Q3

calliditas THERAPEUTICS

CALLIDITAS THERAPEUTICS AB (publ)

Interim Report January 1 – September 30, 2020

Expansion of pipeline

Key Figures

July 1 - September 30, 2020

- No net sales were recognized for the three months ended September 30, 2020 and 2019, respectively.
- Operating loss amounted to SEK 104.9 million and SEK 52.6 million for the three months ended September 30, 2020 and 2019, respectively.
- Loss before income tax amounted to SEK 137.9 million and SEK 50.1 million for the three months ended September 30, 2020 and 2019, respectively.
- Loss per share before and after dilution amounted to SEK 2.77 and SEK 1.30, for the three months ended September 30, 2020 and 2019, respectively.
- Cash amounted to SEK 1,396.9 million and SEK 805.1 million as of September 30, 2020 and 2019, respectively.

January 1 - September 30, 2020

- Net sales amounted to SEK 0.5 million and SEK 138.2 million for the nine months ended September 30, 2020 and 2019, respectively.
- Operating loss amounted to SEK 243.8 million and SEK 10.0 million for the nine months ended September 30, 2020 and 2019, respectively.
- Loss before income tax amounted to SEK 262.9 million and SEK 9.5 million for the nine months ended September 30, 2020 and 2019, respectively.
- Loss per share before and after dilution amounted to SEK 6.09 and SEK 0.26 for the nine months ended September 30, 2020 and 2019, respectively.

Significant Events During the Period July 1 – September 30, 2020, in summary

- In July 2020, Calliditas announced the exercise of the partial over-allotment option from the IPO on The Nasdaq Global Select Market. Calliditas was thereby provided with additional gross proceeds of approximately USD 6.9 million (approximately SEK 63 million) before deduction of issuance costs.
- In August 2020, Calliditas announced it has reached an agreement to acquire a controlling interest in Genkyotex SA, a leader in NOX inhibition therapies.

Significant Events After the Reporting Period, in summary

- In November 2020, Calliditas acquired a controlling interest in Genkyotex SA representing 62,7%.
- In November 2020, Calliditas announced positive topline results from Part A from the pivotal Phase 3 NefIgArd trial.

Investor Presentation November 12, 14:30 CET

Audio cast with teleconference, Q3 2020, November 12, 2020, 14:30 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q3-2020

Teleconference: SE: +46856642707 UK: +443333009034 US: +18332498405

CEO Statement

Expansion of pipeline

On August 13th, we announced a €19.8m acquisition of a majority stake of 62.7% in Genkyotex, a publicly listed life science company in France. After a successful closing of the controlling block, we plan to carry out a simplified mandatory tender offer with a view to acquire the remaining shares outstanding. These activities are targeted to take place in Q4 2020.

We are very excited about this acquisition, which complements our existing and long-standing focus on inflammatory disease. This provides us with a platform with anti-fibrotic and anti-inflammatory compounds, with which we believe can continue to address unmet medical need in orphan diseases and bring solutions to patients across many different therapeutic areas. Setanaxib, the lead compound, targets inhibition of NOX 1 and NOX 4 which are major drivers of fibrogenesis in multiple organs. They produce reactive oxygen species (ROS) and modulate signaling by oxidising signaling proteins, which drive multiple inflammatory and fibrogenic pathways. We believe that we have significant opportunities to leverage this platform to the benefit of patients suffering from fibrotic diseases. We believe that the late stage development, CMC and regulatory expertise which exists in Calliditas can significantly support and enhance the important fundamentals put in place by Genkyotex. We are confident that this will be value driving, for all the company's stakeholders, over the near and medium term.

During the third quarter, we continued to work very hard at ensuring that the NefIgArd trial progressed on track in order to achieve data read out on plan in Q4. Covid continues to be a major issue across the world and constant vigilance and focus of resources is necessary. We also spent significant time and resources on the continued recruitment of patients into Part B of the study. A significant addition to this effort was the recruitment by Everest Medicines of the first Chinese patient into the trial on September 7th. This was not only an important milestone for the NefIgArd trial itself, but also for the effort of bringing the first approved medication for IgA nephropathy (IgAN) to the Chinese market in a timely manner. Everest estimates that there are 2 million people in China living with IgAN, making it a significant health issue.

Whilst the third quarter saw a reduction of the infection levels of the corona pandemic in many parts of the world, it remained a poorly characterized and generally unknown virus which, after nine months of broad activity across the globe and still presents an elusive target for any real solution or effective treatment. During these ongoing uncertainties, we continue to manage and assess scenarios related to our clinical activities in order to continue to execute against our core strategy and deliver against our stated corporate goals. We hope that the intense research and development efforts for therapeutics and vaccines will bear fruit, thereby allowing us all to revert back to some kind of normalcy next year.

After the close of the quarter, on November 8th, we reported positive topline results from our pivotal Phase 3 trial, NefIgArd. The strong data set confirms the results seen in the successful Phase 2b trial and provides further support for locally treating IgAN at the source, offering patients hope of disease modification. We will now assemble the regulatory file and submit for accelerated approval with the

FDA and conditional approval with EMA, which is planned for Q1 and H1 respectively next year. This is an extraordinary achievement and speaks to the collective expertise and commitment of the entire team. There have not been many, if any, therapeutic Phase 3 studies which have been successfully designed and executed by an independent Swedish company for the last ten years, so this is truly an exceptional achievement. We look forward to the next chapter of the journey.

In focus: US election and healthcare costs

In the last quarterly report, I discussed the global impact of Covid-19 on the research and development climate as well as the unprecedented injection of capital into the healthcare sector following the start of the pandemic. In this quarter, however, the public focus has shifted more towards the US presidential election and its potential impact on drug pricing and overall healthcare costs in the US.

For a number of decades, across both Democratic and Republican administrations, there has been political pressure to control healthcare costs. These efforts have spanned from the failed "Hillarycare" in the early 1990's, to George W. Bush's Medicare Modernization Act in the 2000's, to "Obamacare" in 2010. Despite these efforts, healthcare costs in the US have continued to increase. In 2000, total healthcare expenditure, according to Health System Tracker by the KFF & Petersen Centre on Healthcare, amounted to $1.9tn reflecting 13.4% of GDP. By 2005, this had risen to $2.5tn and 15.5% of GDP, and by 2015 to $3.4tn and 17.6% of GDP, equating to $10,500 per capita (constant 2018 dollars).

