Q2

calliditas THERAPEUTICS

CALLIDITAS THERAPEUTICS AB (Publ)

Interim Report January 1 – June 30, 2019

Large China deal further validates Nefecon market potential

Key figures

April 1 - June 30, 2019

- Net sales for the period amounted to SEK 138.2 (-) million.
- Net income (loss) for the period was SEK 83.2 (-18.2) million.
- Earnings before dilution per share totaled SEK 2.36 (-1.08) and earnings after dilution per share totaled SEK 2.35 (-1.08).
- At June 30, 2019, cash and cash equivalents amounted to SEK 534.9 (17.0) million.

January 1 - June 30, 2019

- Net sales for the period amounted to SEK 138.2 (-) million.
- Net income (loss) for the period was SEK 40.6 (-56.4) million.
- Earnings before and after dilution per share totaled SEK 1.15 (-3.37).

Significant events during the period April 1 – June 30, 2019, in summary

- Calliditas signed a license agreement with Everest Medicines, who will develop and commercialize Calliditas' leading drug candidate Nefecon in Greater China and Singapore for IgA Nephropathy (IgAN). Potential future milestone payments linked to the agreement amount to a maximum of USD 106 million (approximately SEK 1.0 billion) plus royalty income in addition to the upfront fee of USD 15 million (SEK 138.2 million) which was recognized as revenue in the second quarter of 2019.
- The Annual General Meeting of Calliditas was held in May and the meeting decided, among other things, on the election of Elmar Schnee (Chairman) and Diane Parks to the Board of Directors.

Significant events after the end of reporting period, in summary

- Calliditas completed a directed new share issue of 3.5 million shares in July, thereby raising approximately SEK 210 million with the aim of expanding ongoing research programs and accelerating activities to further develop the project portfolio. The new issue was subscribed by Swedish and international institutional investors, including BVF Partners L.P.
- Calliditas entered into an exclusive in-licensing agreement of Budenofalk 3mg oral capsule for the US market with Dr Falk Pharma. This positions Calliditas to accelerate its development of the pipeline portfolio related to orphan liver disease, such as Autoimmune hepatitis (AIH).

Investor presentation August 15, 15:00 CET

Audio cast with teleconference, Q2 2019, August 15, 2019, 15:00 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q2-2019

Teleconference: Dial-in number SE +46850558369 UK +443333009265 US: +18338230590

CEO Statement

Large China deal further validates Nefecon market potential

This second quarter of 2019 was very busy and exciting as we concluded a USD 121 million (SEK 1.1 billion) outlicensing deal of Nefecon for Greater China and Singapore. At the time of announcement, this was the largest licensing deal announced between China and Europe for a clinical stage asset. We had undertaken a robust process with regards to finding the right partner for the development and commercialization of Nefecon in China, and there was significant interest from a large number of China-based companies. We are excited to have Everest Medicines as a partner in China, and we look forward to a productive collaboration in order to address a significant unmet medical need in this very large market, which we believe represents a market opportunity equivalent to the US.

China has a population of over 1.4 bn people, which represents about 18% of the world's population and has the second largest prescription drug market in the world, behind the US. In contrast to the US however, the Chinese drug prescription market is estimated to grow at significant double-digit rate on an annual basis over the next five years, setting it on a course to become the largest market. China is also a large market for IgA Nephropathy, as it is a far more prevalent disease in Asia. Around 40% of all renal biopsies in China are related to IgAN. On that basis one could estimate diagnosed IgAN cases to be around 600,000 - 800,000. As kidney biopsies today mainly can be carried out only in the very large hospitals, the actual number of patients, and hence the market opportunity, we believe is vastly larger than what can be derived solely from the existing renal biopsy numbers.

We are therefore excited about the future development plans in China and we look forward to sharing the progress being made there by our partner on an ongoing basis. The real possibility to be the very first approved medication for IgAN in this market is exciting.

Alongside this, our recruitment efforts for the NefIgArd study have been ongoing and we have seen significant progress across all continents. With virtually all centers being open and recruiting in Q2 we have, as expected, seen an increase in screened patient numbers, and we believe that this platform will enable us to recruit the 200 patients required for top line read-out before the end of the year.

In preparation for commercialization in the US, during Q2 we have also commissioned market research to be carried with regards to nephrologists, as well as with payers. The results from these studies, which will further inform us about the pre-commercial activities we need to undertake, as well as the likely pricing and positioning of our drug in the market, is something I look forward to sharing with you during Q3.

We have also spent significant time during Q2 interacting with US based investors, which resulted in a successful directed share issue taking place on July 3, which raised an additional USD 22 million (SEK 210 million) of cash for the company and brought onboard BVF (Biotech Value Fund), a highly renowned US based specialist life science investor, among other investors. This additional capital, in addition to the USD 15 million (SEK 140 million) upfront payment which was received from Everest Medicines after the end of the quarter, will allow us to accelerate our clinical trial program around Nefecon, bringing forward a chronic dosing trial, which we hope to initiate in Q1 2020.

Finally, in August we entered into an exclusive in-licensing agreement of Budenofalk for the American market with Dr. Falk Pharma. This enables us to leverage Dr. Falck's clinical data and expertise in liver indications, such as autoimmune hepatitis (AIH), potentially resulting in both reduced costs and time to market. In addition, the potential to have two separate products gives us more flexibility when it comes to positioning and pricing across different indications. We will now start preparations for an FDA meeting, which is preliminarily planned for Q1 of 2020. Based on positive feedback on the regulatory path for AIH, a late clinical program could be initiated in 2020.

