



## **CALLIDITAS THERAPEUTICS AB (Publ)**

Interim Report January 1 – June 30, 2018

# Successful capital raise and listing on Nasdaq Stockholm

## **Key figures**

April 1 - June 30, 2018

- Net sales for the period was SEK (-) million.
- Net income (loss) for the period was SEK -18.2 (-16.1) million.
- Earnings and diluted earnings per share was SEK -1.08 (-1.10).
- At June 30, 2018, cash and cash equivalents amounted to SEK 17.0 (35.7) million.

### January 1 - June 30, 2018

- Net sales for the period was SEK (-) million.
- Net income (loss) for the period was SEK -56.4 (-27.9) million.
- Earnings and diluted earnings per share was SEK -3.37 (-1.99).

## Significant events during the period April 1 – June 30 2018, in summary

- Calliditas Therapeutics was listed on Nasdaq Stockholm on June 29 in the Mid Cap segment and shares worth a value of SEK 650 million were subscribed for.
- In connection with the listing, outstanding bridge loans of SEK 95.2 million were converted, including accrued interest, to new shares.
- During the second quarter, 2018, the Company filed a new patent application. The application covers method of use for treatment of autoimmune diseases.

## Significant events after the end of reporting period

- 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 August 16, 10:00 CEST**

Audio cast with teleconference, Q2, 2018, August 16, 2018, 10:00 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q2-2018

Teleconference: Dial-in number UK: +442030089811 SE: +46850556453

## **CEO Statement**

# Successful capital raise and listing on Nasdaq Stockholm



It is with great joy that I am in a position to report that the company in June successfully raised SEK 650m on Nasdaq Stockholm to secure the funding necessary to initiate our Phase 3 study of our lead project Nefecon. I would like to thank our existing shareholders as well as our advisors for their help and support in bringing this about. As I have said in my previous reports, we have diligently worked to prepare for the study, and we are now in a good position to launch the study. Like most drug development programs, this has been a long journey, and we are truly excited to be in the position to launch this large-scale Phase 3 study in the severe and under-treated disease IgA nephropathy (IgAN).

Most importantly, I would like to thank the dedicated senior team at Calliditas, which has achieved not only pioneering acceptance by the US authorities Food and Drug Administration (FDA) for a surrogate marker in our Phase 3 study, but was also instrumental in forming and developing the very framework on which the industry is now relying to design surrogate marker based clinical trials in IgAN. It is an outstanding achievement under any circumstance, but even more exciting coming from an independent biotech company based in Sweden. We look forward to continue to break new ground for treatment alternatives in this indication, and I hope to bring you more exciting news over the next several quarters.

The capital raise also positions us for development of our pipeline assets, and we will review our plans in the liver related as well as other areas in order to expand our scientific base and diversify our project portfolio.

## The Virtue of Persistence

The life sciences area is in my view unique with regards to a couple of key components. These include high risk, unpredictability, the potential of extremely attractive returns, long time horizons and significant investments. On the other hand, what should one expect when dealing with such multifaceted issues as the intricacies of the human body and mind, mutating and complex diseases, and the sometimes surprising response of healing? Those who are successful in this industry generally have to be able to live with two conflicting thoughts; the strong conviction and undying enthusiasm regarding the need for - and ultimate success of - their product candidate, and the empirical knowledge about the length of time and statistical probabilities of a successful approval and launch of a drug. It is not an industry for the faint-hearted. In my view, one key attribute of success is simply; persistence.

Clinical programs involve per definition changes and delays, as well as interactions with a significant number of third parties with their own rules, processes and agendas. Furthermore, they require logistical diligence and the orchestration and co-ordination of a very deep and broad skill base. In these circumstances, par for the course is the ability to persist; to have options A, B and C already planned out; to not give up but to revise and review; and to continuously ensure a runway for continued development whilst managing scarce and highly qualified resources. It is also however an industry which offers creativity, commitment, dedication, scientific excellence and a high level of problem solving. It also offers the incredible sense of joy and achievement when things come together, when plans work out, and when the most important goal of all - when patients can access improved treatments and diseases can be halted or cured - is realized. That is when persistence truly pays off. I firmly believe that we at Calliditas are on that path. We are committed – and persistent.

