Q4

calliditas THERAPEUTICS

## CALLIDITAS THERAPEUTICS AB (publ)

### Year-End Report January 1 – December 31, 2020

# Positive Topline Results from Pivotal Phase 3 NefIgArd Trial

**Key Figures**

**October 1 – December 31, 2020**

- Net sales amounted to SEK 0.4 million and SEK 46.6 million for the three months ended December 31, 2020 and 2019, respectively.
- Operating loss amounted to SEK 135.9 million and SEK 18.0 million for the three months ended December 31, 2020 and 2019, respectively.
- Loss before income tax amounted to SEK 173.3 million and SEK 23.0 million for the three months ended December 31, 2020 and 2019, respectively.
- Loss per share before and after dilution amounted to SEK 3.41 and SEK 0.60, for the three months ended December 31, 2020 and 2019, respectively.
- Cash amounted to SEK 996.3 million and SEK 753.5 million as of December 31, 2020 and 2019, respectively.

**January 1 – December 31, 2020**

- Net sales amounted to SEK 0.9 million and SEK 184.8 million for the year ended December 31, 2020 and 2019, respectively.
- Operating loss amounted to SEK 379.7 million and SEK 28.0 million for the year ended December 31, 2020 and 2019, respectively.
- Loss before income tax amounted to SEK 436.2 million and SEK 32.5 million for the year ended December 31, 2020 and 2019, respectively.
- Loss per share before and after dilution amounted to SEK 9.66 and SEK 0.88 for the year ended December 31, 2020 and 2019, respectively.
- For the year ended December 31, 2020 no dividend was proposed.

**Significant Events During the Period October 1 – December 31, 2020, in summary**

- In November 2020, Calliditas announced positive topline results from Part A from the pivotal Phase 3 NefIgArd trial.
- In November 2020, Calliditas acquired a controlling interest in Genkyotex SA followed by a simplified mandatory offer to the shareholders of Genkyotex, after which Calliditas controlled 86.2 percent of the shares in Genkyotex.

**Significant Events After the Reporting Period, in summary**

- In January 2021, Calliditas shared the clinical development plan for setanaxib and additional data from Part A of NefIgArd study at the R&D Day.

## Investor Presentation February 18, 14:30 CET

Audio cast with teleconference, Q4 2020, February 18, 2021, 14:30 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q4-2020

Teleconference: SE: +46850558356 UK: +443333009262 US: +18338230586

## CEO Statement

# Positive Phase 3 Topline Data

On November 8, 2020, we announced positive topline readout of Part A of our Phase 3 pivotal trial, NefIgArd. This global trial recruited patients across 19 countries from over 145 centres and was fully recruited in a year, in line with our original projections. The 200 patients were treated for nine months once daily and the trial's primary endpoint was reduction of proteinuria. There was also a key secondary endpoint, eGFR, which is a measure of the kidney's filtration rate and reflects the actual rate of progression of the underlying disease. These types of large and complex programs are usually conducted by pharma companies who are significantly larger and have access to vast resources. We are therefore exceedingly proud that a small Swedish company successfully managed to not only deliver this data readout but also to do so on time and on budget.

The results were statistically significant and clinically relevant: proteinuria showed a 31% reduction versus baseline, a stronger effect than what was seen in the Phase 2b (27%), which is generally not the case when moving from Phase 2 to Phase 3. In addition, eGFR was stabilised in the treated patient population, which in the end is the true treatment goal. The Phase 2b and Phase 3 trials with Nefecon are the only randomized, double-blind placebo-controlled trials in IgA Nephropathy (IgAN) which have met both primary and secondary endpoints, as well as having this potential disease modifying effect. This is extremely exciting, and we look forward to our interactions with regulators during the year as we progress towards potential approval.

We achieved this data readout despite the raging storm of the COVID-19 pandemic all around us in 2020. The well-established relationships with national co-ordinators and our CRO, in combination with the skill and dedication of our clinical team, were critical pieces of this endeavour, but we are most grateful for the commitment of all the patients and investigators who in the end made this possible. We are now well positioned to be the first approved treatment for IgAN, providing hope for patients that there will indeed be a medication available which holds the promise of delaying the decline of their kidney function and thereby hopefully help keep them out of dialysis and transplantation.

I am immensely proud of every member of the Calliditas team, who all rose to the occasion under challenging circumstances and made possible the positive readout of this robust trial. Everyone in the company contributed to this amazing feat and everyone should be very proud of their achievements. The trial continues, fully recruited with a total of 360 patients included, and will report out the full data set in early 2023.