The changing regulatory landscape in China

In August of 2015, the China State Council issued the "Opinion of Reform of the Drug and Medical device Approval System". The opinion had several stated targets, such as to shorten the IND and NDA timelines, encourage drug innovation, accelerate market authorizations of medical innovations and minimize drug lag. The changes seen since this publication have been nothing but revolutionary. According to a publication by Deloitte Insights[1], the drug lag from EMA and FDA approved products (the amount of time between an approved product in one jurisdiction achieves approval in another jurisdiction) was in 2016 approximately 85 months, which over just a couple of years has been cut to an average of 30 months. The number of products approved in China grew from five in 2016 to 40 in 2017 and 51 in 2018, with over 180 drugs being granted Priority Review in 2018. Similar trends of acceleration and focus can be seen also in other areas related to the regulatory process.

So, what were some of the specific actions taken by the National Medical Products Administration (NMPA), formerly known as Chinease FDA, at the time which is driving this significant change? In my view, three of them stand out for a special mention. Firstly, the clinical trial application period was formally set to be 60 days. Secondly, NMPA became a full regulatory member of The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and finally, the number of reviewers were increased from 200 to 600, with a target of reaching 2,000. The rate at which these reforms are taking place is amazing by any standard, and it is making companies both outside and inside of China sit up and take notice, as the opportunities and market landscape is changing in front of our eyes. This shift in stance will according to most experts lead to a rapidly changing landscape related to both drug development, reimbursement and commercialization in China, resulting in significant reduction of prices of established generics, shifting reimbursement dollars to more innovative products and promoting development of innovative medicines. One thing to keep in mind however when using the definition of "innovative drugs", is that this reflects the existing basis of available drugs in China today and is not necessarily equivalent to the definition used in Europe or the US. This is therefore likely to be significantly broader and encompass many drug categories which we take for granted, having had the benefit of access.

[1] *https://www2.deloitte.com/insights/us/en/industry/life-sciences/innovative-biopharma-china-regulatory-change.html*

It is therefore with great interest that we continue to follow the developments in China, and I am sure that we will see increased deal activity between Europe and China going forward related to both approved and marketed drugs, as well as drugs in clinical development.

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 study NefIgArd in patients with IgA nephropathy.

The randomized, double-blind and placebo-controlled Phase 3 study for lead candidate Nefecon will have a similar design to the successful Phase 2b study. The study is divided into two parts; a treatment part ("Part A") designed to provide efficacy and safety data used for filing for market approval, and a long-term observational part ("Part B"). Up to 450 patients with biopsy-confirmed IgA nephropathy and on optimal or highest tolerable blood pressure medication will be randomized across 19 countries in North and South America, Europe as well as Australia and parts of Asia.

In the first part of the study ("Part A"), the patients will receive either 16 mg Nefecon or placebo, once daily for nine months, on the background of optimized RAS treatment, and will then be followed for three months. The first 200 patients randomized in the study will be included in the read-out which will form the basis for accelerated approval/conditional approval by the FDA and European Medicines Agency (EMA) respectively. Subsequently, all patients will continue into Part B, which is an observational long-term follow up period where their renal function as measured by eGFR (estimated glomerular filtration rate) will be followed and measured.

The primary endpoint in Part A is reduction in proteinuria and will form the basis for accelerated approval in the US and conditional approval in the EU. Whilst regulators have typically required eGFR as a primary endpoint for studies of chronic kidney disease, following extensive data analysis by Calliditas in collaboration with Tufts University, the FDA has agreed to accept proteinuria as the primary endpoint for accelerated approval of Nefecon.

Based on positive data, this will enable a commercialization and marketing of the drug in the US and the EU. Calliditas have licensed the development and commercialization rights of Nefecon in Greater China and Singapore to Everest Medicines.

The company aims to have the necessary data on hand to file for accelerated FDA approval in the first half of 2021.

The Part B study analysis design is based on conservative statistical assumptions in order to validate proteinuria as a surrogate marker. No medication will be provided in this follow-up phase, as it is designed to observe changes in eGFR and related events, (where an event is defined as a relevant reduction in eGFR from baseline). The company plans to conduct an interim analysis during Part B, after approximately 50 such events have occurred, estimated to take place approximately 18 months after the top line readout, which could form the basis for a full approval.

IgA nephropathy – an orphan disease with great unmet medical need

As is the case for many niche indications, there are few well documented sources related to the prevalence and incidence of IgA nephropathy (IgAN, also known as Berger disease). It is a disease which is not completely understood, both with regards to its initial onset as well as its mode of action. In order to address these shortcomings, Calliditas has been instrumental in supporting research into, and collaboration with other organizations and experts, in order to contribute to the understanding of the disease.

Nephrology environment

Today over 30 million Americans have chronic kidney disease, and over 700,000 Americans have kidney failure, also known as end-stage renal disease (ESRD).

In the past decades, few new drugs have been approved to treat kidney disease. Also, the number of clinical trials in nephrology lag behind most other therapeutic areas. In addition, certain products on the market treating other organs and conditions may have adverse side effects on kidney health.

As the public health implications and economic burdens of kidney disease continue to grow, the care and safety of these patients warrants increased attention. Recent regulatory initiatives such as the acceptance of a surrogate marker by the FDA is an actionable change for companies working in this area hoping to translate R&D into medicines for patients.

Disease profile

IgAN was first described by Berger and Hinglais in 1968[2]. It is characterized by the deposition of IgA antibodies in the kidney, causing inflammation and renal damage which impacts the kidney's ability to filter waste from the blood.

IgAN is the most common cause of glomerulonephritis - kidney inflammation - in the world[3].