Renée Aguiar-Lucander, CEO

## **Business overview**

# Orphan Disease – IgA nephropathy

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**

One way in which the company has done the above is through participation in the Kidney Health Initiative (KHI) which was established in September 2012 under a Memorandum of Understanding between the American Society of Nephrology (ASN) and the US Food and Drug Administration (FDA). The reason for establishing this organisation related to the fact that today over 30 million Americans have chronic kidney disease, and approximately 700,000 Americans have kidney failure, also known as end-stage renal disease (ESRD).

In the past decades, very few new drugs have been approved to treat kidney disease. As an example, cited in the publication Kidney News Online in 2017, the last FDA-approved therapy for diabetic nephropathy, the most common reason for ESRD, was 14 years ago. 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, it was felt that the care and safety of these patients warranted increased attention. KHI's role is therefore to help the nephrology community collaborate to improve patient safety and develop novel therapies, as well as to advance scientific understanding of the kidney health and patient

safety implications of new and existing medical products. Furthermore, KHI aims to foster development of therapies for diseases that affect the kidney by creating a collaborative environment in which the FDA and the greater nephrology community can interact to optimize evaluation of drugs, devices, biologics, and food products. KHI has seen its membership grow from 47 organizations in September 2013 to more than 80 organizations in October 2017.

## **Disease Profile**

Immunoglobulin A nephropathy or IgA nephropathy (IgAN, also known as Berger disease) was first described by Berger and Hinglais in 1968<sup>1</sup>. 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, or kidney inflammation, in the world<sup>2</sup>.

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. 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.

## 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 is being planned, 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 downregulates the disease process in the kidney.

Nefecon delivers budesonide directly to the site in the intestine where the aberrant 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 chronic local delivery, thereby minimizing the systemic effects seen with other corticosteroids.

Nefecon's 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.

<sup>&</sup>lt;sup>1</sup> Berger J, Hinglais N Les Depots Intercapillaires d'IgA – IgG. J Urol Nephrol (Paris) 1968 Sep.

<sup>&</sup>lt;sup>2</sup> Cattran DC, Coppo R, Cook HT, et al. The Oxford classification of IgA nephropathy: rationale, clinicopathological correlations, and classifications. Kidney Int 2009 Jul

Calliditas plans to run 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 planning to have the necessary data on hand to file for the accelerated FDA approval in the first half of 2021.

# Significant events during the period January 1 – June 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.
- 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. The total number of shares in the Company as of June 30, 2018 amounted to 33,232,347.
- During the second quarter of 2018, the Company filed a new patent application. The application covers method of use for treatment of autoimmune diseases.

## Significant events after the end of the period

- 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.

## **Financial overview**

## **Key figures**

	Apr-Jun		Jan-	Jan-Dec	
Amounts in SEK 000s	2018	2017	2018	2017	2017
Expenses relating to research and development <sup>2</sup>	(10,000)	(9,517)	(41,531)	(16,756)	(51,686)
Expenses relating to research and development/operating expenses, % <sup>2</sup>	54%	62%	73%	63%	61%
Operating profit (loss)	(18,207)	(15,487)	(56,464)	(26,496)	(84,509)
Earnings per share before and after dilution, $SEK^1$	(1.08)	(1.10)	(3.37)	(1.99)	(5.81)
Total registered shares at the end of period <sup>1</sup>	33,232,347	14,775,000	33,232,347	14,775,000	16,673,000
Equity at the end of the period	7,332	(10,066)	7,332	(10,066)	33,176
Equity ratio at the end of the period %2	11%	neg	11%	neg	53%
Cash and cash equivalents at the end of the period	17,023	35,670	17,023	57,352	57,352

<sup>&</sup>lt;sup>1</sup> Number of shares Jan-Jun 2017 have been adjusted for split 1:250.

## April – June 2018

## Revenue

No revenue was reported for the quarter (-).

Other operating income of SEK 0.4 (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 14.0 (10.7) million. Out of the other external operating expenses for the quarter, SEK 8.4 (7.1) million was attributable to research and development (R&D) and SEK 5.6 (3.6) 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 mainly due to the preparations for the upcoming phase 3 study for Nefecon. The increase of the other external operating expenses attributable to G&A was due to expenses from IPO preparations.

Personnel expenses amounted to SEK 4.6 (4.8) million. The number of employees as of June 30, 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 1.6 (2.5) million was attributable to R&D and SEK 3.0 (2.3) 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 employed personnel decreased, and number of consultants increased, compared to the second guarter 2017.

