Q3

calliditas THERAPEUTICS

CALLIDITAS THERAPEUTICS AB (Publ)

Interim Report January 1 – September 30, 2018

NeflgArd Phase 3-study initiated according to plan

Key figures

July 1 - September 30, 2018

- Net sales for the period amounted to SEK - (-) million.
- Net income (loss) for the period was SEK -31.4 (-18.4) million.
- Earnings and diluted earnings per share totalled SEK -0.91 (-1.21).
- At September 30, 2018, cash and cash equivalents amounted to SEK 685.9 (22.0) million.

January 1 - September 30, 2018

- Net sales for the period amounted to SEK - (-) million.
- Net income (loss) for the period was SEK -87.8 (-46.3) million.
- Earnings and diluted earnings per share totalled SEK -2.90 (-3.21).

Significant events during the period July 1 – September 30, 2018, in summary

- The liquidity from the rights issue of 650 MSEK, before deduction of issue costs, in connection with the listing was received in early July.
- In July, 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 deduction of issue costs.

Investor presentation November 1, 15:00 CEST

Audio cast with teleconference, Q3, 2018, November 1, 2018, 15:00 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q3-2018

Teleconference: Dial-in number UK: +442030089809 SE: +46856642697 US: +18557532237

CEO Statement

Into execution mode

Phase 3 study – NefIgArd™

This quarter, the company went into execution mode with regards to the preparations related to our clinical Phase 3 study NefIgArd. We were excited to get going after receiving the necessary funds in July. We have been submitting requests for approval to ethic committees, negotiated contracts with clinics and continued to tie up the hundreds of ends required in order to initiate such a large, global study. With 19 countries and 149 sites, we believe that this is one of largest clinical studies to be managed out of Sweden today.

As it is a global trial, we do expect countries to come online at different times and for there to be some initial variation in patient recruitment rate as the study gathers pace. We started site initiation visits during the period and we have continued to add to that base subsequent to the period end, at which time we also started patient screening activities. In contrast to our Phase 2b study, the Phase 3 does not have a 3-month run-in period, but rather a screening approach which has the same purpose; to verify that patients are on optimal and stable RAS blockade at time of inclusion. Based on progress to date, we believe that we are on track to dose our first patient in 2H 2018 as planned.

I would also like to send a warm thank you to our Advisory Board, which we had the pleasure of interacting with this quarter; an event which always fills me with awe in regard to their knowledge, thoughtfulness and expertise. We appreciate their insight and guidance.

Supportive biomarker data presented at IIgANN symposium in Argentina

Every other or third year, the International IgA nephropathy Network organizes a symposium to review and discuss progress and new approaches within IgA nephropathy. We attended this event in September, which was held in Buenos Aires, Argentina, and marked the 50th anniversary of the discovery of the disease. Over 200 attendees were on site from the global nephrology and research community, together with company and regulatory representatives. The event reviewed genomics, pathology, pathogenesis, clinical trial data and new findings within the disease.

As previously communicated, Calliditas had five posters accepted for the event out of which three ultimately ended up being selected for oral presentations; Professor Bengt Fellström's presentation regarding further review of Phase 2b data related to albuminuria levels being one of them. The other two oral presentations were based on work carried out at University of Leicester, which for the first time provided biomarker data showing that Nefecon modifies circulating immune complexes and levels of poorly O-galactosylated IgA.

There is an increasing body of evidence supporting the relevance of the gut-kidney axis and mucosal associated lymphoid tissue in the pathogenesis of IgA nephropathy (IgAN). This is the basis for the mode of action of Nefecon and its documented ability to reduce proteinuria and stabilize eGFR in patients with biopsy proven IgAN.