The disease is highly variable, both clinically and in the pathology. Clinical features range from asymptomatic blood in the urine to rapidly progressive nephritis. The condition often leads to chronic kidney disease and is more common in males than in females. The pathology is not fully understood, but IgAN is increasingly considered as an immune complex deposition disease.

IgAN can occur at any age, but the clinical onset is commonly during a patient's twenties or thirties and is more common in men than in women, especially in the western world. It has been estimated that up to 50% of the patients with IgAN will progress to ESRD within 20 years. The disease is designated as an orphan disease in Europe and the US, with an estimated diagnosed patient population of approximately 200,000 in Europe and between 130,000 and 150,000 in the US.

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

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

Nefecon – An Overview

Nefecon is an oral formulation of a locally-acting and potent corticosteroid, budesonide. It is being developed by Calliditas as a potential disease-modifying treatment for patients with IgAN at risk of developing ESRD. Nefecon has obtained orphan designation from both the FDA and EMA.

Calliditas has all the rights to develop and commercialize Nefecon globally, however in China and Singapore, Calliditas has licensed development and commercialization to Everest Medicines. The pivotal clinical phase 3 NefIgArd study with Nefecon was initiated in 2018, following the successful completion of the placebo-controlled randomized Phase 2b study, NEFIGAN, where pronounced reduction in proteinuria and a stabilization of eGFR was demonstrated.

Nefecon is a unique 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.

Liver orphan indications

Beyond IgA nephropathy, Calliditas assesses that Nefecon's patented formulation and release technology also offers potential in treatment of other select autoimmune diseases based on the concentrated release in the ilium and the high exposure to the liver, e.g. the liver diseases primary biliary cholangitis (PBC). In order to potentially reduce costs and shorten time for approval and market access, Calliditas has in-licensed Budenofalk for the US market from Dr. Falk Pharma to initially develop autoimmune hepatitis (AIH).

Primary biliary cholangitis (PBC)

PBC is a progressive and chronic autoimmune disease of the liver that predominantly affects women. The disease starts in the bile ducts within the liver. 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 US. Ocaliva has been granted orphan drug designation for the treatment of PBC.

It is known from previous studies that treatment with systemic steroids may alleviate symptoms of the disease and improve biochemical and histologic findings[5]. No targeted steroid therapy is registered for PBC in the US, nor in Europe. Calliditas assesses that there is a significant unmet medical need to improve outcomes as second-line therapy to the approved therapies with UDCA and Ocaliva. Calliditas estimates that this segment comprises approximately

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

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

42,000 patients in the US. Calliditas have been granted orphan drug designation in the US for the treatment of PBC.

Autoimmune hepatitis (AIH)

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

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 60,000-80,000 patients in the US, meeting the criteria for an orphan disease[6].

There are presently no products approved for treatment of AIH in the US. The combination of Calliditas' clinical development and regulatory expertise with the in-licensing of Budenofalk, provides an opportunity to potentially reach the market within a relatively short period of time. Calliditas have been granted orphan drug designation in the US for the treatment of AIH.

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

Significant events during the period January 1 – June 30, 2019

- Calliditas was granted orphan drug designation (ODD) for the treatment of Autoimmune hepatitis (AIH) by the US Food and Drug Administration (FDA). It is estimated that the patient population in the US amounts to approximately 60,000 – 80,000.
- Calliditas was granted orphan drug status by the FDA for the treatment of primary biliary cholangitis (PBC). Calliditas assesses that there is a significant unmet medical need to improve outcomes as second-line therapy to the approved therapies with UDCA and Ocaliva. Calliditas estimates that this segment comprises approximately 42,000 patients in the US.
- The Annual General Meeting of Calliditas was held in May and the AGM resolved, among other things, on the election of Elmar Schnee (Chairman) and Diane Parks to the Board of Directors.
- Calliditas and Everest Medicines entered into a license agreement to develop and commercialize Calliditas' leading drug candidate Nefecon in Greater China and Singapore for the chronic autoimmune kidney disease IgA Nephropathy (IgAN). Under the terms of the agreement, Calliditas will receive an initial upfront payment of USD 15 million at signing of the agreement, as well as future payments linked to pre-defined development, regulatory and commercialization milestones up to an additional USD 106 million, including an option worth up to USD 20 million for the development of Nefecon in other potential indications. Everest will also pay typical royalties on future sales.

Significant events after the end of reporting period

- Calliditas completed a directed new share issue of 3.5 million shares in July, thereby raising approximately SEK 210 million with the aim of expanding ongoing research programs and accelerating activities to further develop the project portfolio. The new issue was subscribed by Swedish and international institutional investors, including BVF Partners L.P.
- In August Calliditas entered into an exclusive in-licensing agreement of Budenofalk 3mg oral capsule for the US market with Dr Falk Pharma. Calliditas will leverage Dr. Falk's clinical trial data and expertise in liver indications, such as Autoimmune hepatitis (AIH) with a view to accelerate approval and market access. This positions Calliditas to accelerate its development of the pipeline portfolio related to orphan liver disease, such as Autoimmune hepatitis (AIH). The deal has an upfront payment of EUR 1.5 million and foresees additional regulatory related payments, subject to market approval from the US Food and Drug Administration (FDA). The total deal value amounts to EUR 40 million, including future sales milestones and comes with typical royalties.

