633**	**65,366**

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 the full-year of 2018 has been approved for publication on February 7, 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 12-15 of the Annual Report for 2017.

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, 2018, have had a significant impact on the company's financial reporting.

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.

IFRS 9 Financial instruments

The standard concerns the recognition of financial assets and liabilities and replaces IAS 39. The Group applies the standard from January 1, 2018. The standard has not had a material impact on the consolidated financial statements. All financial assets and liabilities reported at amortized cost meet the criteria for recognition at amortized cost also in accordance with IFRS 9.

IFRS 15 Revenue from Contracts with Customers

This standard replaces all previously issued standards and interpretations that concern revenue with a combined model for revenue recognition. The Group applies the standard from January 1, 2018. The standard has not had a material impact on the consolidated financial statements since the Group has not recognized any revenue because it has not obtained a permit to sell its products in the relevant markets.

IFRS 16 Leasing

IFRS 16 will enter into force on January 1, 2019. IFRS 16 replaces IAS 17 Lease Agreement, with new accounting requirements for lessee. All leases, except short-term and minor leasing con-

tracts, shall be reported as an asset with right of use and as a corresponding liability in the leaseholder's balance sheet. The standard is expected to provisionally mean that most of the leases reported in these financial statements as operating leases will be reported as assets and liabilities in the financial statement. This will also cause the cost of these to be reported broken down into interest expense and depreciation. Calliditas applies the simplified transition model and based on available information, Calliditas estimates that right of use assets and attributable lease liabilities will increase by approximately SEK 1.8 million as of January 1, 2019.

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. For more information, reference is made to the listing prospectus, pages 12-20, published in connection with the IPO on Nasdaq Stockholm.

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 more information, reference is made to the listing prospectus published in connection with IPO on Nasdaq Stockholm, pages 12-20, and the Annual Report 2017.

Note 4 Related-party transactions

In March 2018, the Company entered into a mandatory convertible loan with a principal amount of SEK 30.0 million from existing shareholders with an annual interest of 8 percent with a maturity of 12 months. In connection with the listing on Nasdaq Stockholm in June 2018, all outstanding bridge loans totalling SEK 95.2 million were converted, including accrued interest, to new shares at a conversion price of SEK 45 per share, which corresponds to the Offering price for the IPO on Nasdaq Stockholm.

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

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**
Total registered shares at the beginning of period	35,202,347	16,531,500	16,673,000	13,262,500
New issue of shares during the period	-	141,500	18,529,347	3,410,500
Total registered shares at the end of period[1]	**35,202,347**	**16,673,000**	**35,202,347**	**16,673,000**
Share capital at the end of period, SEK thousand	1,408	667	1,408	667
Equity at the end of period, SEK thousand	618,175	33,176	618,175	33,176
Earnings per share before and after dilution, SEK[1]	(1.26)	(2.43)	(5.09)	(5.81)
Average number of shares during the period[1]	35,202,347	16,673,673	25,948,037	14,927,736

[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 2,518,086 options outstanding in option programs 2015, 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 -34 (-40) thousand are included in equity as of December 31, 2018.

Note 7 Warrants program 2018/2022

During the fourth quarter of 2018, a total of 856,586 warrants were issued to employees and consultants in the Group. The reason for this is the company's need to recruit and retain key employees. The warrants have a maturity of 3 years and the subscription price for the options is SEK 74.30 per share. In total, the participants paid aa warrant premium of SEK 2.8 million. The subscribed warrants have been valued using the Black & Scholes model, which means that the warrant value is based on the volume-weighted average value for the closing price during the 10 trading days prior valuation date. Volatility was set at 32.8 percent and is based on closing prices for the share and a discount since the volatility of the share price is to decrease as the share's history becomes longer. Since there is no liquid market for unlisted warrants, a discount for the lack of liquidity has been taken into account and the risk-free interest rate is the return on a government bond with the same maturity as the warrant.

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	The total operating expenses attributable to research and development.	The indicator helps the reader of the financial statements to analyse the expenses allocated to research and development.
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.
Operating profit (loss)	Total operating expenses plus other operating income for the period. The measure is presented in the income statement.	The key performance indicator help those who read the financial statements to analyze the operating income less operating expenses.

Reconciliations of alternative performance measures

	Oct-Dec		Jan-Dec	
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**
Expenses relating to research and development/operating expenses, %				
Personnel expenses related to R&D[1,3]	(2,831)	(4,303)	(5,961)	(13,324)
Other external operating expenses related to R&D	(31,341)	(22,854)	(93,299)	(38,362)
Expenses related to research and development	**(34,172)**	**(27,157)**	**(99,260)**	**(51,686)**
Personnel expenses related to G&A[2]	(4,227)	(2,138)	(13,129)	(7,293)
Other external operating expenses related to G&A	(6,372)	(11,279)	(20,757)	(25,624)
Expenses related to general and administration	**(10,599)**	**(13,417)**	**(33,886)**	**(32,917)**
Depreciation and amortization	(13)	(13)	(51)	(51)
Total operating expenses	**(44,784)**	**(40,587)**	**(133,197)**	**(84,654)**
Expenses relating to research and development/operating expenses, %	76%	67%	75%	61%
Expenses relating to general and administration/operating expenses, %	24%	33%	25%	39%
Equity ratio at the end of the period %				
Total shareholders' equity at the end of the period	618,175	33,176	618,175	33,176
Total assets at the end of the period	648,417	62,288	648,417	62,288
Equity ratio at the end of the period %	**95%**	**53%**	**95%**	**53%**

[1] Research and development costs (R&D).

[2] General and administrative costs (G&A).

[3] A credit amount of SEK 1,499 thousand for social security expenses paid for research and development (R&D) personnel for the years 2014-2017 is included in Jan-Dec 2018.

Annual General Meeting 2019

Calliditas Therapeutic's Annual General Meeting will be held on Wednesday, May 8, at 16:00 CET at Apotekarsocieten's premises, Wallingatan 26A, Stockholm.

In accordance with the dividend policy adopted by the Board, no dividend is proposed for the financial year 2018.

Financial calendar

Publication of the Annual Report	First week of April, 2019
Interim report for the period 1 January – 31 March 2019	May 8, 2019
Annual General Meeting 2019	May 8, 2019
Interim report for the period 1 January – 30 June 2019	August 15, 2019
Interim report for the period 1 January – 30 September 2019	November 14, 2019
Year-end report for the period 1 January – 31 December 2019	February 14, 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.