Based on samples collected in the NefIgAn Phase 2b study, Professor Jonathan Barratt and his team at Leicester University have carried out analyses measuring serum levels of circulating IgA-IgG complexes (IgA-IC) and galactose deficient IgA1 (Gd-IgA1) respectively. For the first time a drug-induced modulation of circulating immune complex levels in IgAN was shown, with

similar patterns of changes in the levels of galactose deficient IgA1, with no difference observed in total IgA, and IgG. This supporting evidence that Nefecon modulates key pathogenic antibodies involved in IgAN. In addition, the team also analysed secretory IgA and IgA specific for a group of dietary antigens. Changes related to gut permeability was measured using fatty-acid-binding-protein 2 (FABP2), also known as intestinal-type fatty acid-binding protein (I-FABP).

The analysis showed that there was a statistically significant drug related decrease in the serum levels of secretory IgA at the end of the treatment. There was also a significant decrease in the serum levels of IgA specific for gliadin and casein. I-FABP levels were more likely to increase in the placebo group during the trial, and when the team looked at a subgroup of patients who exhibited the greatest reduction in I-FABP in the 16mg treatment group, there was a significant increase in I-FABP post treatment suggesting that the drug might beneficially modulating the mucosal permeability in these patients.

This is the first time that data has been presented in the form of biomarkers which provide evidence-based support for the assumed mode of action of Nefecon. We are very excited that this kind of data could be established in this rare disease and look forward to sharing additional biomarker data during 2019.

Capital Market access as a catalyst for creating cluster effects

Sweden has been particularly successful in providing access to the public markets for life science companies, especially since 2014. Today there are as we know many listed life science companies across Nasdaq Stockholm's Main market and First North segment, with a growing market capitalization based both on new entrants as well as good performance from existing companies based on positive data and innovation. Is this sufficient to create a lasting cluster effect? The value of clusters is well known and is often used to explain the number of successful companies coming out of places such as Basel, Oxford, Cambridge and Boston.

So, has Sweden managed to create and fund a sufficient number of companies to reach the critical mass required to create a cluster effect? To some extent, the answer probably lies in how the existing infrastructure is able to deal with a potentially more uncertain macro outlook. Fuelled by research amongst others from Karolinska, Sahlgrenska, Uppsala and Lund and supported by a small but active local venture capital base, I believe that access to the public market has been crucial to building the scale and breadth of the life sciences sector in Sweden. I really hope that the model will prove to be self-sustaining from now on and enable exciting and promising companies to raise the financing necessary to complete R&D programs and build lasting companies which in turn will contribute to this cluster effect in Sweden.

Renée Aguiar-Lucander, CEO

Business overview

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 pathologically. 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. Pathology is not fully understood, but IgAN is increasingly considered to be 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 a diagnosed patient population, according to company estimate, 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.*

Nefecon – An Overview

Nefecon is Calliditas' lead asset and 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 European Medicines Agency (EMA).

A Phase 3 registration study with Nefecon has been initiated, following the successful completion of a placebo-controlled randomized Phase 2b study, titled 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 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.

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.

Calliditas is currently starting a global Phase 3 study designed on a similar basis as its Phase 2b study as the final pivotal study prior to registration. The company is projecting to have the necessary data on hand to file for the accelerated FDA approval in the first half of 2021.

NefIgArd study design

The randomized double-blind and placebo-controlled Phase 3 study 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 including, Australia, North America and selected European countries.

In the first part of the study, 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 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.

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

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 track events, (where an event is defined as a relevant reduction in eGFR from baseline). Calliditas plans to conduct an interim analysis during Part B, after 50 such events have occurred to seek full approval.

Significant events during the period January 1 – September 30, 2018

- In March 2018, the company executed a mandatory convertible loan with a principal amount of SEK 30.0 million from existing shareholders with an annual interest rate of 8% and a maturity of 12 months.
- 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 institutional investors as well as the general public in Sweden, and the offering was substantially over-subscribed.
- In connection with the listing in June, 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.
- During the second quarter of 2018, the company filed a new patent application. The application covers method of use for treatment of autoimmune diseases.
- The liquidity from the rights issue of 650 MSEK, before deduction of issue costs, in connection with the listing was received in early July.
- 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. The total number of shares in the company after the over-allotment issue amounted to 35,202,347.

Significant events after the end of the period

- No significant events after the end of the reporting period.