We also concluded the purchase of a controlling block in Genkyotex in Q4. This is a company we had followed for quite a long time, and where we found the clinical data intriguing and their approach clearly differentiated. Even though their Phase 2 trial in primary biliary cholangitis (PBC) did not meet its endpoint, there was a clear impact on fibrosis across various metrics and very interesting quality of life data, including a statistically significant effect on fatigue, the most common symptom of patients suffering from PBC. As we know, there are several reasons why

earlier clinical trials fail to meet their endpoint, and it is not always a question of whether the drug is active or efficacious or not, but may depend on the trial design, choice of endpoint or dosing levels.

Genkyotex had positive interactions with the FDA in 2020, which resulted in plans for an adaptive pivotal Phase 2/3 design in PBC. In parallel, there was a Phase 1 PK study carried out looking into higher dosing, which read out positively in early 2021. We feel excited about taking on a pioneering role in the area of NOX inhibitors and look forward to sharing future clinical results with you. In addition to the data in PBC, comprehensive and compelling animal-based data indicated that setanaxib, the lead compound, might also have an important role to play in oncology, more precisely in solid tumours where today's immunotherapy has limited reach.

On November 3, 2020, we therefore closed a transaction resulting in Calliditas taking a controlling stake in Genkyotex of 62.7% of the shares. We subsequently launched a simplified mandatory tender offer which closed on December 16, resulting in a holding of 86.2%. We will continue to pursue a strategy to expand ownership of Genkyotex during 2021.

In the fourth quarter, we were also awarded the 2020 Sweden Bio award. This was an extraordinary honour and something which we are very proud of. The rationale for the award referred to the impressive professionalism and perseverance demonstrated in terms of the clinical development of Nefecon in a rare kidney disease, whilst pursuing commercialisation in the US and entering into partnering agreements to provide Nefecon to patients around the world.

We look forward to 2021 and the excitement of completing our regulatory filings, as well as a potential approval in the US, thus making it possible for us to start commercialisation of Nefecon in the US in Q4 2021.

## The probabilities of drug development

There is a fairly recent publication by the Biotechnology innovation organization Amplion and Biomedtracker, claiming to be the largest study of clinical drug development success rates to date. Covering 2006-2015, a total of 9,985 clinical and regulatory phase transitions, from 7,455 development programs across 1,103 companies, were recorded and analyzed.

By calculating the number of programs progressing to the next phase versus the total number of progressing and suspended programs, there was an assessment of the success rate at each of the four phases of development: Phase I, II, III, and regulatory filing. The study aimed to measure clinical development success rates with a broad set of data to strengthen benchmarking metrics for company sponsored, FDA registration enabling drug development programs.

One of the key measures of success used in this report was the Likelihood of Approval (LOA) from Phase I. This LOA success rate is simply a multiplication of the success rates of all four phases, a compounded probability calculation. For example, if each phase had a 50% chance of success, then the LOA from Phase I would be 0.5 x 0.5 x 0.5 x 0.5 = 6.25%.

The overall results were in line with previous studies in this area, reflecting a fairly high success rate in Phase 1 and Phase 3 with the Phase 2 transition being lower. The Phase I transition success rate was 63.2% (n=3,582). As this phase is typically conducted for safety testing and is not dependent on efficacy results for candidates to advance, it is common for this phase to have the highest success rate among the clinical phases across most categories. It is also the category where a failure may not always be reported publicly, which might affect the overall probability. The Phase II transition success rate was 30.7% (n=3,862) which reflects proof-of-concept and also the conscious choice to pursue the large, very expensive Phase III studies, resulting in termination not only for clinical efficacy reasons but also for commercial viability reasons. In Phase III, the overall rate of success was 58.1% (n=1,491) which reflects the risk related to the longest and most expensive trials to conduct.

The probability of an FDA approval after submitting a New Drug Application (NDA) or Biologics License Application (BLA), taking into account re-submissions, was 85.3% (n=1,050). Multiplying these individual phase components to obtain the compound probability of progressing from

Phase I to FDA approval (LOA) reveals that only 9.6% (n=9,985) of drug development programs from start to finish successfully make it to market.

With this backdrop, the level of continuous commitment from entrepreneurs and investors to explore, investigate and support the development of new treatments to address unmet medical needs reflect the amazing power of innovation, creativity and positive thinking which drives humanity towards relentless search for new and better solutions to difficult problems.