While there has been a lot of focus on drug costs, over 50% of healthcare costs relate to hospital and physician services while only 9% relate to prescription drugs. This number was 7% in 1970, so while prescription drugs are significant, they are not the biggest contributor to the rapid growth of healthcare costs. However, given the increased amount out-of-pocket/co-payments associated with prescription drugs, pharmaceutical pricing has become an important political issue. Given the "separation of powers" within the US political system and the different regional interests at play, it has proven difficult to enact meaningful healthcare reform in the US. Thus, if the Democrats do win control of the Presidency and Senate whilst retaining the House, there will most likely be significant pressure for some kind of healthcare reform. Biden has talked about improving Obamacare by providing a public insurance option, meaning a government-run health insurance agency that would compete with private health insurance companies. The argument being that allowing for wider access to healthcare, having more people covered by insurance and taking preventative medication – as opposed to being hospitalized or visiting emergency rooms for primary care – might ultimately be better for the drug industry and society in general.

A new President would however inherit a once-in-a-century healthcare crisis. How that will impact overall priorities and healthcare reform is unclear. So far, a lot of the discussion has centered on the Affordable Care Act (ACA) also known as Obamacare. The ACA was initially fairly unpopular but has since grown in popularity, due to provisions related to pre-existing conditions and allowing adult children to stay on a parent's insurance. Trump has consistently been trying to repeal this Act since taking office in 2016 and is now attempting to get it overturned by the Supreme Court, a hearing which will start after the election. No clear Republican alternative to ACA has been presented, so the actual consequences of it being overturned are unclear. Biden has promised to strengthen the ACA in the case of an electoral victory. However, real changes to the system would need to involve Medicare and Medicaid, hospital & physician charges, PBMs and private insurance companies, making this an extraordinary complex and time-consuming exercise even with a broad political mandate. Will there be incremental changes to the healthcare landscape, both related to services and pharmaceuticals after the election irrespective of who ends up in the White House? Most likely yes, but I am not sure that we will see significant, wholesale changes over the next four years that would have a major negative impact on pharmaceutical companies operating in the US.

By the time that this gets published, we will all know the answer to the question: "Who will be the next US President?" Let's see what the future brings…

Renée Aguiar-Lucander, CEO

Business Overview

Nefecon – an overview

Calliditas' lead product candidate, Nefecon, is a novel oral formulation of budesonide - an established, highly potent local immunosuppressant - for the treatment of the autoimmune renal disease IgA nephropathy (IgAN). IgAN is a progressive, chronic disease, for which there is a high unmet medical need and no approved treatments. Over time, it results in deterioration of kidney function in patients, many of whom end up at risk of developing end-stage renal disease (ESRD) with the need for dialysis or kidney transplant. Nefecon is currently the only pharmaceutical candidate in development for IgAN that is intended to be disease-modifying. It has been granted orphan drug designation for the treatment of IgAN in the United States and the European Union.

Calliditas retains worldwide rights to Nefecon other than in Greater China and Singapore, where we have established a strategic collaboration and are out-licensing development and commercialization to Everest Medicines. Nefecon is the only compound in development for IgAN that has met the key primary and secondary endpoints in a randomized, double-blind, placebo-controlled Phase 2b clinical trial. In this trial of 150 patients, treatment with Nefecon was associated with a statistically significant and clinically meaningful reduction of protein in the urine, or proteinuria, and stabilization of kidney function with a generally well-tolerated safety profile. Calliditas is currently conducting a global pivotal Phase 3 clinical trial, from which we reported positive top-line data from Part A in the fourth quarter of 2020.

Nefecon is presently the only pharmaceutical candidate in development that is designed to target the ileum, with the goal of being a disease-modifying treatment. Although IgAN manifests in the kidney, most scientific studies have found that the pathogenesis of IgAN begins in the ileum. Patients with IgAN have elevated levels of a subclass of IgA antibodies produced in the gut that lack units of galactose, a type of sugar, at their hinge region.

Nefecon is designed to release a high dose of a locally acting immunosuppressive agent in the ileum to reduce the formation of secretory galactose-deficient IgA antibodies and their appearance in the blood. Nefecon's active ingredient is budesonide that has been used for decades in other indications. After the active ingredient has been released and has had its effect in the intestinal mucosa, it enters the liver, where 90% is cleared in first pass metabolism, resulting in the inactivation of a majority of the active ingredient before the substance reaches the systemic circulation. This high metabolism limits systemic immunosuppressive activity and avoids the significant side effects associated with the systemic corticosteroids that are currently used off-label to treat IgAN, of which only 20% to 30% are cleared in first pass metabolism.

The NefIgArd study

Calliditas is currently conducting a global, pivotal Phase 3 clinical trial in IgAN, referred to as NefIgArd. NefIgArd is a double-blind, placebo-controlled, two-part trial designed to evaluate reduction of the surrogate marker proteinuria as its primary endpoint, the same endpoint used in our previously completed Phase 2b NEFIGAN clinical trial. The study is divided into two parts: a treatment part (Part A) and an observational part (Part B).

Part A is a pivotal efficacy and safety trial that we expect to form the basis for submissions of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). The primary endpoint of Part A is the decrease in proteinuria in the first 200 randomized and dosed patients. In addition, a secondary endpoint of Part A is the difference in kidney function between treated and placebo patients as measured by eGFR over a nine-month period, which is also expected to

be informative of the primary endpoint of Part B. In November 2020, Calliditas announced positive topline results from Part A, where the trial met both its primary objective and its key secondary endpoint. On the basis of these results, Calliditas plans to submit for accelerated approval in the United States with the FDA in Q1 2021 followed by a submission for conditional approval in European Union with the EMA in H1 2021.

Part B of the trial is a post-approval trial designed to confirm the long-term clinical benefit of observed proteinuria reduction. Following completion of enrollment in Part A in December 2019, Calliditas is now continuing to recruit an additional 160 patients during 2020 in order to power Part B to assess the difference in kidney function between treated and placebo patients as measured by eGFR over a two-year period from the start of dosing of each patient. Despite a slowing in recruitment rates due to the COVID-19 pandemic, we expect to report data from Part B in 2022/2023, based on existing patients recruited and expected enrollment in China.

Across both parts, NefIgArd will enroll a total of 360 patients and generate nine months of dosing data, as well as an aggregate of 15 months of follow-up data from Parts A and B. If approved, Calliditas intends to market and commercialize Nefecon in the United States as an on-label treatment specifically designed to have a disease-modifying effect for IgAN by preserving kidney function and thereby avoiding progression to ESRD.