<sup>&</sup>lt;sup>2</sup> Non-IFRS performance measure, see definitions page.

## **Earnings**

Loss for the period was SEK -18.2 (-16.1) million, resulting in loss per share, before and after dilution of SEK -1.08 (-1.10).

#### 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 -18.2 (-15.5) million, and the decreased in cash flow from operating activities was mainly due to the preparations for the upcoming phase 3 study for Nefecon.

Cash flow from financing activities amounted to SEK 0.6 (36.0) million for the quarter. The main part of the cash flow from the IPO share issue occurred in July 2018 and was recorded in the consolidated financial statements at that point. Due to differences in accounting principles between the consolidated financial statements and the parent company financial statements, the share issue amount was recorded as a receivable in the parent company as of 30 June 2018, but not in the consolidated financial statements.

Cash flow for the quarter was SEK -36.1 (24.0) million. As of June 30, 2018, cash and cash equivalents amounted to SEK 17.0 (35.7) million.

## January - June 2018

#### Revenue

No revenue was reported for the period (-).

Other operating income of SEK 0.6 (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 49.7 (17.4) million. Out of the other external operating expenses for the period, SEK 39.4 (10.6) million was attributable to research and development (R&D) and SEK 10.3 (6.8) 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 intensification of the preparations for the upcoming phase 3 study for Nefecon. The increase of the other external operating expenses attributable to G&A was due to expenses for IPO preparations.

Personnel expenses amounted to SEK 7.3 (9.2) million. The average number of employees in the period was 10 (11). 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 2.1 (6.2) million was attributable to R&D and SEK 5.2 (3.0) million was attributable to G&A. The decrease in personnel expenses attributable to R&D was mainly due the abovementioned 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 -56.4 (-27.9) million, resulting in loss per share, before and after dilution of SEK -3.37 (-1.99).

#### Tax

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

#### Cash flow and investment

Cash flow from operating activities for the period amounted to SEK -56.4 (-26.5) million, and the decreased in cash flow from operating activities was mainly due to the preparations for the upcoming phase 3 study for Nefecon.

Cash flow from financing activities amounted to SEK 30.1 (36.0) 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. The bridge loan was fully converted into new shares in connection with the IPO in June, 2018. The main part of the cash flow from the IPO share issue occurred in July 2018 and was recorded in the consolidated financial statements at that point.

Cash flow for the period was SEK -40.4 (11.4) million.

## Changes in equity and number of shares

As of June 30, 2018, equity amounted to SEK 7.3 (-10.0) million. The positive effect on equity from the new share offering in June 2018, will be recorded in the third quarter in the consolidated financial statements, since the liquidity from the offering was received after the end of the reporting period. The number of registered shares amounted to 33,232,347 (14,775,000), and the number of shares increase in the second quarter with a total of 16,559,347, whereof 14,444,444 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.

#### **Auditor's review**

This report has not been reviewed by the company's auditors.



The Board of Directors and CEO declare that the interim report gives a fair view of the business development, financial position and result of operation of the Parent Company and the Group, and describes significant risks and uncertainties that the parent company and its subsidiaries are facing.

Stockholm August 16, 2018

**Board of Directors** 

Thomas Eklund Bengt Julander Olav Hellebo

Chairman of the Board Member of the Board Member of the Board

Lennart Hansson Ann-Tove Kongsnes Hilde Furberg

Member of the Board Member of the Board Member of the Board

Renée Aguiar-Lucander

CEO

## **Financial statements**

## **Condensed Consolidated Income Statement**

	Apr-	Jun	Jan	Jan-Jun		
Amounts in SEK 000s Notes	2018	2017	2018	2017	2017	
Net sales	-	-	-	-	-	
Other operating income	351	-	596	94	145	
Total operating income	351	-	596	94	145	
Operating expenses						
Other external operating expenses	(13,988)	(10,671)	(49,699)	(17,396)	(63,986)	
Personnel expenses	(4,558)	(4,803)	(7,336)	(9,168)	(20,617)	
Depreciation and amortization	(12)	(13)	(25)	(26)	(51)	
Total operating expenses	(18,558)	(15,487)	(57,060)	(26,590)	(84,654)	
Operating profit (loss)	(18,207)	(15,487)	(56,464)	(26,496)	(84,509)	
Net financial items	22	(624)	42	(1,375)	(2,285)	
Profit (loss) before taxes	(18,185)	(16,111)	(56,422)	(27,871)	(86,794)	
Income taxes	-	-	-	-	-	
Net income (loss) for the period	(18,185)	(16,111)	(56,422)	(27,871)	(86,794)	
Attributable to:						
Equity holder of the parent company	(18,185)	(16,111)	(56,422)	(27,871)	(86,794)	
Earnings and diluted earnings per share (SEK)	(1.08)	(1.10)	(3.37)	(1.99)	(5.81)	