However, we are now at the very last stage of this chain as we prepare to seek drug approval, which is clearly a very significant achievement and hugely exciting, more so because this journey has truly been one of perseverance and a pioneering spirit. We are still the only company globally which has peer reviewed, positive clinical results from large, controlled studies in this indication, which I believe is an achievement in itself. In addition, we are now on the brink of submitting an application for regulatory approval and, subject to a successful outcome, being able to offer the first ever approved medication for IgAN with the promise this brings to patients with this disease. I cannot wait to keep you informed about of our continued journey this year.

Renée Aguiar-Lucander, CEO

## Business Overview

# Nefecon – an overview

Calliditas is a clinical-stage biopharmaceutical company focused on identifying, developing, and commercializing novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet medical needs. 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 the only compound in development for IgAN that has met the primary and key secondary endpoints in a randomized, double-blind, placebo-controlled Phase 3 clinical trial, and that is intended to be disease-modifying. Nefecon targets the ileum, the distal region of the small intestine, which is the presumed origin of the pathogenesis of IgAN. The ileum is the location of the highest concentration of the Peyer's patches, which are responsible for the production of the secretory immunoglobulin A (IgA) antibodies that are found in elevated levels in patients with IgAN.

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, budesonide, 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.

Calliditas has been granted orphan drug designation for the treatment of IgAN in the United States and the European Union. We retain 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.

# The NefIgArd study

Calliditas is currently conducting a global, pivotal Phase 3 clinical trial in adults with primary IgAN, referred to as NefIgArd. NefIgArd is a double-blind, placebo-controlled, two-part Phase 3 clinical trial designed to evaluate the same endpoint used in our previously completed Phase 2b NEFIGAN clinical trial. We randomized our first patient in NefIgArd in November 2018. The first part of NefIgArd, which we refer to as Part A, is a pivotal efficacy and safety trial. The primary endpoint of Part A is the reduction in proteinuria in the first 200 randomized and dosed patients, and a key secondary endpoint is the difference in kidney function between treated and placebo patients as measured by eGFR. In November 2020, we reported positive top-line data from Part A of the trial.

Treatment with Nefecon was associated with a statistically significant and clinically relevant reduction of proteinuria and stabilization of kidney function. The primary endpoint analysis showed a 31% mean reduction in the 16 mg arm versus baseline, with placebo showing a 5% mean reduction versus baseline, resulting in a 27% mean reduction at nine months of the 16 mg arm versus placebo (p=0.0005). The key secondary endpoint, eGFR, showed a treatment benefit of 7% versus placebo at nine months, reflecting stabilization in the treatment arm and a 7% decline of eGFR in the placebo arm (p=0.0029). This reflected an absolute decline of 4.04

ml/min/1.73m2 in the placebo group over 9 months compared to a 0.17 ml/min/1.73m2 decline in the treatment arm. In addition, the trial showed that Nefecon was generally well-tolerated and in keeping with the Phase 2b safety profile.

On the basis of the positive results from Part A of NefIgArd, we intend to submit a New Drug Application (NDA) in the first quarter of 2021 for accelerated approval by the United States Food and Drug Administration (FDA,) followed by a Marketing Authorisation Application (MAA) for conditional approval by the European Medicines Agency (EMA) in the first half of 2021.

The second part of NefIgArd, which we refer to as Part B, is a post-approval confirmatory trial designed to provide evidence of long-term renal benefit. In January 2021, we completed the enrolment of all 360 patients in NefIgArd, which includes 200 patients previously enrolled in Part A and another 160 patients enrolled in Part B. Part B will assess the difference in kidney function between treated and placebo patients, as measured by eGFR, over a two-year period. Each patient will be dosed for 9 months and then monitored off-drug for the remainder of the trial period, generating an aggregate of 15 months of follow-up data. We intend to report data from Part B in early 2023, subject to any impact from the COVID-19 pandemic to our business. We believe that the key secondary endpoint in Part A, a measure of eGFR over a nine-month period, is informative of the primary endpoint of Part B.

If approved by the FDA, we intend to market and commercialize Nefecon in the United States as a 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. The standard of care for ESRD is dialysis or kidney transplant, which represents a significant health economic burden as well as a material impact on patients' quality of life.

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, are predominantly found. Peyer's patches produce secretory IgA antibodies, which 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 which, potentially in combination with increased intestinal permeability, leads to these antibodies appearing in the blood. The galactose-deficient IgA antibodies are immunogenic when found in the circulation and trigger 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 currently no approved therapy for IgAN. Initially, patients with IgAN are typically given antihypertensive medications, as recommended by the non-profit organization Kidney Disease: Improving Global Outcome (KDIGO). This treatment regimen 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, as a significant proportion of patients experience continued deterioration of kidney function and with no approved treatment options currently available, physicians attempt to control disease progression with a variety of off-label treatments.