IgA Nephropathy – an orphan disease with great unmet medical need

IgAN, sometimes referred to as Berger's disease, is a serious progressive autoimmune disease of the kidney, in which up to 50% of patients end up at risk of developing ESRD within ten to twenty years. Although IgAN manifests in the kidney, most scientific studies have found that the pathogenesis of IgAN begins in the ileum, where masses of lymphatic tissue, known as Peyer's patches, produce secretory IgA antibodies. IgA antibodies play a key role in the immune system by protecting the body from foreign substances, such as food-derived factors, bacteria and viruses.

Patients with IgAN have elevated levels of a subclass of IgA antibodies produced in the gut that lack units of galactose, a type of sugar, at their hinge region. The hinge region is a flexible amino acid stretch in the central part of the heavy chains of the IgA antibody. In IgAN patients, a combination of genetic predisposition and environmental, bacterial or dietary factors are presumed to lead to an increased production of these galactose-deficient IgA antibodies, potentially in combination with increased intestinal permeability, leading to these antibodies appearing in the blood. The galactose-deficient IgA antibodies are immunogenic when found in the circulation, which triggers autoantibodies, which are antibodies created by the body in response to a constituent of its own tissue. This in turn leads to the formation of pathogenic immune complexes, or clusters of antibodies, which deposit in the membranes of the glomeruli, the kidney's filtration apparatus. These trapped immune complexes initiate an inflammatory cascade that damages the membranes, resulting in protein and blood leaking into the urine. Ultimately the glomeruli are destroyed, reducing the kidney's ability to remove waste products from the blood. As the disease progresses, waste products that are normally removed from the blood accumulate, resulting in potentially life-threatening complications that in many patients will lead to the need for dialysis or kidney transplant.

Despite a need for new therapies, there have been few new drugs developed for chronic kidney diseases during the last decade and there is no approved therapy for IgAN. Patients with IgAN are typically initially given antihypertensive medications, as recommended by the non-profit organization Kidney Disease: Improving Global Outcome (KDIGO). This treatment regimen initially

attempts to manage the symptoms of IgAN by decreasing blood pressure and reducing proteinuria but does not address the underlying cause of IgAN. Over time, physicians attempt to control disease progression with a variety of off-label treatments, as a significant proportion of patients experience continued deterioration of kidney function, with no approved treatment options currently available.

For IgAN patients whose disease has progressed, clinicians may treat patients with systemic immunosuppressive agents, primarily consisting of high doses of systemic corticosteroids, such as prednisone, prednisolone and methylprednisolone. While some published reports indicate that these agents may reduce proteinuria, this high dosing of systemic corticosteroids is also associated with a wide range of adverse events, including high blood pressure, weight gain, diabetes, serious infections and osteoporosis. For patients who ultimately develop ESRD, the standard of care is dialysis or kidney transplant, which represents a significant health economic burden as well as a material impact on patients' quality of life.

IgAN is an orphan disease that we estimate affects approximately 130,000 to 150,000 people in the United States and approximately 200,000 people in Europe. A significantly higher prevalence has been observed in Asia, including Greater China, where IgAN has historically been a leading cause of ESRD. We estimate that IgAN affects approximately two million people in Greater China and approximately 180,000 people in Japan. Calliditas estimates the U.S. market opportunity for IgAN to be approximately $9.0 billion to $10.0 billion annually, based on our estimate of the prevalence of the disease in the United States and primary market research conducted by IQVIA that Calliditas commissioned to assess preliminary reimbursement levels perceived acceptable by U.S.-based payors. In this market, Calliditas intends to primarily focus on treating those IgAN patients that are at risk of progressing to ESRD.

Liver orphan indications

Beyond IgAN, Calliditas is exploring applications of Nefecon or its active ingredient for other autoimmune diseases in which it may have therapeutic potential, such as Primary biliary cholangitis (PBC) and Autoimmune hepatitis (AIH).

Calliditas is initially evaluating Nefecon for the treatment of PBC, a progressive and chronic autoimmune disease of the liver that causes damage to the small bile ducts that drain bile from the liver. This damage can result in cholestasis and the destruction of the bile ducts, which leads to liver cell damage and ultimately liver failure, resulting in the need for a liver transplant. There are currently no approved therapies that specifically address the autoimmune response that is believed to drive PBC, nor the inflammatory consequences of this autoimmune response.

Nefecon is designed to deliver high peak concentrations of its active ingredient to the intestine, which is then transported directly to the liver in order to locally reduce the autoimmune processes that drive PBC. Calliditas has received orphan drug designation for the treatment of PBC by the FDA.

In addition, Calliditas has in-licensed Budenofalk 3 mg oral capsules from the German pharmaceutical company Dr. Falk Pharma GmbH, or Falk Pharma, in order to obtain regulatory approval and commercialize Budenofalk in the United States for the treatment of AIH, another rare immune inflammatory liver indication. Budenofalk has been tested in a large randomized, controlled clinical trial in AIH patients and is approved for the treatment of AIH in several countries in Europe, but there has been no clinical development or regulatory approval in the United States. Budenofalk is a formulation of budesonide originally developed to treat Crohn's disease which we believe has the potential to complement our activities in the United States. Calliditas has received orphan drug designation for the treatment of AIH using budesonide by the FDA and plan to discuss the development plans with the FDA for AIH in 2020 and, subject to any further impact from the COVID-19 pandemic, we plan to discuss the development plans with the FDA for PBC in the first quarter of 2021.