Financial overview

Key figures

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	2018	2017	2018	2017	2017
Expenses relating to research and development[2]	(24,055)	(7,773)	(65,088)	(24,529)	(51,686)
Expenses relating to research and development/operating expenses, %[2]	77%	44%	74%	56%	61%
Operating profit (loss)	(31,273)	(17,474)	(87,737)	(43,970)	(84,509)
Earnings per share before and after dilution, SEK[1]	(0.91)	(1.21)	(2.90)	(3.21)	(5.81)
Total registered shares at the end of period[1]	35,202,347	16,531,500	35,202,347	16,531,500	16,673,000
Equity at the end of the period	659,568	12,067	659,568	12,067	33,176
Equity ratio at the end of the period %[2]	96%	44%	96%	44%	53%
Cash and cash equivalents at the end of the period	685,871	21,952	685,871	21,952	57,352

[1] Number of shares Jan-Sep 2017 have been adjusted for split 1:250.
[2] Non-IFRS performance measure, see definitions page.

July – September 2018

Revenue

No revenue was reported for the quarter (-).

Other operating income of SEK 0.1 (0.0) million consist of the company's foreign exchange profit on operating liabilities.

Operating expenses

Other external operating expenses for the quarter were SEK 26.6 (12.5) million. Out of the other external operating expenses for the quarter, SEK 22.6 (4.9) million was attributable to research and development (R&D) and SEK 4.1 (7.5) 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 intensified preparations for the NeflgArd study for Nefecon.

Personnel expenses amounted to SEK 4.7 (5.0) million. The number of employees as of September 30, 2018 was 10 (8), and the average number of employees in the quarter was 10 (9). Out of the personnel expenses for the quarter, SEK 1.5 (2.8) million was attributable to R&D and SEK 3.2 (2.2) 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 third quarter of 2017.

Earnings

Loss for the quarter was SEK -31.4 (-18.4) million, resulting in loss per share, before and after dilution of SEK -0.91 (-1.21).

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 -15.2 (-16.7) million.

Cash flow from financing activities amounted to SEK 684.2 (3.1) million for the quarter. The cash flow from the IPO base share issue in June 2018 and the over-allotment share issue in July 2018 occurred in July 2018 and was recorded in the consolidated financial statements in the third quarter.

Cash flow for the quarter was SEK 669.0 (-13.6) million. As of September 30, 2018, cash and cash equivalents amounted to SEK 685.9 (22.0) million.

January – September 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 76.5 (29.9) million. Out of the other external operating expenses for the period, SEK 62.0 (15.5) million was attributable to research and development (R&D) and SEK 14.6 (14.3) 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 for the NeflgArd study for Nefecon.

Personnel expenses amounted to SEK 11.8 (14.2) 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 3.1 (9.0) million was attributable to R&D and SEK 8.7 (5.2) 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.

Earnings

Loss for the period was SEK -87.8 (-46.3) million, resulting in loss per share, before and after dilution of SEK -2.90 (-3.21).

Tax

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

Cash flow and investment

Cash flow from operating activities for the period amounted to SEK -85.7 (-41.4) million, and the decreased in cash flow from operating activities was due to the preparations for the NefIgArd study for Nefecon.

Cash flow from financing activities amounted to SEK 714.3 (39.1) million for the period. During the first quarter a mandatory convertible bridge loan with a total principal amount of SEK 30.0 million was raised from existing shareholders and later fully converted into new shares in connection with the IPO in June 2018. The cash flow from share issue from the IPO contributed with a net amount of SEK 684.2 million

Cash flow for the period was SEK 628.6 (-2.2) million.

Changes in equity and number of shares

As of September 30, 2018, equity amounted to SEK 659.6 (12.0) million. The number of registered shares amounted to 35,202,347 (16,531,500), and the total number of share 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 largely relevant for the parent company.