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.

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.

# Pipeline: Liver orphan indications

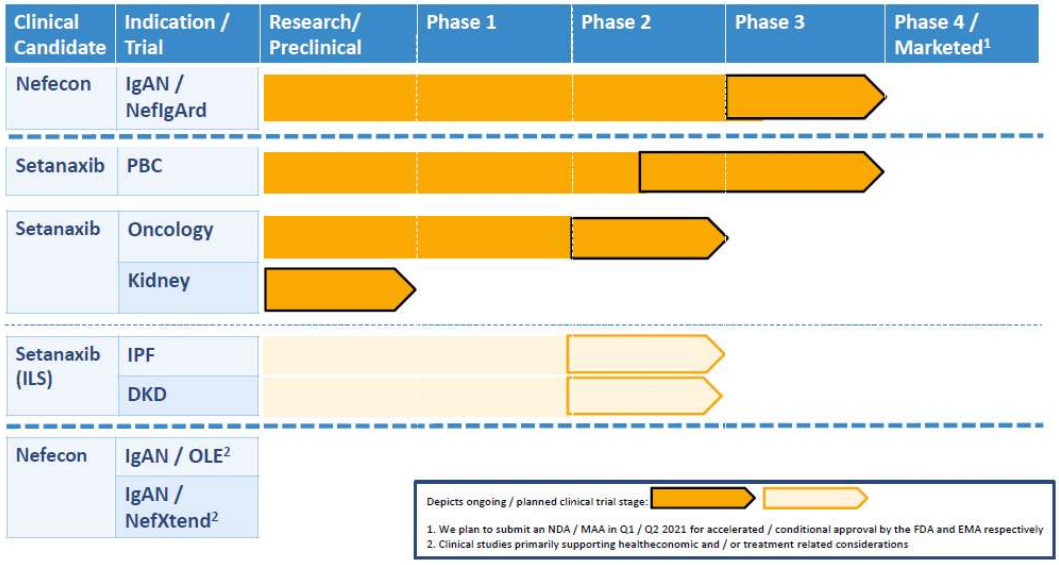
Beyond IgAN, Calliditas is exploring applications of Nefecon, its active ingredient budesonide, and other compounds for other orphan autoimmune diseases such as Primary Biliary Cholangitis (PBC) and Autoimmune Hepatitis (AIH).

PBC is a progressive and chronic autoimmune disease in which the small bile ducts that drain bile from the liver are damaged. This damage can result in cholestasis and the destruction of the bile ducts, which leads to liver cell damage and ultimately liver failure and the need for a liver transplant. PBC is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 140,000 patients in the United States. There are currently no approved therapies that specifically address the autoimmune response that is believed to drive PBC or the inflammatory consequences of this autoimmune response. Nefecon is designed to deliver high peak concentrations of its active ingredient to the intestine. This active ingredient is then transported directly to the liver, where it can locally reduce the autoimmune processes that drive PBC. We have received orphan drug designation for the treatment of PBC by the FDA.

However, while we will continue to evaluate Nefecon for the treatment of PBC, we are planning to evaluate setanaxib as our first candidate in this indication. Through our recent acquisition of a controlling interest in Genkyotex, we have acquired access to a novel NOX inhibitor platform that includes lead compound setanaxib. Setanaxib has completed a Phase 2 trial in PBC and recently received orphan drug designation for the treatment of PBC in the United States and Europe. Based on its Phase 2 results, which indicated clinically relevant anti-fibrotic activity despite failing to achieve the primary endpoint, Genkyotex had interactions with the FDA during 2020 regarding the clinical development pathway for setanaxib in PBC. In January 2021, Genkyotex

reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to 1,600 mg/day. Based on this positive data, Genkyotex plans to initiate a Phase 2/3 trial in PBC in the second half of 2021, incorporating higher dosing than that used in the Phase 2 trial and using alkaline phosphatase, or ALP, as a primary endpoint. The final design and protocol are subject to further feedback and commentary by the FDA.

We also intend to explore oncology indications involving fibrotic components such as CAFs and head and neck cancer using setanaxib administered with checkpoint inhibitors to address tumor drug resistance related to fibroblasts. To this end, Genkyotex plans to initiate a Phase 2 proof-of-concept study in head and neck cancer in 2021, which will study administration of setanaxib in conjunction with immunotherapy targeting CAFs.