Significant Events During the Period January 1 – September 30, 2020

- In January 2020, EMA Paediatric Committee (PDCO) adopted a positive opinion on the Paediatric Investigation Plan (PIP) for Nefecon for the treatment of primary IgA nephropathy. With successful completion of the agreed PIP, Nefecon would be eligible for up to an additional two years of marketing exclusivity in the EU, on top of the ten-year EU market exclusivity after market approval.
- In March 2020, Calliditas held an Extra General Meeting where authorization for the Board of Directors to issue up to 11 million new shares for a potential equity offering and listing in the United States was approved. At the meeting the adoption of new articles of association and the adoption of a new incentive program were also approved.
- In April 2020, Calliditas announced that Dr. Richard Philipson had been appointed as Chief Medical Officer (CMO). He is a physician with 24 years of experience in the pharmaceutical industry with over 16 years at GSK and his most recent employment was as CMO at Trizell Ltd. Having worked in both large pharmaceutical companies and smaller biotechs, Dr. Philipson has extensive experience in rare diseases, having brought several products from early development to the market.
- In April 2020, Calliditas anticipated that the COVID-19 pandemic will not significantly impact the ongoing clinical activities related to NefIgArd study. This was due to the facts that the Part A of the study was fully recruited in December 2019, that Nefecon is an oral formulation which patients are able to take at home, and that the trial is global and requires limited interaction among participants and the healthcare system. The overall impact of the COVID-19 pandemic on the study has been limited.
- In June 2020, Calliditas completed an initial public offering on The Nasdaq Global Select Market in the United States, which was completed by the issuance of 9,230,770 new common shares for gross proceeds of approximately USD 90 million (approximately SEK 828 million) before deduction of issuance costs. Trading of the ADSs on The Nasdaq Global Select Market commenced on June 5, 2020, under the symbol “CALT”.
- In June 2020, the Annual General Meeting (AGM) of Calliditas was held and, among other things, the AGM resolved on the election of Molly Henderson to the Board of Directors.
- In July 2020, the exercise of the partial over-allotment option from the IPO on The Nasdaq Global Select Market was completed. Calliditas was thereby provided with additional gross proceeds of approximately USD 6.9 million (approximately SEK 63 million), which means that Calliditas has been provided with in total approximately USD 96.9 million (approximately SEK 891 million) in gross proceeds from the U.S. IPO before deduction of issuance costs.
- In August 2020, Calliditas announced it has reached an agreement to acquire a controlling interest in Genkyotex SA, a leader in NOX inhibition therapies.

Significant Events After the Reporting Period

- In 2020, Calliditas acquired a controlling interest in Genkyotex SA, a biopharmaceutical company specializing in NOX therapies with offices in France and Switzerland. Its unique platform enables the identification of orally available small-molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis and inflammation. The purpose of the acquisition is it adds a late-stage orphan pipeline asset and platform in inflammation and fibrosis to Calliditas product portfolio in orphan diseases.

  Calliditas acquired 7,236,515 ordinary shares of Genkyotex from Genkyotex's largest shareholders and management team (the "Block Sellers"), representing 62.7% of the share capital and voting rights for EUR 19.8 million in cash at EUR 2.73 per share. The acquisition date was November 3, 2020, when Calliditas acquired a controlling influence over Genkyotex.

  A mandatory simplified cash tender offer on the same terms for the remaining outstanding shares will be launched. Total acquisition cost for 100% of Genkyotex shares outstanding will amount to approximately EUR 31.7 million, in addition to this a potential future value relating to contingent rights amounting to a maximum of EUR 55 million, subject to future regulatory approvals of Setanaxib.

  The accounting of the business combination could not be initiated at the time of approval of these interim condensed consolidated financial statements, as Calliditas did not have access to adequate financial information. The company has therefore not yet been able to present a preliminary Purchase price allocation (PPA).

- In November 2020, Calliditas announced positive topline results from Part A of the global Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon versus placebo in patients with primary IgA nephropathy (IgAN).

  The trial met its primary objective of demonstrating a statistically significant reduction in urine protein creatinine ratio, UPCR or proteinuria, after nine months of treatment with 16 mg of Nefecon compared to placebo, with significant continued improvement at 12 months. The trial also met the key secondary endpoint showing a statistically significant difference in estimated glomerular filtration rate or eGFR after nine months of treatment with Nefecon compared to placebo. Collectively the efficacy data from nine months treatment with 16 mg of Nefecon indicated a significant and beneficial effect on key factors correlated to the progression to end stage renal disease (ESRD) for IgAN patients.

  On the basis of these results, Calliditas plans to submit for accelerated approval with the US Food and Drug Administration (FDA) in Q1 2021 followed by a submission for conditional approval with the European Medicines Agency in H1 2021.

Financial Overview

Key Figures

(SEK in thousands, except share amounts or as otherwise indicated)	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2020	2019	2020	2019	2019
Net sales	-	-	474	138,243	184 829
Research and development expenses	(64,887)	(46,186)	(167,379)	(108,117)	(149,826)
Research and development expenses/ Total operating expenses in %[1]	62%	88%	69%	73%	70%
Operating loss	(104,891)	(52,638)	(243,779)	(9,976)	(28,019)
Loss before income tax for the period	(137,942)	(50,139)	(262,878)	(9,528)	(32,501)
Loss per share before and after dilution	(2.77)	(1.30)	(6.09)	(0.26)	(0.88)
Cash flow from/(used in) operating activities	(103,316)	83,109	(189,107)	(25,576)	(71,011)

(SEK in thousands, except share amounts or as otherwise indicated)	September 30,		December 31,
	2020	2019	2019
Total registered shares at the end of period	49,941,584	38,707,638	38,707,638
Equity at the end of the period	1,376,788	809,967	788,071
Equity ratio at the end of the period in %[1]	96%	96%	93%
Cash at the end of the period	1,396,869	805,075	753,540

[1] Alternative performance measure, see definitions on page 25

January – September 2020

Revenue

Net sales amounted to SEK 0.5 million and SEK 138.2 million for the nine months ended September 30, 2020 and 2019, respectively. There were no net sales recognized for the three months ended September 30, 2020 and 2019, respectively. The decrease by SEK 137.7 million were derived from the out-licensing of Nefecon for China as part of the license agreement with Everest Medicines, which occurred in 2019. In 2020, the net sales were derived from the delivery of Nefecon to China with Everest Medicines. For additional information see Note 4.

Operating Expenses

Total operating expenses amounted to SEK 104.9 million and SEK 52.6 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, total operating expenses amounted to SEK 244.3 million and SEK 148.2 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 64.9 million and SEK 46.2 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, research and development expenses amounted to SEK 167.4 million and SEK 108.1 million, respectively. The increase of SEK 18.7 million for the third quarter and SEK 59.3 million for the nine months ended September 30, 2020 is both primarily due to the

increased activity in the NefIgArd study and increased expenses for Nefecon product development compared to the same periods last year.

Administrative and Selling Expenses

Administrative and selling expenses amounted to SEK 41.0 million and SEK 10.3 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, administrative and selling expenses amounted to SEK 77.8 million and SEK 39.1 million, respectively. The increase of SEK 30.7 million for the third quarter and SEK 38.7 million for the nine months ended September 30, 2020 and 2019 is primarily due to the increased activity and increase of headcount in the pre-commercial organization and to expenses for the completion of the initial public offering and listing on The Nasdaq Global Select Market in the United States and the ongoing acquisition of Genkyotex SA.