Financial overview

Key figures

	Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Expenses relating to research and development/operating expenses, %[1]	59%	55%	65%	73%	75%
Net income (loss) for the period	83,167	(18,185)	40,611	(56,422)	(132,049)
Earnings per share before dilution, SEK[1]	2.36	(1.08)	1.15	(3.37)	(5.09)
Earnings per share after dilution, SEK[1]	2.35	(1.08)	1.15	(3.37)	(5.09)
Cash flow from operating activities	(59,303)	(36,647)	(108,685)	(70,482)	(128,191)
Total registered shares at the end of period	35,202,347	33,232,347	35,202,347	33,232,347	35,202,347
Equity at the end of the period	659,023	7,332	659,023	7,332	618,175
Equity ratio at the end of the period %[1]	93%	11%	93%	11%	95%
Cash and cash equivalents at the end of the period	534,863	17,023	534,863	17,023	646,175

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

January – June 2019

Revenue

The revenue was SEK 138.2 million (-) for both the second quarter of 2019 and for the first six months of 2019 and stems from the out-licensing of Nefecon for China to Everest Medicines.

Total operating expenses

Operating expenses for the second quarter of 2019 amounted to SEK 52.9 (18.2) million and SEK 95.6 (56.5) million for the first six months of 2019.

Research and development expenses

Research and development costs increased by SEK 21.2 million to SEK 31.2 (10.0) million during the second quarter of 2019. Research and development costs for the first six months of 2019 increased by SEK 20.9 million to SEK 61.9 (41.0) million. The cost increase is related to the operation of the NefIgArd study for Nefecon where the first patient was included in the study in Q4 2018.

Sales and administration expenses

During the second quarter of 2019, sales and administration expenses increased by SEK 10.4 million to SEK 19.0 (8.6) million. For the first six months of 2019, the increase was SEK 12.8 million to SEK 28.8 (16.0) million. The increase for both the quarter and the first six months is mainly explained by transaction related costs in connection with the out-licensing of Nefecon to Everest Medicines in China, and for the initiation of commercial preparations for a potential future launch of Nefecon in the US.

Earnings

Net income (loss) for the period amounted to SEK 83.2 (-18.2) million for the second quarter of 2019 and SEK 40.6 (-56.4) million for the first six months of 2019, resulting in earnings per share before and after dilution of SEK 2.36 (-1.08) and SEK 2.35 (-1.08) respectively for the second quarter of 2019 and SEK 1.15 (-3.37) and SEK 1.15 (-3.37) respectively for the first half of 2019. Improvement in earnings for the second quarter and the first half of 2019 compared to the same periods last year, mainly derives from the above described revenue from the out-licensing of Nefecon in China to Everest Medicines.

Tax

No tax expenses were reported for the second quarter of 2019 (-) or the first six months of 2019 (-), as Calliditas has tax losses that is not capitalized since future income is not considered sufficiently secure to enable deferred tax assets to be capitalized.

Cash flow and cash position

The cash flow from operating activities amounted to SEK -59.3 (-36.6) million for the second quarter of 2019 and SEK -108.7 (-70.5) million for the first six months of 2019. The continued negative cash flow is according to plan and is mainly explained by the company's increased clinical activities in connection with the operation of the NefIgArd study for Nefecon. The USD 15 million payment from Everest Medicines for the Nefecon out-licensing in China was received after the end of the period and will have a positive impact on the cash flow in the third quarter.

The cash flow amounted to SEK -61.5 (-36.1) million for the second quarter of 2019 and SEK -111.0 (-40.4) million for the first six months of 2019. Cash and cash equivalents as of June 30, 2019, amounted to SEK 534.9 (17.0) million.

Changes in equity and number of shares

As of June 30, 2019, equity amounted to SEK 659.0 (7.3) million. The number of shares as of June 30, 2019, amounted to 35,202,347 (33,232,347).

Employees

As of June 30, 2019, the number of employees in Calliditas Therapeutics was 14 (10). The number of average employees in the second quarter of 2019 was 14 (10) and 13 (10) for the first six months of 2019.

Incentive programs

During the second quarter of 2019, the implementation began of the warrants program 2019/2022 for Calliditas staff and the LTIP 2019 stock option program for the Board of Directors, which both was decided by the Annual General Meeting in May, 2019. For more information, see Note 8.

Parent company

Since the operations for the parent company are consistent with those of the group in all material respects, the comments for the group are also relevant for the parent company.

Auditor's review

This report has not been reviewed by the company's 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 15, 2019

Board of Directors

Elmar Schnee	Bengt Julander	Thomas Eklund
Chairman of the Board	*Board member*	*Board member*
Diane Parks	Lennart Hansson	Hilde Furberg
Board member	*Board member*	*Board member*

Renée Aguiar-Lucander

CEO

Financial statements

Condensed consolidated income statement

		Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**	**2018**
Net sales	4	138,243	-	138,243	-	-
Total operating income		**138,243**	**-**	**138,243**	**-**	**-**
Operating expenses						
Research and development expenses		(31,191)	(10,000)	(61,931)	(41,033)	(99,260)
Sales and administration expenses		(18,996)	(8,558)	(28,797)	(16,027)	(33,937)
Other operating revenue[1]		567	351	1,053	596	715
Other operating expenses[1]		(3,237)	-	(5,906)	-	-
Total operating expenses		**(52,857)**	**(18,207)**	**(95,581)**	**(56,464)**	**(132,482)**
Operating profit (loss)		**85,386**	**(18,207)**	**42,662**	**(56,464)**	**(132,482)**
Net financial items		(2,219)	22	(2,051)	42	433
Profit (loss) before taxes		**83,167**	**(18,185)**	**40,611**	**(56,422)**	**(132,049)**
Income taxes		-	-	-	-	-
Net income (loss) for the period		**83,167**	**(18,185)**	**40,611**	**(56,422)**	**(132,049)**
Attributable to:						
Equity holder of the parent company		83,167	(18,185)	40,611	(56,422)	(132,049)
Earnings per share before dilution (SEK)		2.36	(1.08)	1.15	(3.37)	(5.09)
Earnings per share after dilution (SEK)		2.35	(1.08)	1.15	(3.37)	(5.09)