Calliditas has also exclusively in-licensed Budenofalk 3 mg oral capsules for the U.S. market from the German pharmaceutical company Falk Pharma. Our license covers all indications for the United States market, excluding orphan indications outside of liver targets. Budenofalk is a formulation of budesonide originally developed to treat Crohn's disease, and has been approved for the treatment of Crohn's disease and acute episodes of collagenous colitis in several countries in Europe. It has also 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. We therefore believe Budenofalk also has the potential to address AIH for patients in the United States, where there are currently no approved therapies for the treatment of this disease, and to complement our activities in that geography.

AIH is a rare disease associated with chronic inflammation of the liver. Based on the current knowledge of AIH's pathophysiology, the origin of the autoimmune response is believed to be production of cytotoxic T-cells and B-cell derived autoantibodies directed towards liver cells or their components, resulting in inflammation that eventually destroys the liver cells and leads to fibrosis. AIH often presents as a slow progressing disease of the liver, leading to cirrhosis at variable rates with complications such as liver failure and liver cancer. AIH is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 50,000 to 80,000 patients in the United States.

We have received orphan drug designation for the treatment of AIH using budesonide by the FDA, and have discussed the development plans with the FDA for AIH during 2020. However, additional interaction is required before establishing any definitive clinical development plans.

# Significant Events During the Period January 1 – December 31, 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.
- 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 would not significantly impact the ongoing clinical activities related to NefIgArd study. This was due to the facts that 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 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, and also saw significant continued improvement at 12 months. The trial also met the key secondary endpoint showing a statistically significant difference in estimated glomerular filtration rate eGFR after nine months of treatment with Nefecon compared to placebo. Collectively the efficacy data from nine months of 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.
- In November 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.

After the acquisition of the controlling interest, a mandatory simplified cash tender offer was launched and after the end of the acceptance period Calliditas controlled 86.2% of the shares in Genkyotex. The acquisition costs, excluding transaction costs, for the 86.2% amounted to EUR 27.8 million (SEK 287.0 million). In addition to this there are a potential future milestone payment relating to contingent rights amounting to a maximum of EUR 55 million, subject to future regulatory approvals of setanaxib.

## Significant Events After the Reporting Period

- In January 2021, Calliditas announced the clinical development plan for setanaxib and additional data from Part A of NefIgArd study at the R&D Day. Following the positive results from the Phase 1 study in January of 2021, which evaluated higher doses of setanaxib in healthy volunteers, Calliditas is planning to initiate a pivotal Phase 2/3 study in PBC, starting in 2H 2021, with final design and protocol details subject to feedback from the US Food and Drug Administration (FDA). In addition, Calliditas plans to initiate a Phase 2 proof-of-concept study in head and neck cancer this year which will study administration of setanaxib in conjunction with immunotherapy targeting CAFs (cancer associated fibroblasts). Calliditas also provided selected data from the recently concluded Part A of the Phase 3 study NefIgArd with the lead candidate drug Nefecon, for the treatment of IgA Nephropathy. The data presented included overall baseline characteristics, rate of discontinuation of study treatment (9.5%) and rate of discontinuation from the study (3.5%). It was also confirmed that no adverse clinical effects were seen with regards to weight gain, blood pressure or HbA1c, reflecting a safety profile in keeping with the Phase 2b trial.

## Financial Overview

# Key Figures

| (SEK in thousands, except share amounts or as otherwise indicated) | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Net sales | 400 | 46,586 | 874 | 184,829 |
| Research and development expenses | (73,992) | (41,709) | (241,371) | (149,826) |
| Research and development expenses/ Total operating expenses in %[1] | 54% | 65% | 63% | 70% |
| Operating loss | (135,941) | (18,043) | (379,720) | (28,019) |
| Loss before income tax | (173,273) | (22,973) | (436,151) | (32,501) |
| Loss per share before and after dilution | (3.41) | (0.60) | (9.66) | (0.88) |
| Cash flow from/(used in) operating activities | (120,074) | (45,435) | (309,181) | (71,011) |

| (SEK in thousands, except share amounts or as otherwise indicated) | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Total registered shares at the end of period | 49,941,584 | 38,707,638 |
| Equity attributable to equity holders of the Parent Company at the end of the period | 1,210,491 | 788,071 |
| Equity ratio at the end of the period in %[1] | 80% | 93% |
| Cash at the end of the period | 996,304 | 753,540 |

[1] Alternative performance measure, see definitions on page 29

# January – December 2020

### Revenue

Net sales amounted to SEK 0.9 million and SEK 184.8 million for the year ended December 31, 2020 and 2019, respectively. Net sales amounted to SEK 0.4 million and SEK 46.6 million for the three months ended December 31, 2020 and 2019, respectively. The decrease by SEK 46.2 million for the three months ended December 31, 2020 and the decrease by SEK 183.9 million for the year ended December 31, 2020 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 136.3 million and SEK 64.6 million for the three months ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 and 2019, total operating expenses amounted to SEK 380.6 million and SEK 212.8 million, respectively.