Other Operating Incomes and Expenses

Other operating income amounted to SEK 1.0 million and SEK 3.8 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, other operating income amounted to SEK 1.0 million and SEK 3.5 million, respectively. The decrease for both periods was primarily relating to disadvantageous exchange rate development on operating receivables and liabilities.

No other operating expenses were recognized for the three months ended September 30, 2020 and 2019, respectively, as well as, for the nine months ended September 30, 2020. For the nine months ended September 30, 2019 other operating expenses amounted to SEK 4.5 million. The decrease for the periods primarily relates to a more favorable exchange rate development on operating liabilities.

Net Financial Income/(Expenses)

Net financial income/(expenses) amounted to (SEK 33.1 million) and SEK 2.5 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, net financial income/(expenses) amounted to (SEK 19.1 million) and SEK 0.5 million, respectively. The decrease of SEK 35.6 million for the three months ended September 30, 2020 and 2019 and the decrease of SEK 19.6 million for the nine months ended September 30, 2020 and 2019 are both primarily derived by unrealized foreign currency transaction losses on cash accounts, primarily due to a weakened USD against SEK.

Tax

Income tax expenses are, in all material respects, consistent period over period and primarily relates to the U.S. subsidiary Calliditas Therapeutics Inc. The Group's tax losses carried forward have not been recognized as deferred tax assets. Deferred tax assets will be recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized.

Result for the Period

For the three months ended September 30, 2020 and 2019, loss for the period amounted to SEK 138.0 million and SEK 50.1 million, and the corresponding loss per share before and after dilution amounted to SEK 2.77 and SEK 1.30, respectively. The increase in the loss for the period were primarily derived from the increased activity in R&D, the increased activity in the pre-commercial organization, and to expenses for the completion of the IPO on The Nasdaq Global Select Market in the United States and to the negative effect of the net financial income/(expenses).

For the nine months ended September 30, 2020 and 2019, loss for the period amounted to SEK 263.1 million and SEK 9.5 million, and the corresponding loss per share before and after dilution

amounted to SEK 6.09 and SEK 0.26, respectively. The increase in the loss for the period were primarily derived from revenues from the out-licensing of Nefecon for China as part of the license agreement with Everest Medicines, which occurred in the second quarter 2019. Furthermore, the increase in the loss for the period were derived from the increased expenses relating to the increased activity in R&D, to the pre-commercial organization and to the IPO on The Nasdaq Global Select Market in the United States in 2020.

Cash Flow and Cash Position

Cash flow from/(used in) operating activities amounted to (SEK 103.3 million) and SEK 83.1 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, cash flow from/(used in) operating activities amounted to (SEK 189.1 million) and (SEK 25.6 million), respectively. The cash flow used in operating activities during these periods are explained by the Group's increased clinical activities as well as work within the Group's administrative and commercial functions.

The Group had non-material cash flows used in investing activities for both the three months ended and the nine months ended September 30, 2020. For the three months ended September 30, 2019 cash flow used in investing activities amounted to SEK 15.8 million and for the nine months ended cash flow used in investing activities amounted to SEK 17.8 million and were derived from the in-licensing of Budenofalk 3mg from Dr. Falk Pharma.

Cash flow from financing activities amounted to SEK 70.2 million and SEK 200.4 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, cash flow from financing activities amounted to SEK 847.9 million and SEK 200.1 million, respectively. The decrease in cash flow from financing activities for the three months ended September 30, 2020 and 2019, was primarily due to the direct share issue of SEK 210.3 million, which was completed in July 2019 compared to the exercise of the partial over-allotment option from the U.S. IPO on The Nasdaq Global Select Market in July 2020. The increase in cash flow from financing activities for the nine months ended September 30, 2020 and 2019, was primarily due to the initial public offering, as well as, the exercise of the partial over-allotment option, on The Nasdaq Global Select Market and the exercise of the warrant program 2017/2020.

Net increase/(decrease) in cash amounted to (SEK 33.1 million) and SEK 267.7 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, net increase/(decrease) in cash amounted to SEK 658.8 million and SEK 156.7 million, respectively. Cash amounted to SEK 1,396.9 million and SEK 805.1 million as of September 30, 2020 and 2019, respectively.

Changes in Shareholders' Equity and Number of Shares

Shareholders' equity amounted to SEK 1,376.8 million and SEK 810.0 million as of September 30, 2020 and 2019, respectively. The number of shares amounted to 49,941,584 and 38,707,638 as of September 30, 2020 and 2019, respectively. The increase in the number of shares between the periods is due to the initial public offering on The Nasdaq Global Select Market in the United States of 9.2 million new common shares in June 2020 and the following exercise of the partial over-allotment option from the IPO of 0.7 million new common shares in July 2020. Furthermore, during the period the increase is due to the exercise of the Warrant Program 2017/2020 of 1.3 million new common shares.

Personnel

The number of employees were 23 and 14 employees as of September 30, 2020 and 2019, respectively. The total number of full-time equivalent (FTE), including the consultants, were 34 and 21 people as of September 30, 2020 and 2019, respectively. The average number of employees were 24 and 14 employees for the three months ended September 30, 2020 and 2019,

respectively and 20 and 13 for the nine months ended September 30, 2020 and 2019, respectively.

Incentive Programs

During the third quarter of 2020, Calliditas implemented an option program for employees and key consultants in the company ("ESOP 2020"). 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.

Stockholm November 12, 2020

Renée Aguiar-Lucander

CEO

Review report

Calliditas Therapeutics AB, corporate identity number 556659-9766

Introduction

We have reviewed the condensed interim report for Calliditas Therapeutics AB as at September 30, 2020 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 *Review of Interim Financial Statements Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

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

Stockholm 12 November 2020

Ernst & Young AB

Anna Svanberg
Authorized Public Accountant

Financial Statements

Condensed Consolidated Statements of Income

		Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
(SEK in thousands, except per share amounts)	Notes	2020	2019	2020	2019	2019
Net sales	4	-	-	474	138,243	184,829
Research and development expenses		(64,887)	(46,186)	(167,379)	(108,117)	(149,826)
Administrative and selling expenses		(41,037)	(10,295)	(77,843)	(39,092)	(62,882)
Other operating income		1,033	3,843	969	3,515	4,385
Other operating expenses		-	-	-	(4,525)	(4,525)
Operating loss		**(104,891)**	**(52,638)**	**(243,779)**	**(9,976)**	**(28,019)**
Net financial income/(expenses)		(33,051)	2,499	(19,099)	448	(4,482)
Loss before income tax		**(137,942)**	**(50,139)**	**(262,878)**	**(9,528)**	**(32,501)**
Income tax expense		(80)	-	(185)	-	(77)
Loss for the period attributable to shareholders of the Parent Company		**(138,022)**	**(50,139)**	**(263,063)**	**(9,528)**	**(32,578)**
Loss per share before and after dilution		(2.77)	(1.30)	(6.09)	(0.26)	(0.88)