## **Condensed Consolidated Statement of Comprehensive Income**

	Apr-	Apr-Jun		Jan-Jun		lan-Dec
Amounts in SEK 000s	2018	2017	2018	2017		2017
Net income (loss) for the period	(18,185)	(16,111)	(56,422)	(27,871)		(86,794)
Other comprehensive income						
Currency translation effect	(2)	(4)	(7)	(7)		(4)
Total comprehensive income (loss)	(18,187)	(16,115)	(56,429)	(27,878)		(86,798)
Attributable to:						
Equity holder of the parent company	(18,187)	(16,115)	(56,429)	(27,878)		(86,798)
Total comprehensive income (loss)	(18,187)	(16,115)	(56,429)	(27,878)		(86,798)

## **Condensed Consolidated Balance Sheet**

	As of		As of
Amounts in SEK 000s Notes	30.06.2018	30.06.2017	31.12.2017
Non-current assets			
Property, plant and equipment	132	183	158
Financial non-current assets	341	291	341
Total non-current assets	473	474	499
Current assets			
Other current assets 7	49,169	1,721	4,437
Cash and cash equivalents 5	17,023	35,670	57,352
Total current assets	66,192	37,391	61,789
Total assets	66,665	37,865	62,288
Shareholders' equity			
Share capital	1,329	591	667
Additional paid in capital	385,941	250,383	352,959
Retained earnings, including net loss for the period	(379,938)	(261,040)	(320,450)
Total shareholders' equity attributable to shareholders of the parent company $4,\!8$	7,332	(10,066)	33,176
Current liabilities			
Accounts payable 5	5,941	5,911	13,684
Shareholder loans	-	35,874	470
Other current liabilities 7	42,895	1,121	683
Accrued expenses and deferred revenue 5	10,497	5,025	14,275
Total current liabilities	59,333	47,931	29,112
Total liabilities and shareholders' equity	66,665	37,865	62,288

## **Condensed Consolidation Statement of Changes in Equity**

	Apr-	Apr-Jun		Jan-J	lun	Jan-De	c
Amounts in SEK 000s Notes	2018	2017		2018	2017	20	)17
Opening balance	24,941	(25,986)		33,176	(14,223)	(14,22	23)
Profit/loss of the period	(18,185)	(16,111)	-	(56,422)	(27,871)	(86,79	94)
Other comprehensive income	(2)	(4)	-	(7)	(7)		(4)
Comprehensive income (loss) for the period	(18,187)	(16,115)		(56,429)	(27,878)	(86,79	<del>9</del> 8)
Transaction with owners							
New issue of ordinary shares 8	578	32,035		578	32,035	72,2	:05
Cost attributable to new share issue	-	-		-	-	(5	50)
Premiums received from warrants	-	-		-	-	2	207
Warrants	-	-		8	-	2	213
Contribution from shareholders 4	-	-		29,999	-	61,6	22
Total transaction with owners	578	32,035		30,585	32,035	134,1	.97
Closing balance	7,332	(10,066)		7,332	(10,066)	33,1	.76