#### Research and Development Expenses

Research and development expenses amounted to SEK 74.0 million and SEK 41.7 million for the three months ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 and 2019, research and development expenses amounted to SEK 241.4 million and SEK

149.8 million, respectively. The increase of SEK 32.3 million for the three months ended December 31, 2020 and 2019, was primarily related to the increased expenses for the NefIgArd trials and related clinical activities as well as the Genkyotex Phase 1 high-dose setanaxib trial. The increase of SEK 91.6 million for the year ended December 31, 2020 was primarily related to the increased activity in the NefIgArd trials and related clinical activities compared to the same period last year.

### Administrative and Selling Expenses

Administrative and selling expenses amounted to SEK 63.9 million and SEK 23.8 million for the three months ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 and 2019, administrative and selling expenses amounted to SEK 141.7 million and SEK 62.9 million, respectively. The increase of SEK 40.1 million for the fourth quarter and SEK 78.8 million for the year ended December 31, 2020 compared to the same periods 2019 was primarily related to the generally increased activity and increase of headcount, including for the pre-commercial organization and to expenses related to dual listings and the acquisition of Genkyotex SA.

### Other Operating Incomes and Expenses

Other operating income amounted to SEK 1.5 million and SEK 0.9 million for the three months ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 and 2019, other operating income amounted to SEK 2.5 million and SEK 4.4 million, respectively. The decrease for the year ended December 31, 2020 and 2019 was primarily related to disadvantageous exchange rate development on operating receivables and liabilities.

No other operating expenses were recognized for the three months ended December 31, 2020 and 2019, respectively, as well as, for the year ended December 31, 2020. For the year ended December 31, 2019 other operating expenses amounted to SEK 4.5 million. The decrease for the period primarily relates to a more favourable exchange rate development on operating liabilities.

## Net Financial Income/(Expenses)

Net financial income/(expenses) amounted to (SEK 37.3 million) and (SEK 4.9 million) for the three months ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 and 2019, net financial income/(expenses) amounted to (SEK 56.4 million) and (SEK 4.5 million), respectively. The decrease of SEK 32.4 million for the three months ended December 31, 2020 and 2019 and the decrease of SEK 51.9 million for the year ended December 31, 2020 and 2019 are both primarily derived by unrealized foreign currency transaction losses on cash accounts held in USD, 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 December 31, 2020 and 2019, loss for the period amounted to SEK 173.4 million and SEK 23.1 million, and the corresponding loss per share before and after dilution amounted to SEK 3.41 and SEK 0.60, respectively. For the year ended December 31, 2020

and 2019, loss for the period amounted to SEK 436.5 million and SEK 32.6 million, and the corresponding loss per share before and after dilution amounted to SEK 9.66 and SEK 0.88, respectively. The increase in the loss for both the periods 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 2019. Furthermore, the increase in the loss for both the periods were derived from the increased activity in R&D, increased expenses from administration and pre-commercial activities and to the negative effect of the net financial income/(expenses).

### Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 120.1 million and SEK 45.4 million for the three months ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 and 2019, cash flow used in operating activities amounted to SEK 309.2 million and SEK 71.0 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.

Cash flow used in investing activities amounted to SEK 172.6 million for both the three months ended and for the year ended December 31, 2020, which were derived from the acquisition of shares in Genkyotex SA. For the three months ended December 31, 2019 cash flow used in investing activities amounted to SEK 0.3 million and for the year ended December 31, 2019 cash flow used in investing activities amounted to SEK 18.1 million and were derived from the in-licensing of Budenofalk 3mg from Dr. Falk Pharma.

Cash flow from/(used in) financing activities amounted to (SEK 79.3 million) and (SEK 1.3 million) for the three months ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 and 2019, cash flow from financing activities amounted to SEK 768.6 million and SEK 198.8 million, respectively. The increase in cash flow used in financing activities for the three months ended December 31, 2020 and 2019, were primarily derived from a simplified public mandatory cash offer of Genkyotex SA. The increase in cash flow from financing activities for the year ended December 31, 2020 and 2019 amounted to SEK 569.8 million, were primarily derived from 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. Further, the cash flow used in financing activities were derived from a simplified public mandatory cash offer of Genkyotex SA. For the year ended December 31, 2019 cash flow from financing activities were primarily derived from the direct share issue of net SEK 199.4 million, which was completed in July 2019.