Condensed Consolidated Statements of Comprehensive Income

		Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
(SEK in thousands)	Notes	2020	2019	2020	2019	2019
Loss for the period		(138,022)	(50,139)	(263,063)	(9,528)	(32,578)
Other comprehensive income						
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:						
Exchange differences on translation of foreign operations		(22)	42	(20)	27	(11)
Total other comprehensive loss		**(138,044)**	**(50,097)**	**(263,083)**	**(9,501)**	**(32,589)**
Total comprehensive loss attributable to shareholders of the Parent Company		**(138,044)**	**(50,097)**	**(263,083)**	**(9,501)**	**(32,589)**

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	September 30, 2020	September 30, 2019	December 31, 2019
ASSETS				
Non-current assets				
Intangible assets		16,066	15,775	16,066
Equipment		89	110	104
Right-of-use assets		4,144	6,587	5,959
Non-current financial assets		2,111	1,939	1,939
Total non-current assets		**22,410**	**24,411**	**24,068**
Current assets				
Accounts receivable		-	-	46,586
Other current assets	6	20,904	11,360	21,006
Cash		1,396,869	805,075	753,540
Total current assets		**1,417,773**	**816,435**	**821,132**
TOTAL ASSETS		**1,440,183**	**840,846**	**845,200**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Share capital		1,998	1,548	1,548
Additional paid-in capital		2,126,016	1,273,473	1,274,664
Retained earnings, including net loss for the period		(751,226)	(465,054)	(488,141)
Total shareholders' equity attributable to shareholders of the Parent Company	7,8	**1,376,788**	**809,967**	**788,071**
Non-current liabilities				
Provisions	8	1,931	45	175
Other non-current liabilities		1,034	4,210	3,584
Total non-current liabilities		**2,965**	**4,255**	**3,759**
Current liabilities				
Accounts payable		19,872	14,941	24,384
Other current liabilities		3,922	3,285	3,471
Accrued expenses and deferred revenue		36,636	8,398	25,515
Total current liabilities		**60,430**	**26,624**	**53,370**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,440,183**	**840,846**	**845,200**

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Notes	September 30, 2020	September 30, 2019	December 31, 2019
Opening shareholders' equity		**788,071**	**618,175**	**618,175**
Loss for the period		(263,063)	(9,528)	(32,578)
Other comprehensive income/(loss)		(20)	27	(11)
Total comprehensive income/(loss) for the period		**(263,083)**	**(9,501)**	**(32,589)**
Transactions with owners:				
New share issue	7	891,388	210,317	210,317
Cost attributable to new share issue	7	(97,686)	(10,915)	(10,915)
Exercise of warrants	7	54,919	-	-
Premiums from warrants issuance		-	1,749	2,834
Share-based payments	8	3,179	142	249
Total transactions with owners		**851,800**	**201,293**	**202,485**
Closing shareholders' equity		**1,376,788**	**809,967**	**788,071**

Condensed Consolidated Statements of Cash Flows

		Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
(SEK in thousands)	Notes	2020	2019	2020	2019	2019
Operating activities						
Operating loss		(104,891)	(52,638)	(243,779)	(9,976)	(28,019)
Adjustment for non-cash-items		4,937	857	6,866	1,438	2 308
Interest received		-	-	-	-	926
Interest paid		(60)	(117)	(321)	(219)	(325)
Income taxes paid		(427)	-	(427)	-	-
Cash flow used in operating activities before changes in working capital		**(100,441)**	**(51,898)**	**(237,661)**	**(8,757)**	**(25,110)**
Cash flow from/(used in) changes in working capital		(2,875)	135,007	48,554	(16,819)	(45,901)
Cash flow from/(used in) operating activities		**(103,316)**	**83,109**	**(189,107)**	**(25,576)**	**(71,011)**
Cash flow used in investing activities		(1)	(15,775)	(2)	(17,781)	(18,072)
Cash flow used in investing activities		**(1)**	**(15,775)**	**(2)**	**(17,781)**	**(18,072)**
New share issue		63,388	210,317	891,388	210,317	210,317
Cost attributable to new share issue		(19,157)	(10,915)	(95,937)	(10,915)	(12,664)
Premiums from warrants issuance		26,591	1,533	54,919	1,749	2,834
Repayment of loans		(636)	(580)	(2,488)	(1,063)	(1,652)
Cash flow from financing activities		**70,186**	**200,355**	**847,882**	**200,088**	**198,835**
Net increase/(decrease) in cash		**(33,131)**	**267,689**	**658,773**	**156,731**	**109,752**
Cash at the beginning of the period		**1,459,569**	**534,863**	**753,540**	**646,175**	**646,175**
Net foreign exchange gains/(loss) on cash		(29,569)	2,523	(15,444)	2,169	(2,387)
Cash at the end of the period		**1,396,869**	**805,075**	**1,396,869**	**805,075**	**753,540**

Condensed Parent Company Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Year Ended December 31, 2019
Net sales	4	-	-	474	138,243	184,829
Research and development expenses		(64,888)	(46,186)	(167,380)	(108,117)	(149,826)
Administrative and selling expenses		(36,236)	(10,248)	(73,582)	(39,389)	(63,410)
Other operating income		1,032	3,843	969	3,515	4,385
Other operating expenses		-	-	-	(4,540)	(4,540)
Operating loss		**(100,092)**	**(52,591)**	**(239,519)**	**(10,288)**	**(28,562)**
Net financial income/(expenses)		(32,980)	2,614	(18,741)	635	(7,624)
Loss before income tax		**(133,072)**	**(49,977)**	**(258,260)**	**(9,653)**	**(36,186)**
Income tax expense		-	-	-	-	-
Loss for the period		**(133,072)**	**(49,977)**	**(258,260)**	**(9,653)**	**(36,186)**

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Notes	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019	Year Ended December 31, 2019
Loss for the period		(133,072)	(49,977)	(258,260)	(9,653)	(36,186)
Other comprehensive income/(loss)		-	-	-	-	-
Total comprehensive income/(loss)		**(133,072)**	**(49,977)**	**(258,260)**	**(9,653)**	**(36,186)**