Stockholm November 1, 2018

Calliditas Therapeutics AB

Renée Aguiar-Lucander, CEO

Review report

Calliditas Therapeutics AB, corporate identity number 556659-9766

Introduction

We have reviewed the condensed interim report for Calliditas Therapeutics AB as at September 30, 2018 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

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

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

Conclusion

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

Stockholm 1 November 2018

Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

Financial statements

Condensed Consolidated Income Statement

		Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	*Notes*	**2018**	**2017**	**2018**	**2017**	**2017**
Net sales		-	-	-	-	-
Other operating income		80	67	676	97	145
Total operating income		**80**	**67**	**676**	**97**	**145**
Operating expenses						
Other external operating expenses		(26,644)	(12,521)	(76,539)	(29,853)	(63,986)
Personnel expenses		(4,696)	(5,008)	(11,836)	(14,176)	(20,617)
Depreciation and amortization		(13)	(12)	(38)	(38)	(51)
Total operating expenses		**(31,353)**	**(17,541)**	**(88,413)**	**(44,067)**	**(84,654)**
Operating profit (loss)		**(31,273)**	**(17,474)**	**(87,737)**	**(43,970)**	(84,509)
Net financial items		(130)	(905)	(88)	(2,280)	(2,285)
Profit (loss) before taxes		**(31,403)**	**(18,379)**	**(87,825)**	**(46,250)**	**(86,794)**
Income taxes		-	-	-	-	-
Net income (loss) for the period		**(31,403)**	**(18,379)**	**(87,825)**	**(46,250)**	**(86,794)**
Attributable to:						
Equity holder of the parent company		(31,403)	(18,379)	(87,825)	(46,250)	(86,794)
Earnings and diluted earnings per share (SEK)		(0.91)	(1.21)	(2.90)	(3.21)	(5.81)

Condensed Consolidated Statement of Comprehensive Income

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**	**2017**
Net income (loss) for the period	(31,403)	(18,379)	(87,825)	(46,250)	(86,794)
Other comprehensive income					
Currency translation effect	-	3	(7)	(4)	(4)
Total comprehensive income (loss)	**(31,403)**	**(18,376)**	**(87,832)**	**(46,254)**	**(86,798)**
Attributable to:					
Equity holder of the parent company	(31,403)	(18,376)	(87,832)	(46,254)	(86,798)
Total comprehensive income (loss)	**(31,403)**	**(18,376)**	**(87,832)**	**(46,254)**	**(86,798)**

Condensed Consolidated Balance Sheet

Amounts in SEK 000s	Notes	As of 30.09.2018	As of 30.09.2017	As of 31.12.2017
Non-current assets				
Property, plant and equipment		119	170	158
Financial non-current assets		341	291	341
Total non-current assets		**460**	**461**	**499**
Current assets				
Other current assets		1,502	4,738	4,437
Cash and cash equivalents	5	685,871	21,952	57,352
Total current assets		**687,373**	**26,690**	**61,789**
Total assets		**687,833**	**27,151**	**62,288**
Shareholders' equity				
Share capital		1,408	661	667
Additional paid in capital		1,069,501	290,822	352,959
Retained earnings, including net loss for the period		(411,341)	(279,416)	(320,450)
Total shareholders' equity attributable to shareholders of the parent company	4,6	**659,568**	**12,067**	**33,176**
Current liabilities				
Accounts payable	5	19,291	4,284	13,684
Shareholder loans		-	17	470
Other current liabilities		647	812	683
Accrued expenses and deferred revenue	5	8,327	9,971	14,275
Total current liabilities		**28,265**	**15,084**	**29,112**
Total liabilities and shareholders' equity		**687,833**	**27,151**	**62,288**