Net increase/(decrease) in cash amounted to (SEK 372.0 million) and (SEK 47.0 million) for the three months ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 and 2019, net increase/(decrease) in cash amounted to SEK 286.8 million and SEK 109.8 million, respectively. Cash amounted to SEK 996.3 million and SEK 753.5 million as of December 31, 2020 and 2019, respectively.

### Changes in Equity Attributable to Equity Holders of the Parent Company and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 1,210.5 million and SEK 788.1 million as of December 31, 2020 and 2019, respectively. The number of shares amounted to 49,941,584 and 38,707,638 as of December 31, 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 34 and 16 employees as of December 31, 2020 and 2019, respectively. The total number of full-time equivalent (FTE), including the consultants, were 46 and 22 people as of December 31, 2020 and 2019, respectively. The average number of employees were 31 and 16 employees for the three months ended December 31, 2020 and 2019, respectively and 23 and 14 for the year ended December 31, 2020 and 2019, respectively.

## Incentive Programs

For the three months ended December 31, 2020, there has been no additional allocation within incentive programs. For more information on incentive programs, see Note 10.

## 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 auditor.

Stockholm February 18, 2021

Renée Aguiar-Lucander

*CEO*

# Financial Statements

## Condensed Consolidated Statements of Income

| (SEK in thousands, except per share amounts) | Notes | Three Months Ended December 31, 2020 | Three Months Ended December 31, 2019 | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|---|---|---|
| Net sales | 4 | 400 | 46,586 | 874 | 184,829 |
| Research and development expenses | | (73,992) | (41,709) | (241,371) | (149,826) |
| Administrative and selling expenses | | (63,881) | (23,790) | (141,724) | (62,882) |
| Other operating income | | 1,532 | 870 | 2,501 | 4,385 |
| Other operating expenses | | - | - | - | (4,525) |
| **Operating loss** | | **(135,941)** | **(18,043)** | **(379,720)** | **(28,019)** |
| Net financial income/(expenses) | | (37,332) | (4,930) | (56,431) | (4,482) |
| **Loss before income tax** | | **(173,273)** | **(22,973)** | **(436,151)** | **(32,501)** |
| Income tax expense | | (175) | (77) | (360) | (77) |
| **Loss for the period** | | **(173,448)** | **(23,050)** | **(436,511)** | **(32,578)** |
| Attributable to: | | | | | |
| Equity holders of the Parent Company | | (170,431) | (23,050) | (433,494) | (32,578) |
| Non-controlling interests | | (3,017) | - | (3,017) | - |
| | | **(173,448)** | **(23,050)** | **(436,511)** | **(32,578)** |
| Loss per share | | | | | |
| Before and after dilution to ordinary equity holders of the Parent Company | | (3.41) | (0.60) | (9.66) | (0.88) |

## Condensed Consolidated Statements of Comprehensive Income

| (SEK in thousands) | Notes | Three Months Ended December 31, 2020 | Three Months Ended December 31, 2019 | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|---|---|---|
| **Loss for the period** | | **(173,448)** | **(23,050)** | **(436,511)** | **(32,578)** |
| **Other comprehensive income** | | | | | |
| *Other comprehensive income/(loss) that may be re-classified to profit or loss in subsequent periods:* | | | | | |
| Exchange differences on translation of foreign operations | | (9,332) | (38) | (9,352) | (11) |
| **Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods** | | **(9,332)** | **(38)** | **(9,352)** | **(11)** |
| *Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:* | | | | | |
| Remeasurement gain on defined benefit plans | | 1,216 | - | 1,216 | - |
| **Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods** | | **1,216** | **-** | **1,216** | **-** |
| **Other comprehensive loss for the period** | | **(8,117)** | **(38)** | **(8,137)** | **(11)** |
| **Total comprehensive loss for the period** | | **(181,565)** | **(23,088)** | **(444,648)** | **(32,589)** |
| Attributable to: | | | | | |
| Equity holders of the Parent Company | | (175,260) | (23,088) | (438,343) | (32,589) |
| Non-controlling interests | | (6,305) | - | (6,305) | - |
| | | **(181,565)** | **(23,088)** | **(444,648)** | **(32,589)** |