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	September 30, 2020	September 30, 2019	December 31, 2019
ASSETS				
Non-current assets				
Intangible assets		16,066	15,775	16,066
Equipment		86	110	104
Non-current financial assets		3,665	5,428	2,040
Total non-current assets		**19,817**	**21,313**	**18,210**
Current assets				
Accounts receivable		-	-	46,586
Other current assets	6	26,666	11,540	21,005
Cash		1,396,277	804,146	752,448
Total current assets		**1,422,943**	**815,686**	**820,039**
TOTAL ASSETS		**1,442,760**	**836,999**	**838,249**
SHAREHOLDERS' EQUITY AND LIABILITIES				
Restricted Shareholders' equity				
Share capital		1,998	1,548	1,548
Statutory reserve		3,092	3,092	3,092
		5,090	**4,640**	**4,640**
Non-restricted shareholders' equity				
Share premium reserve		2,116,721	1,268,334	1,268,334
Retained earnings		(482,211)	(450,181)	(448,989)
Net profit/(loss) for the period		(258,260)	(9,653)	(36,186)
		1,376,250	**808,500**	**783,159**
Total shareholders' equity	7,8	**1,381,340**	**813,140**	**787,799**
Non-current liabilities				
Provisions	8	1,931	45	175
Other non-current liabilities		105	-	50
Total non-current liabilities		**2,036**	**45**	**225**
Current liabilities				
Accounts payable		19,636	14,876	24,362
Other current liabilities		3,973	836	1,332
Accrued expenses and deferred revenue		35,775	8,102	24,531
Total current liabilities		**59,384**	**23,814**	**50,225**
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		**1,442,760**	**836,999**	**838,249**

Notes to Condensed Consolidated Financial Statements

Note 1 Description of Business

Calliditas Therapeutics AB (publ) ("Calliditas" or the "Parent Company"), with corporate registration number 556659-9766, and its subsidiaries (collectively, the "Group") conduct development activities in pharmaceuticals. These interim condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the nine months ended September 30, 2020 and September 30, 2019. All the Group's significant business operations are conducted in the Parent Company.

Calliditas is a Swedish public limited company registered in and with its registered office in Stockholm. The registered address of the corporate headquarters is Kungsbron 1, C8, Stockholm, Sweden. Calliditas is listed at Nasdaq Stockholm in the Mid Cap segment with ticker "CALTX" and from June 5, 2020 Calliditas is also listed, in the form of ADSs, on The Nasdaq Global Select Market in the United States under the ticker "CALT".

These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on November 12, 2020.

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 the Group's results.

Note 2 Accounting Policies

These interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard No. 34 (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, 2020, have had a significant impact on the Group's financial reporting. Relevant accounting principles can be found on pages 38-42 of the Annual Report for 2019.

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 on page 25.

Note 3 Risks and Uncertainties in the Group and the Parent Company

Operational Risks

Research and drug development up to product approval and 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 insufficient 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 profiles, the future value of the product portfolio may be lower than expected. The operations may also be impacted negatively by regulatory decisions, such as decisions on approvals and price changes.

COVID-19

A novel strain coronavirus, known as COVID-19, has rapidly developed from an initial event in Wuhan, China, to a worldwide pandemic and infections have been reported globally. Calliditas has clinical trial sites in the global Phase 3 NefIgArd trial based in areas currently affected by this coronavirus and the future spread of the virus and its impact on global markets, the supply chain,

and research sites remains unknown. Calliditas has not yet experienced any major disturbances in the NeflgArd trial. The extent to which the coronavirus impacts the operations and the NeflgArd trial will depend on the type, degree and duration of the various restrictions put in place to contain the virus or treat those affected. This today varies in different geographies, and future developments cannot be predicted with reasonable assurance.

The pandemic may negatively impact our trial as a result of disruptions, such as travel bans, quarantines, and inability of patients to access the trial sites and provide samples as well as interruptions in the supply chain, which could result in delays and impact on the data integrity of the trial.

The continued spread of the coronavirus globally, may negatively impact our operations, including our trials. It could also negatively affect the operations of key governmental agencies, such as the FDA and EMA, which may delay the development of our product candidates, or could result in the inability of our suppliers to deliver components or raw materials on a timely basis, each of which in turn could have a negative impact on our business and results of operations.

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 Group is primarily affected by foreign exchange risk, since the development costs for Nefecon are mainly paid in USD and EUR. Further, the Group carry cash in USD to meet future expected costs in USD in connection with a potential commercialization of Nefecon in United States. Regarding the Group and the Parent Company's financial risk management, the risks are essentially unchanged compared with the description in the Annual Report for 2019.

For more information and full disclosure regarding the operational- and financial risks, reference is made to the Annual Report for 2019 and the registration statement F-1, made effective with the SEC in connection with the initial public offering in the United States in June 2020.

Note 4 Revenue from Contracts with Customers

The Group's revenues for the nine months ended September 30, 2020 consisted of revenues for the delivery of study-related drugs within the framework of the out-licensing of Nefecon in connection with the agreement with Everest Medicines to Greater China and Singapore.

Revenue for the provision of drug for conducting clinical trials was recognized at a point in time, which occurred when control over the drug was transferred to Everest Medicines. Calliditas has not completed all performance obligations within the agreement as of the delivery of study-related drugs to Everest Medicines. The remaining performance obligations amounts to SEK 400 thousand and SEK 874 thousand as of September 30, 2020 and 2019, respectively, and are expected to be completed during 2020 – 2021.

Set out below is the Group's revenue from contracts with customers:

	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
(SEK in thousands)	2020	2019	2020	2019	2019
Type of good or service					
Out-licensing	-	-	-	138,243	184,829
Provision of drugs	-	-	474	-	-
Total	**-**	**-**	**474**	**138,243**	**184,829**
Geographical markets					
China, Hong Kong, Macau, Taiwan and Singapore	-	-	474	138,243	184,829
Total	**-**	**-**	**474**	**138,243**	**184,829**

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

The Groups' financial assets comprise of long-term receivables, derivatives, other current receivables and cash, all of which, except derivatives, are recognized at amortized cost. Derivatives are recognized at fair value through profit or loss, which consist of currency options amounting to SEK 851 thousand and SEK 1,590 thousand as of September 30, 2020 and 2019, respectively. Currency options are presented as "Other current assets" and valued at fair value based on calculation using the Black-Scholes option pricing model (Level 2) as of September 30, 2020 and 2019. The Group's financial liabilities comprise of accounts payable and other current liabilities, which are recognized at amortized cost. The carrying amount is an approximation of the fair value.