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

Condensed consolidated statement of comprehensive income

	Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Net income (loss) for the period	83,167	(18,185)	40,611	(56,422)	(132,049)
Other comprehensive income					
Currency translation effect	(4)	(2)	(15)	(7)	6
Total comprehensive income (loss)	**83,163**	**(18,187)**	**40,596**	**(56,429)**	**(132,043)**
Attributable to:					
Equity holder of the parent company	83,163	(18,187)	40,596	(56,429)	(132,043)
Total comprehensive income (loss)	**83,163**	**(18,187)**	**40,596**	**(56,429)**	**(132,043)**

Condensed consolidated statement of financial position

Amounts in SEK 000s	*Notes*	2019-06-30	2018-06-30	2018-12-31
Non-current assets				
Other material assets	2	7,413	132	107
Financial non-current assets		2,670	341	341
Total non-current assets		**10,083**	**473**	**448**
Current assets				
Other current assets		161,530	49,169	1,794
Cash and cash equivalents	6	534,863	17,023	646,175
Total current assets		**696,393**	**66,192**	**647,969**
Total assets		**706,476**	**66,665**	**648,417**
Shareholders' equity				
Share capital		1,408	1,329	1,408
Additional paid in capital		1,072,571	385,941	1,072,319
Retained earnings, including net loss for the period		(414,956)	(379,938)	(455,552)
Total shareholders' equity attributable to shareholders of the parent company	5,7	**659,023**	**7,332**	**618,175**
Non-current liabilities				
Provision for social security contributions incentive program	8	11	-	-
Other non-current liabilities	2	4,865	-	-
Total non-current liabilities		**4,876**	**-**	**-**
Current liabilities				
Accounts payable	6	32,481	5,941	22,643
Other current liabilities	2	3,313	42,895	904
Accrued expenses	6	6,783	10,497	6,695
Total current liabilities		**42,577**	**59,333**	**30,242**
Total liabilities and shareholders' equity		**706,476**	**66,665**	**648,417**

Condensed consolidation statement of changes in equity

		Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**	**2018**
Opening balance		575,608	24,941	618,175	33,176	33,176
Profit/loss of the period		83,167	(18,185)	40,611	(56,422)	(132,049)
Other comprehensive income		(4)	(2)	(15)	(7)	6
Comprehensive income (loss) for the period		83,163	(18,187)	40,596	(56,429)	(132,043)
Transaction with owners						
New issue of ordinary shares	7	-	578	-	578	738,650
Cost attributable to new share issue		-	-	-	-	(54,433)
Premiums received from warrants	8	216	-	216	-	2,826
Share based renumeration	8	36	-	36	8	-
Contribution from shareholders		-	-	-	29,999	29,999
Total transaction with owners		**252**	**578**	**252**	**30,585**	**717,042**
Closing balance		**659,023**	**7,332**	**659,023**	**7,332**	**618,175**

Condensed consolidated statement of cash flows

		Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**	**2018**
Operating activities						
Operating profit (loss)		85,386	(18,207)	42,662	(56,464)	(132,482)
Adjustment for non-cash-items		437	13	581	26	51
Interest received		-	6	-	6	6
Interest paid		(3,177)	(2)	(3,201)	(5)	(8)
Cash flow from operating activities before working capital		**82,646**	**(18,190)**	**40,042**	**(56,437)**	**(132,433)**
Cash flow from changes in working capital		(141,949)	(18,457)	(148,727)	(14,045)	4,242
Cash flow from operating activities		**(59,303)**	**(36,647)**	**(108,685)**	**(70,482)**	**(128,191)**
Cash flow from investing activities		(2,006)	-	(2,006)	-	-
Cash flow from financing activities	7	(138)	578	(267)	30,116	716,572
Cash flow for the period		**(61,447)**	**(36,069)**	**(110,958)**	**(40,366)**	**588,381**
Cash & cash equivalents, beginning of period		596,850	53,074	646,175	57,352	57,352
Net increase (decrease) in cash & cash equivalents		(61,447)	(36,069)	(110,958)	(40,366)	588,381
Exchange-rate difference in cash and cash equivalents		(540)	18	(354)	37	442
Cash & cash equivalents, end of period		**534,863**	**17,023**	**534,863**	**17,023**	**646,175**

Condensed parent company income statement

		Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	*Notes*	**2019**	**2018**	**2019**	**2018**	**2018**
Net sales	4	138,243	-	138,243	-	-
Gross profit		**138,243**	**-**	**138,243**	**-**	**-**
Operating expenses						
Research and development expenses		(31,191)	(10,000)	(61,931)	(41,033)	(99,260)
Sales and administration expenses		(19,341)	(8,527)	(29,141)	(15,956)	-
Other operating revenue[1]		560	351	1,038	596	(33,805)
Other operating expenses[1]		(3,236)	-	(5,906)	-	715
Total operating expenses		**(53,208)**	**(18,176)**	**(95,940)**	**(56,393)**	**(132,350)**
Operating profit (loss)		**85,035**	**(18,176)**	**42,303**	**(56,393)**	**(132,350)**
Net financial items		(2,155)	11	(1,979)	12	427
Profit (loss) before taxes		**82,880**	**(18,165)**	**40,324**	**(56,381)**	**(131,923)**
Income taxes		-	-	-	-	-
Net income (loss) for the period		**82,880**	**(18,165)**	**40,324**	**(56,381)**	**(131,923)**