## **Condensed Consolidated Statement of Cash Flows**

	Apr-	Jun	Jan-	Jan-Jun		
Amounts in SEK 000s Notes	2018	2017	2018	2017	2017	
Operating activities						
Operating profit (loss)	(18,207)	(15,487)	(56,464)	(26,496)	(84,509)	
Adjustment for non-cash-items	13	13	26	26	332	
Interest received	6	-	6	-	-	
Interest paid	(2)	(3)	(5)	(3)	(11)	
Cash flow from operating activities before working capital	(18,190)	(15,477)	(56,437)	(26,473)	(84,188)	
Cash flow from changes in working capital	(18,457)	3,443	(14,045)	1,841	16,181	
Cash flow from operating activities	(36,647)	(12,034)	(70,482)	(24,632)	(68,007)	
Cash flow from investing activities	-	-	-	-	(50)	
Cash flow from financing activities 8	578	36,037	30,116	36,037	101,224	
Cash flow for the period	(36,069)	24,003	(40,366)	11,405	33,167	
Cash & cash equivalents, beginning of period	53,074	11,721	57,352	24,241	24,241	
Net increase (decrease) in cash & cash equivalents	(36,069)	24,003	(40,366)	11,405	33,167	
Exchange-rate difference in cash and cash equivalents	18	(54)	37	24	(56)	
Cash & cash equivalents, end of period	17,023	35,670	17,023	35,670	57,352	

## **Condensed Parent Company Income Statement**

	'	Apr	Apr-Jun		Jan-Jun		
Amounts in SEK 000s	Notes	2018	2017	2018	2017	2017	
Net sales		-	-	-	-	-	
Other operating income		351	-	596	94	151	
Gross profit		351	-	596	94	151	
Operating expenses							
Other external operating expenses		(13,960)	(11,005)	(49,631)	(17,753)	(64,422)	
Personnel expenses		(4,555)	(4,258)	(7,333)	(8,253)	(19,568)	
Depreciation and amortization		(12)	(13)	(25)	(26)	(51)	
Total operating expenses		(18,527)	(15,276)	(56,989)	(26,032)	(84,041)	
Operating profit (loss)		(18,176)	(15,276)	(56,393)	(25,938)	(83,890)	
Net financial items		11	(624)	12	(1,375)	(2,958)	
Profit (loss) before taxes		(18,165)	(15,900)	(56,381)	(27,313)	(86,848)	
Income taxes		-	-	-	-	-	
Net income (loss) for the period		(18,165)	(15,900)	(56,381)	(27,313)	(86,848)	

## **Condensed Parent Company Statement of Other Comprehensive Income**

	Apr-	Apr-Jun		Jan-Jun			Jan-Dec
Amounts in SEK 000s	2018	2017		2018	2017		2017
Net income (loss) for the period	(18,165)	(15,900)		(56,381)	(27,313)		(86,848)
Other comprehensive income	-	-		-	-		-
Total comprehensive income	(18,165)	(15,900)		(56,381)	(27,313)		(86,848)

## **Condensed Parent Company Balance Sheet**

	As	of	As of
Amounts in SEK 000s Notes	30.06.2018	30.06.2017	31.12.2017
Non-current assets			
Property, plant and equipment	132	183	158
Financial non-current assets	3,830	4,270	3,830
Total non-current assets	3,962	4,453	3,988
Current assets			
Other current assets 7	651,073	1,644	4,394
Cash and cash equivalents 5	16,621	35,027	56,984
Total current assets	667,694	36,671	61,378
Total assets	671,656	41,124	65,366
Shareholders' equity			
Share capital	1,329	591	667
Statutory reserve	3,092	3,092	3,092
Restricted equity	4,421	3,683	3,759
Additional paid in capital	987,218	250,383	290,426
Retained earnings, including net loss for the period	(379,498)	(260,463)	(257,954)
Non-restricted equity	607,720	(10,080)	32,472
Total shareholders' equity 4,8	612,141	(6,397)	36,231
Non-current liabilities			
Other liabilities	77	-	-
Total non-current liabilities	77	-	-
Current liabilities			
Accounts payable 5	5,875	5,885	13,672
Shareholder loans	-	35,874	470
Other current liabilities 7	42,895	873	752
Accrued expenses and deferred revenue 5	10,669	4,899	14,241
Total current liabilities	59,439	47,521	29,135
Total liabilities and shareholders' equity	671,656	41,124	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 second quarter of 2018 has been approved for publication on August 16, 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.

## 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, 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.

### **Note 5 Financial instruments**

Calliditas financial assets and liabilities comprise of cash and cash equivalents, Financial noncurrent 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 Significant events after the reporting period

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, also 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 associated costs.