Condensed Consolidation Statement of Changes in Equity

Amounts in SEK 000s	Notes	Jul-Sep 2018	Jul-Sep 2017	Jan-Sep 2018	Jan-Sep 2017	Jan-Dec 2017
Opening balance		7,332	(10,066)	33,176	(14,223)	(14,223)
Profit/loss of the period		(31,403)	(18,379)	(87,825)	(46,250)	(86,794)
Other comprehensive income		-	3	(7)	(4)	(4)
Comprehensive income (loss) for the period		**(31,403)**	**(18,376)**	**(87,832)**	**(46,254)**	**(86,798)**
Transaction with owners						
New issue of ordinary shares	6	738,072	40,170	738,650	72,205	72,205
Cost attributable to new share issue		(54,433)	(50)	(54,433)	(50)	(50)
Premiums received from warrants		-	176	-	176	207
Warrants		-	213	8	213	213
Contribution from shareholders	4	-	-	29,999	-	61,622
Total transaction with owners		**683,639**	**40,509**	**714,224**	**72,544**	**134,197**
Closing balance		**659,568**	**12,067**	**659,568**	**12,067**	**33,176**

Condensed Consolidated Statement of Cash Flows

		Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	*Notes*	**2018**	**2017**	**2018**	**2017**	**2017**
Operating activities						
Operating profit (loss)		(31,273)	(17,474)	(87,737)	(43,970)	(84,509)
Adjustment for non-cash-items		12	293	38	319	332
Interest received		-	-	6	-	-
Interest paid		(2)	(3)	(7)	(6)	(11)
Cash flow from operating activities before working capital		**(31,263)**	**(17,184)**	**(87,700)**	**(43,657)**	**(84,188)**
Cash flow from changes in working capital		16,040	459	1,995	2,300	16,181
Cash flow from operating activities		**(15,223)**	**(16,725)**	**(85,705)**	**(41,357)**	**(68,007)**
Cash flow from investing activities		-	-	-	-	(50)
Cash flow from financing activities	6	684,198	3,081	714,314	39,118	101,224
Cash flow for the period		**668,975**	**(13,644)**	**628,609**	**(2,239)**	**33,167**
Cash & cash equivalents, beginning of period		17,023	35,670	57,352	24,241	24,241
Net increase (decrease) in cash & cash equivalents		668,975	(13,644)	628,609	(2,239)	33,167
Exchange-rate difference in cash and cash equivalents		(127)	(74)	(90)	(50)	(56)
Cash & cash equivalents, end of period		**685,871**	**21,952**	**685,871**	**21,952**	**57,352**

Condensed Parent Company Income Statement

		Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	*Notes*	**2018**	**2017**	**2018**	**2017**	**2017**
Net sales		-	-	-	-	-
Other operating income		80	73	676	103	151
Gross profit		**80**	**73**	**676**	**103**	**151**
Operating expenses						
Other external operating expenses		(26,778)	(12,598)	(76,409)	(30,287)	(64,422)
Personnel expenses		(4,500)	(4,865)	(11,833)	(13,118)	(19,568)
Depreciation and amortization		(13)	(12)	(38)	(38)	(51)
Total operating expenses		**(31,291)**	**(17,475)**	**(88,280)**	**(43,443)**	**(84,041)**
Operating profit (loss)		**(31,211)**	**(17,402)**	**(87,604)**	**(43,340)**	**(83,890)**
Net financial items		(125)	(905)	(113)	(2,280)	(2,958)
Profit (loss) before taxes		**(31,336)**	**(18,307)**	**(87,717)**	**(45,620)**	**(86,848)**
Income taxes		-	-	-	-	-
Net income (loss) for the period		**(31,336)**	**(18,307)**	**(87,717)**	**(45,620)**	**(86,848)**

Condensed Parent Company Statement of Other Comprehensive Income

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**	**2017**
Net income (loss) for the period	(31,336)	(18,307)	(87,717)	(45,620)	(86,848)
Other comprehensive income	-	-	-	-	-
Total comprehensive income	**(31,336)**	**(18,307)**	**(87,717)**	**(45,620)**	**(86,848)**