Condensed parent company statement of other comprehensive income

	Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Net income (loss) for the period	82,880	(18,165)	40,324	(56,381)	(131,923)
Other comprehensive income	-	-	-	-	-
Total comprehensive income	**82,880**	**(18,165)**	**40,324**	**(56,381)**	**(131,923)**

Condensed parent company balance sheet

Amounts in SEK 000s	*Notes*	2019-06-30	2018-06-30	2018-12-31
Non-current assets				
Property, plant and equipment		199	132	107
Financial non-current assets		6,159	3,830	3,830
Total non-current assets		**6,358**	**3,962**	**3,937**
Current assets				
Other current assets		161,217	651,073	1,793
Cash and cash equivalents	6	534,225	16,621	645,903
Total current assets		**695,442**	**667,694**	**647,696**
Total assets		**701,800**	**671,656**	**651,633**
Shareholders' equity				
Share capital		1,408	1,329	1,408
Statutory reserve		3,092	3,092	3,092
Restricted equity		**4,500**	**4,421**	**4,500**
Additional paid in capital		1,069,072	987,218	1,069,072
Retained earnings, including net loss for the period		(411,496)	(379,498)	(452,222)
Non-restricted equity		**657,576**	**607,720**	**616,850**
Total shareholders' equity	5,8	**662,076**	**612,141**	**621,350**
Non-current liabilities				
Provision for social security contributions incentive program	8	11	-	-
Other non-current liabilities		-	77	77
Total non-current liabilities		11	77	77
Current liabilities				
Accounts payable	6	32,135	5,875	22,628
Other current liabilities		938	42,895	904
Accrued expenses	6	6,640	10,669	6,674
Total current liabilities		**39,713**	**59,439**	**30,206**
Total liabilities and shareholders' equity		**701,800**	**671,656**	**651,633**

Notes

Note 1 General information

This report covers the Swedish parent company Calliditas Therapeutics AB, Swedish corporate identity no. 556659-9766 and its subsidiaries. All the Group's significant business operations are conducted in the parent company.

The parent company is a Swedish public limited company registered in and with its registered office in Stockholm. The head office is located at Kungsbron 1, Stockholm, Sweden. Calliditas Therapeutics AB is listed at Nasdaq Stockholm in the Mid Cap segment with ticker CALTX.

The interim report for January – June, 2019, has been approved for publication on August 15, 2019, according to the Board of Director's decision.

This report may include forward looking statements. Actual outcomes may deviate from what has been stated. Internal factors such as successful management of research projects, and intellectual property rights may affect future results. There are also external conditions, e.g. the economic climate, political changes and competing research projects that may affect Calliditas results.

Note 2 Accounting policies

Calliditas applies International Financial Reporting standards (IFRS) as adopted by the European Union. Relevant accounting principles can be found on pages 34-36 of the Annual Report for 2018.

The ESMA (European Securities and Markets Authority) guidelines on alternative key performance ratios are applied, which means disclosure requirements regarding financial measures that are not defined in accordance with IFRS. For key ratios not defined by IFRS, see the Definitions and reconciliations of alternative performance measures.

The interim report for the group has been prepared in accordance with IAS 34 Interim Financial Reporting. The parent company applies the Swedish Financial Reporting Board recommendation RFR2 Accounting for legal entities. None of the new or amended standards and interpretations that became effective January 1, 2019, have had a significant impact on the company's financial reporting.

Change of accounting principle

From January 1, 2019, Calliditas has switched to presenting costs in the income statement based on function instead of on the basis of cost type. The purpose of the change is to provide more relevant information about the Group's and the parent company's financial results, as a function-divided presentation better reflects the practice in the industry in which the company operates. The change constitutes a voluntary change of accounting principle and is applied with full retroactivity. The effects of the change in the income statements for the preceding periods are shown below:

	Before adjustment	Adjustment	After adjustment
Group, Apr-Jun, 2018			
Research and development expenses	-	(10,000)	(10,000)
Sales and administration expenses	-	(8,558)	(8,558)
Other operating revenue	351	-	351
Other external operating expenses	(13,988)	13,988	-
Personnel expenses	(4,558)	4,558	-
Depreciation and amortization	(12)	12	-
Total operating expenses	**(18,207)**	**-**	**(18,207)**

	Before adjustment	Adjustment	After adjustment
Group, Jan-Jun, 2018			
Research and development expenses	-	(41,033)	(41,033)
Sales and administration expenses	-	(16,027)	(16,027)
Other operating revenue	596	-	596
Other external operating expenses	(49,699)	49,699	-
Personnel expenses	(7,336)	7,336	-
Depreciation and amortization	(25)	25	-
Total operating expenses	**(56,464)**	**-**	**(56,464)**
Group, Jan-Dec, 2018			
Research and development expenses	-	(99,260)	(99,260)
Sales and administration expenses	-	(33,937)	(33,937)
Other operating revenue	715	-	715
Other external operating expenses	(114,056)	114,056	-
Personnel expenses	(19,090)	19,090	-
Depreciation and amortization	(51)	51	-
Total operating expenses	**(132,482)**	**-**	**(132,482)**
Parent Company, Apr-Jun, 2018			
Research and development expenses	-	(10,000)	(10,000)
Sales and administration expenses	-	(8,527)	(8,527)
Other operating revenue	351	-	351
Other external operating expenses	(13,960)	13,960	-
Personnel expenses	(4,555)	4,555	-
Depreciation and amortization	(12)	12	-
Total operating expenses	**(18,176)**	**-**	**(18,176)**
Parent Company, Jan-Jun, 2018			
Research and development expenses	-	(41,033)	(41,033)
Sales and administration expenses	-	(15,956)	(15,956)
Other operating revenue	596	-	596
Other external operating expenses	(49,631)	49,631	-
Personnel expenses	(7,333)	7,333	-
Depreciation and amortization	(25)	25	-
Total operating expenses	**(56,393)**	**-**	**(56,393)**
Parent Company, Jan-Dec, 2018			
Research and development expenses	-	(99,260)	(99,260)
Sales and administration expenses	-	(33,805)	(33,805)
Other operating revenue	715	-	715
Other external operating expenses	(113,927)	113,927	-
Personnel expenses	(19,087)	19,087	-
Depreciation and amortization	(51)	51	-
Total operating expenses	**(132,350)**	**-**	**(132,350)**