### Note 7 IPO related assets and liabilities

	As	of	As of		
Amounts in SEK 000s	30.06.2018	30.06.2017	31.12.2017		
Consolidated balance sheet					
IPO related current assets	47,516	-	-		
Non-IPO related current assets	1,653	1,721	4,437		
Other current assets	49,169	1,721	4,437		
IPO related current liabilities	42,250	-	-		
Non-IPO related current liabilities	645	1,121	683		
Other current liabilities	42,895	1,121	683		
Parent balance sheet					
IPO related current assets	650,000	-	-		
Non-IPO related current assets	1,073	1,644	4,394		
Other current assets	651,073	1,644	4,394		
IPO related current liabilities	42,251	-	-		
Non-IPO related current liabilities	644	873	752		
Other current liabilities	42,895	873	752		

## **Note 8 Equity**

	Apr-	Jun	Jan-	Jan-Dec	
Amounts in SEK 000s	2018	2017	2018	2017	2017
Total registered shares at the beginning of period <sup>1</sup>	16,673,000	13,262,500	16,673,000	13,262,500	13,262,500
New issue of shares during the period <sup>1</sup>	16,559,347	1,512,500	16,559,347	1,512,500	3,410,500
Total registered shares at the end of period <sup>1</sup>	33,232,347	14,775,000	33,232,347	14,775,000	16,673,000
Share capital at the end of period, SEK thousand	1,329	591	1,329	591	667
Equity at the end of period, SEK thousand	7,332	(10,066)	7,332	(10,066)	33,176
Earnings per share before and after dilution, SEK <sup>1</sup>	(1.08)	(1.10)	(3.37)	(1.99)	(5.81)
Average number of shares during the period $^{1,2}$	16,854,971	14,691,896	16,762,996	13,981,146	14,927,736

 $<sup>^{1}</sup>$  Number of shares Jan - June 2017 have been adjusted for split 1:250.

Reserves for translation difference of SEK -48 (0) thousand are included in equity as of June 30, 2018.

<sup>&</sup>lt;sup>2</sup> 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.

During June, the number of shares and votes in Calliditas Therapeutics AB has increased due to new share issues and the conversion of all outstanding bridge loans to new shares in connection with the listing of the Company's shares on Nasdaq Stockholm. As of June 30, 2018, the number of shares and votes in the Company is 33,232,347.

The positive effect on equity from the new share offering as of 29 June, 2018, will be recorded in the third quarter in the consolidated financial statements, since the liquidity from the offering was received after the end of the reporting period.

# 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.
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 finance 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.
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## **Reconciliations of alternative performance measures**

	Apr-Jun		Jan	Jan-Jun	
Amounts in SEK 000s	2018	2017	2018	2017	2017
Expenses relating to research and development/operating expenses, %					
Personnel expenses related to R&D <sup>1,3</sup>	(1,597)	(2,455)	(2,128)	(6,189)	(13,324)
Other external operating expenses related to R&D	(8,403)	(7,062)	(39,403)	(10,567)	(38,362)
Expenses related to research and development	(10,000)	(9,517)	(41,531)	(16,756)	(51,686)
Personnel expenses related to G&A <sup>2</sup>	(2,961)	(2,348)	(5,208)	(2,979)	(7,293)
Other external operating expenses related to G&A	(5,585)	(3,609)	(10,296)	(6,829)	(25,624)
Expenses related to general and administration	(8,546)	(5,957)	(15,504)	(9,808)	(32,917)
Depreciation and amortization	(12)	(13)	(25)	(26)	(51)
Total operating expenses	(18,558)	(15,487)	(57,060)	(26,590)	(84,654)
Expenses relating to research and development/operating expenses, %	54%	62%	73%	63%	61%
Expenses relating to general and administration/operating expenses, %	46%	38%	27%	37%	39%
Equity ratio at the end of the period %					
Total shareholders' equity at the end of the period	7,332	(10,066)	7,332	(10,066)	33,176
Total assets at the end of the period	66,665	37,865	66,665	37,865	62,288
Equity ratio at the end of the period %	11%	neg	11%	neg	53%

<sup>&</sup>lt;sup>1</sup> Research and development costs (R&D).

 $<sup>^{\</sup>rm 2}$  General and administrative costs (G&A).

<sup>&</sup>lt;sup>3</sup> 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-Jun 2018.

## Financial calendar

Interim report for the period 1 January – 30 September 2018

Year-end report for the period 1 January – 31 December 2018

1 November 2018 7 February 2019



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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.