Note 7 Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	September 30,		December 31,
	2020	2019	2019
Total registered shares at the beginning of period	38,707,638	35,202,347	35,202,347
New issue of shares during the period	11,233,946	3,505,291	3,505 291
Total registered shares at the end of period	**49,941,584**	**38,707,638**	**38,707,638**
Share capital at the end of period	1,998	1,548	1,548
Shareholders' Equity at the end of period	1,376,788	809,967	788,071

(SEK in thousands, except per share amounts and number of shares)	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2020	2019	2020	2019	2019
Loss per share before and after dilution	(2.77)	(1.30)	(6.09)	(0.26)	(0.88)
Weighted-average number of shares outstanding for the period, before and after dilution	49,751,058	38,593,335	43,165,505	36,345,098	36,940,587

Reserves for translation from foreign operations amounted to (SEK -20 thousand) and SEK 27 thousand, which are included in equity as of September 30, 2020 and 2019, respectively.

In June, 2020, Calliditas completed an initial public offering on The Nasdaq Global Select Market in the United States, by way of issuance of 9,230,770 new common shares, consisting of a public offering of 8,306,770 common shares in the form of American Depositary Shares ("ADSs"), with each ADS representing two common shares, and a concurrent private placement of 924,000 common shares. Furthermore, in July 2020, the exercise of the partial over-allotment option from the IPO on The Nasdaq Global Select Market was completed, by way of issuance of 706,676 new common shares in the form of American Depositary Shares ("ADSs"), with each ADS representing two common shares.

In addition, Calliditas has during the period completed a registration of issue of shares of 1,296,500 common shares, which referred to the exercise of the Warrant Program 2017/2020.

Note 8 Incentive Programs

Warrant Program 2018/2022

The warrants in Warrant Program 2018/2022 may be exercised from January 1, 2022 until March 31, 2022 and each warrant will entitle the participant to subscribe for one new share in the Parent Company at a subscription price of SEK 74.30 per share. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model.

Warrant Program 2019/2022

The warrants in the Warrant Program 2019/2022 may 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 Parent Company at a subscription price of SEK 74.50 per share. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model.

Board LTIP 2019

This is a performance-based long-term incentive program for certain Calliditas Board members. A total of 57,032 share awards were granted under the program during the second quarter of 2019. The share awards are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2019 Annual General Meeting to June 1, 2022.

Board LTIP 2020

This is a performance-based long-term incentive program for certain Calliditas Board members. A total of 31,371 share awards were granted under the program during the second quarter of 2020. The share rights are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2020 Annual General Meeting to July 1, 2023.

ESOP 2020

In 2020, Calliditas implemented an option program for employees and key consultants in Calliditas. The options were allotted free of charge to participants of the program. The options have a three-year vesting period calculated from the allotment date, provided that, with customary exceptions, the participants remain as employees of, or continue to provide services to, Calliditas. Once the options are vested, they can be exercised within a one-year period.

Each vested option entitles the holder to acquire one share in Calliditas at a predetermined price. The price per share is to be equivalent to the weighted average price that the company's shares were traded for on Nasdaq Stockholm during the ten trading days preceding the allotment date. The options have, at the time of issue, been valued according to the Black & Scholes valuation model.

Summary of Outstanding Incentive Programs

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of September 30, 2020
Incentive programs				
Warrant program 2018/2022	856,586	-	-	856,586
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2019	-	-	57,032	57,032
Board LTIP 2020	-	-	31,371	31,371
ESOP 2020	-	1,089,000	-	1,089,000
Total outstanding as of September 30, 2020	**1,279,086**	**1,089,000**	**88,403**	**2,456,489**

	Warrants Outstanding	Share Awards Outstanding	Total Outstanding as of September 30, 2019
Incentive programs			
Warrant program 2017/2020	1,296,500	-	1,296,500
Warrant program 2018/2022	856,586	-	856,586
Warrant program 2019/2022	422,500	-	422,500
Board LTIP 2019	-	57,032	57,032
Total outstanding as of September 30, 2019	**2,575,586**	**57,032**	**2,632,618**

Definitions and reconciliations of alternative performance measures

Definitions of Performance Measures

Performance Measures	Definitions
Earnings/(loss) per share before/after dilution	Earnings/(loss) for the period divided by the average number of shares 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, which is in accordance with IAS 33 Earnings Per Share.
Share capital at the end of the period	Share capital at the end of respective period. The measure is extracted from the statements of financial position.
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.
Shareholders' equity at the end of the period	Shareholders' equity at the end of respective period. The measure is extracted from the statements of financial position.
Cash at the end of the period	Cash at the end of respective period. The measure is extracted from the statements of financial position.

Definitions of Alternative Performance Measures

Alternative Key Performance Indicator	Definitions	Reason for Inclusion
Research and development expenses/Total operating expenses in %	Research and development expenses, divided by total operating expenses, which is the sum of research and development expenses, administrative and selling expenses, other operating income and expenses.	The key performance indicator helps the reader of the interim financial statements to analyse the portion of the Groups expenses that are attributable to the Group's research and development activities.
Equity ratio at the end of the period in %	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 shareholders.

Reconciliations of Alternative Performance Measures

	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
(SEK in thousands or as otherwise indicated)	2020	2019	2020	2019	2019
Research and development expenses/Total operating expenses in %					
Research and development expenses	(64,887)	(46,186)	(167,379)	(108,117)	(149,826)
Administrative and selling expenses	(41,037)	(10,295)	(77,843)	(39,092)	(62,882)
Other operating income/expenses	1,033	3,843	969	(1,010)	(140)
Total operating expenses	**(104,891)**	**(52,638)**	**(244,253)**	**(148,219)**	**(212,848)**
Research and development expenses/Total operating expenses in %	**62%**	**88%**	**69%**	**73%**	**70%**

	September 30,		December 31,
(SEK in thousands or as otherwise indicated)	2020	2019	2019
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	1,376,788	809,967	788,071
Total assets at the end of the period	1,440,183	840,846	845,200
Equity ratio at the end of the period in %	**96%**	**96%**	**93%**

Financial Calendar

Year-end report for the period January 1 – December 31, 2020	February 18, 2021
Interim report for the period January 1 – March 31, 2021	May 13, 2021
Interim report for the period January 1 – June 30, 2021	August 19, 2021
Interim report for the period January 1 – September 30, 2021	November 18, 2021

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Forward-Looking Statements
This interim report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Calliditas'' business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in the section entitled "Risk Factors" Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this interim report represent Calliditas'' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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.