The change has not had any effect on the Group's or the Parent Company's financial position, cash flows, or earnings per share, for any of the periods.

IFRS 16 Leasing

IFRS 16 is applied by the Group as of January 1, 2019. IFSR 16 replaces IAS 17, and according to the new standard, lessees must report the obligation to pay lease payments as a lease debt in the balance sheet. The right to use the underlying asset during the leasing period is reported as an asset. Depreciation of the asset is recognized in profit or loss as well as an interest on the lease debt. Leasing fees paid are reported partly as interest payment and partly as amortization of the lease liability. The standard excludes leasing agreements with a lease term of less than 12 months (short-term leases) and leasing agreements for assets that have a low value.

The standard means that the majority of existing leases are reported as assets and liabilities in the balance sheet. This means that the cost for these is reported divided into interest expenses and depreciation. In the parent company, the exception is applied in RFR 2 regarding leasing agreements. This means that the parent company's principles for reporting leases are unchanged. Calliditas applies the simplified transition method. The transition to IFRS 16 meant that the Group had the right to use assets and leasing liabilities of SEK 1,819 thousand as of January 1, 2019. The transition to IFRS 16 also meant that the operating profit for the Group for the first six months 2019 improved by SEK 66 thousand, and that the result for the period decreased by SEK 26 thousand compared with the corresponding accounting principles applied in the previous year.

Reconciliation of operational leasing commitments, *Amounts in SEK 000s*	
Commitments for operational leasing agreements December 31, 2018	**1,983**
Discounting effects	(164)
Reported leasing liabilities as of January 1, 2019	**1,819**

Leasing agreements, *Amounts in SEK 000s*	**Right of use assets**	**Lease liabilities**
Opening balance January 1, 2019	**1,819**	**1,819**
Additional agreements	7,527	7,527
Revaluation of agreements	-1,608	-1,624
Depreciation	-524	-
Amortization	-	-483
Outgoing balance on June 30, 2019	**7,214**	**7,239**

During the period, a revaluation of the agreement has taken place, as a result of changed assessments regarding whether a lease agreement for premises will be extended. Utility rights assets are reported in the line of tangible fixed assets, long-term portion of leasing liabilities are reported in the line of other non-current liabilities and short-term part of leasing liabilities is reported in the line of other current liabilities in the Group's consolidated statement of financial position.

Note 3 Risks and uncertainties in the group and the parent company

Operational risks

Research and drug development up to approved registration is subject to considerable risk and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to the technological risk such as the risk for insufficiency efficacy, intolerable side effects or manufacturing problems. Competing pharmaceuticals can capture market share or reach the market faster, or if competing research projects achieve better product profile, the

future value of the product portfolio may be lower than expected. The operations may also be impacted negatively by regulatory decisions, such as approvals and price changes.

Financial risk management

Calliditas' financial policy governing the management of financial risks has been designed by the Board of Directors and represents the framework of guidelines and rules in the form of risk mandated and limits for financial activities.

The Company is primarily affected by foreign exchange risk since the development costs for Nefecon are mainly paid in USD and EUR. Regarding the Group and parent company's financial risk management, the risks are essentially unchanged compared with the description in the annual report for 2018.

For more information regarding the operational- and financial risks, reference is made to the listing prospectus published in connection with IPO on Nasdaq Stockholm, pages 12-20, and page 28 in the Annual Report of 2018.

Note 4 Revenue

Revenue is reported when a promised product or service is transferred to the counterparty, which can be done over time or at a specific time. Revenue is the amount that the Group / Parent Company expects to receive as compensation for transferred goods or services.

The Group's and Parent Company's revenues during the period consisted of revenues for the out-licensing of Nefecon within the framework of the agreement with Everest Medicines on the out-licensing of Nefecon to China.

Revenue for out-licensing is reported at a time, which occurs when control over the intangible asset is transferred to the counterparty. Variable remuneration (for example, attributable to future regulatory or sales-based milestones) is not recognized until there is no longer any significant uncertainty as to whether these will occur. Compensation attributable to royalties is not recognized until the sale that results in the right to royalty arises. Revenue attributable to the supply of drug is recognized at a time when the control of the goods is transferred to the counterparty

The Group and the Parent Company have identified two performance commitments under the agreement: 1) Out-licensing and 2) Provision of drugs for conducting clinical trials. The share of the transaction amount attributable to the supply of drug for clinical trial has been calculated by calculating a price based on the cost of the goods, plus a normal trade margin. The proportion attributable to out-licensing has been calculated as a residual of the remaining transaction price after deduction of other performance commitments.