Condensed Parent Company Balance Sheet

Amounts in SEK 000s	*Notes*	As of 30.09.2018	As of 30.09.2017	As of 31.12.2017
Non-current assets				
Property, plant and equipment		119	170	158
Financial non-current assets		3,830	4,406	3,830
Total non-current assets		**3,949**	**4,576**	**3,988**
Current assets				
Other current assets		1,486	4,678	4,394
Cash and cash equivalents	5	685,592	21,572	56,984
Total current assets		**687,078**	**26,250**	**61,378**
Total assets		**691,027**	**30,826**	**65,366**
Shareholders' equity				
Share capital		1,408	661	667
Statutory reserve		3,092	3,092	3,092
Restricted equity		**4,500**	**3,753**	**3,759**
Additional paid in capital		1,069,072	290,432	290,426
Retained earnings, including net loss for the period		(410,834)	(278,380)	(257,954)
Non-restricted equity		**658,238**	**12,052**	**32,472**
Total shareholders' equity	4,6	**662,738**	**15,805**	**36,231**
Non-current liabilities				
Other liabilities		77	-	-
Total non-current liabilities		**77**	**-**	**-**
Current liabilities				
Accounts payable	5	19,269	4,263	13,672
Shareholder loans		-	17	470
Other current liabilities		647	811	752
Accrued expenses and deferred revenue	5	8,296	9,930	14,241
Total current liabilities		**28,212**	**15,021**	**29,135**
Total liabilities and shareholders' equity		**691,027**	**30,826**	**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.

The interim report for the third quarter of 2018 has been approved for publication on November 1, 2018, 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.

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

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**	**2017**
Total registered shares at the beginning of period[1]	33,232,347	14,775,000	16,673,000	13,262,500	13,262,500
New issue of shares during the period[1]	1,970,000	1,756,500	18,529,347	3,269,000	3,410,500
Total registered shares at the end of period[1]	**35,202,347**	**16,531,500**	**35,202,347**	**16,531,500**	**16,673,000**
Share capital at the end of period, SEK thousand	1,408	661	1,408	661	667
Equity at the end of period, SEK thousand	659,568	12,067	659,568	12,067	33,176
Earnings per share before and after dilution, SEK[1]	(0.91)	(1.21)	(2.90)	(3.21)	(5.81)
Average number of shares during the period[1,2]	34,581,369	15,202,723	30,316,401	14,387,273	14,927,736

[1] Number of shares Jan - Sep 2017 have been adjusted for split 1:250.
[2] 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 1,661,500 options outstanding in option programs 2015 and 2017. 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 -47 (-40) thousand are included in equity as of September 30, 2018.

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

	Jul-Sep		Jan-Sep		Jan-Dec
Amounts in SEK 000s	**2018**	**2017**	**2018**	**2017**	**2017**
Expenses relating to research and development/operating expenses, %					
Personnel expenses related to R&D[1,3]	(1,500)	(2,832)	(3,130)	(9,021)	(13,324)
Other external operating expenses related to R&D	(22,555)	(4,941)	(61,958)	(15,508)	(38,362)
Expenses related to research and development	**(24,055)**	**(7,773)**	**(65,088)**	**(24,529)**	**(51,686)**
Personnel expenses related to G&A[2]	(3,196)	(2,176)	(8,706)	(5,155)	(7,293)
Other external operating expenses related to G&A	(4,089)	(7,516)	(14,581)	(14,345)	(25,624)
Expenses related to general and administration	**(7,285)**	**(9,692)**	**(23,287)**	**(19,500)**	**(32,917)**
Depreciation and amortization	(13)	(12)	(38)	(38)	(51)
Total operating expenses	**(31,353)**	**(17,477)**	**(88,413)**	**(44,067)**	**(84,654)**
Expenses relating to research and development/operating expenses, %	77%	44%	74%	56%	61%
Expenses relating to general and administration/operating expenses, %	23%	55%	26%	44%	39%
Equity ratio at the end of the period %					
Total shareholders' equity at the end of the period	659,568	12,067	659,568	12,067	33,176
Total assets at the end of the period	687,833	27,151	687,833	27,151	62,288
Equity ratio at the end of the period %	**96%**	**44%**	**96%**	**44%**	**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-Sep 2018.

Financial calendar

Year-end report for the period 1 January – 31 December 2018	February 7, 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 7, 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.