A breakdown of the Group's revenue looks as follows:

	Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
By type of revenue					
Licensing	138,243	-	138,243	-	-
Net sales	**138,243**	**-**	**138,243**	**-**	**-**
By geographic area					
Asia	138,243		138,243	-	-
Net sales	**138,243**	**-**	**138,243**	**-**	**-**

Note 5 Related-party transactions

During the reporting period, no significant related-party transactions have taken place. For information about incentive programs please see note 8.

Note 6 Financial instruments

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

Note 7 Equity

	Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Total registered shares at the beginning of period	35,202,347	16,673,000	35,202,347	16,673,000	16,673,000
New issue of shares during the period	-	16,559,347	-	16,559,347	18,529,347
Total registered shares at the end of period[1]	**35,202,347**	**33,232,347**	**35,202,347**	**33,232,347**	**35,202,347**
Share capital at the end of period, SEK thousand	1,408	1,329	1,408	1,329	1,408
Equity at the end of period, SEK thousand	659,023	7,332	659,023	7,332	618,175
Earnings per share before dilution, SEK	2.36	(1.08)	1.15	(3.37)	(5.09)
Earnings per share after dilution, SEK	2.35	(1.08)	1.15	(3.37)	(5.09)
Average number of shares before dilution for the period[1]	35,202,347	16,854,971	35,202,347	16,762,996	25,948,037
Average number of shares after dilution for the period[1]	35,436,980	16,854,971	35,335,047	16,762,996	25,948,037

[1] When calculating earnings per share after dilution, the weighted average is adjusted by the number of outstanding ordinary shares for the dilution effect of the weighted average of all potential ordinary shares with real value compared to the average price for the period.

Reserves for translation difference of SEK -49 (-47) thousand are included in equity as of June 30, 2019.

Note 8 Incentive programs

Warrants Program 2019/2022

During the second quarter of 2019, a total of 52,000 warrants were issued to employees and consultants in the Group. The reason is the company's need to recruit and retain key employees. The warrants in the Warrants Program 2019/2022 can be exercised between October 1, 2022 and December 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the company at a subscription price of SEK 74.50 per share. At the time of the grant, the warrants were valued at market value according to Black & Scholes valuation model.

Board LTIP 2019

This is a performance-based long-term incentive program for some members of Calliditas. A total of 57,032 share rights have been granted under the program during the second quarter of 2019. The share rights are subject to performance-based earnings based on the development of Calliditas share price during the period from the date of the 2019 AGM to 1 June 2022.

Summary of outstanding incentive programs

	Warrants allocated	Granted share rights	Total allocation 2019-06-30
Incentive program			
Warrants program 2017/2020	1,296 500		1,296,500
Warrants program 2018/2022	856,586		856,586
Warrants program 2019/2022	52,000		52,000
Board LTIP 2019		57,032	57,032
Total allocation June 30 2019	**2,205,086**	**57,032**	**2,262,188**

Definitions and reconciliations of alternative performance measures

Definitions of performance measures

Earnings per share before/after dilution	Earnings for the period divided by the average number of share before and after dilution. Diluted earnings per share is calculated by adjusting the weighted average number of common share outstanding to assume conversion of all dilutive potential common shares.
Share capital at the end of the period	Share capital at the end of respective period. The measure is extracted from the balance sheet.
Total outstanding shares at the beginning of period	Total outstanding shares at the beginning of respective period.
Total outstanding shares at the end of period	Total outstanding shares at the end of respective period.
Average number of outstanding shares during the period	Average number of outstanding shares of respective period.
Equity at the end of the period	Equity position at the end of respective period. The measure is extracted from the balance sheet.
Cash and cash equivalents at the end of the period	Cash and cash equivalents at the end of respective period. The measure is extracted from the balance sheet.

Definitions of alternative performance measures

Alternative key performance indicator	Definition	Reason for inclusion
Expenses relating to research and development/operating expenses	The total operating expenses attributable to research and development, divided by the total operating expenses.	The key performance indicator helps the reader of the financial statements to analyse the portion of the company's expenses that are attributable to the Company's core business.
Equity ratio at the end of the period %	The ratio at the end of respective period is calculated by dividing total shareholders' equity by total assets.	The equity ratio measures the proportion of the total assets that are financed by stockholders.

Reconciliations of alternative performance measures

	Apr-Jun		Jan-Jun		Jan-Dec
Amounts in SEK 000s	**2019**	**2018**	**2019**	**2018**	**2018**
Expenses relating to research and development/operating expenses, %					
Research and development expenses	(31,191)	(10,000)	(61,931)	(41,033)	(99,260)
Sales and administration expenses	(18,996)	(8,558)	(28,797)	(16,027)	(33,937)
Other operating revenue/expenses	(2,670)	351	(4,853)	596	715
Total operating expenses	**(52,857)**	**(18,207)**	**(95,581)**	**(56,464)**	**(132,482)**
Expenses relating to research and development/operating expenses, %	59%	55%	65%	73%	75%
Equity ratio at the end of the period %					
Total shareholders' equity at the end of the period	659,023	7,332	659,023	7,332	618,175
Total assets at the end of the period	706,476	66,665	706,476	66,665	648,417
Equity ratio at the end of the period %	**93%**	**11%**	**93%**	**11%**	**95%**

Financial calendar

Interim report for the period January 1 – September 30, 2019	November 14, 2019
Year-end report for the period January 1 – December 31, 2019	February 14, 2020
Interim report for the period January 1 – March 31, 2020	May 14, 2020

calliditas
THERAPEUTICS

Contact:

Renée Aguiar-Lucander
Chief Executive Officer

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

www.calliditas.com

This report has been prepared in a Swedish original and has been translated into English. In case of differences between the two, the Swedish version shall apply.