## Condensed Consolidated Statements of Financial Position

| | | December 31, | |
|---|---|---|---|
| (SEK in thousands) | Notes | 2020 | 2019 |
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible assets | 6,7 | 461,367 | 16,066 |
| Equipment | | 163 | 104 |
| Right-of-use assets | | 5,244 | 5,959 |
| Non-current financial assets | | 2,225 | 1,939 |
| Deferred tax assets | | 600 | - |
| **Total non-current assets** | | **469,599** | **24,068** |
| | | | |
| **Current assets** | | | |
| Accounts receivable | | - | 46,586 |
| Other current assets | 8 | 40,547 | 21,006 |
| Cash | | 996,304 | 753,540 |
| **Total current assets** | | **1,036,851** | **821,132** |
| **TOTAL ASSETS** | | **1,506,450** | **845,200** |
| | | | |
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| Share capital | | 1,998 | 1,548 |
| Additional paid-in capital | | 2,133,179 | 1,274,664 |
| Retained earnings, including net loss for the period | | (924,686) | (488,141) |
| **Equity attributable to equity holders of the Parent Company** | | **1,210,491** | **788,071** |
| Non-controlling interests | | 45,809 | **-** |
| **Total equity** | 9,10 | **1,256,300** | **788,071** |
| | | | |
| **Non-current liabilities** | | | |
| Provisions | 7,10 | 55,361 | 175 |
| Pension liabilities | | 8,296 | - |
| Deferred tax liabilities | 7 | 79,996 | - |
| Other non-current liabilities | | 878 | 3,584 |
| **Total non-current liabilities** | | **144,531** | **3,759** |
| | | | |
| **Current liabilities** | | | |
| Accounts payable | | 53,827 | 24,384 |
| Other current liabilities | | 10,406 | 3,471 |
| Accrued expenses and deferred revenue | | 41,386 | 25,515 |
| **Total current liabilities** | | **105,619** | **53,370** |
| **TOTAL EQUITY AND LIABILITIES** | | **1,506,450** | **845,200** |

## Condensed Consolidated Statements of Changes in Equity

| (SEK in thousands) | Notes | December 31, 2020 | December 31, 2019 |
|---|---|---|---|
| **Opening balance equity attributable to equity holders of the Parent Company** | | **788,071** | **618,175** |
| Loss for the period | | (433,494) | (32,578) |
| Other comprehensive loss for the period | | (4,849) | (11) |
| **Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company** | | **(438,343)** | **(32,589)** |
| **Transactions with owners:** | | | |
| New share issue | 9 | 891,388 | 210,317 |
| Costs attributable to new share issue | 9 | (97,686) | (10,915) |
| Exercise of warrants | 9 | 59,251 | - |
| Premiums from warrants issuance | | - | 2,834 |
| Share-based payments | 10 | 6,012 | 249 |
| Purchase of non-controlling interests | | 1,798 | - |
| **Total transactions with owners** | | **860,763** | **202,485** |
| **Closing balance equity attributable to equity holders of the Parent Company** | | **1,210,491** | **788,071** |
| **Opening balance equity attributable to non-controlling interests** | | **-** | **-** |
| Total comprehensive loss for the period | | (6,305) | - |
| Non-controlling interests from business combinations | | 136,084 | - |
| Purchase of non-controlling interests | | (83,970) | - |
| **Closing balance equity attributable to non-controlling interests** | | **45,809** | **-** |
| **Closing balance equity** | | **1,256,300** | **788,071** |

## Condensed Consolidated Statements of Cash Flows

| | | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|---|
| (SEK in thousands) | Notes | 2020 | 2019 | 2020 | 2019 |
| **Operating activities** | | | | | |
| Operating loss | | (135,941) | (18,043) | (379,720) | (28,019) |
| Adjustment for non-cash-items | | 8,599 | 870 | 15,465 | 2,308 |
| Interest received | | 1,912 | 926 | 1,912 | 926 |
| Interest paid | | (72) | (106) | (393) | (325) |
| Income taxes paid | | (101) | - | (528) | - |
| **Cash flow used in operating activities before changes in working capital** | | **(125,603)** | **(16,353)** | **(363,264)** | **(25,110)** |
| Cash flow from/(used in) changes in working capital | | 5,529 | (29,082) | 54,083 | (45,901) |
| **Cash flow used in operating activities** | | **(120,074)** | **(45,435)** | **(309,181)** | **(71,011)** |
| Cash flow used in investing activities | | (172,605) | (291) | (172,607) | (18,072) |
| **Cash flow used in investing activities** | | **(172,605)** | **(291)** | **(172,607)** | **(18,072)** |
| New share issue | | - | - | 891,388 | 210,317 |
| Costs attributable to new share issue | | - | (1,749) | (95,937) | (12,664) |
| Premiums from warrants issuance | | 4,332 | 1,085 | 59,251 | 2,834 |
| Purchase of non-controlling interests | | (82,172) | - | (82,172) | - |
| Repayment of loans | | (1,484) | (589) | (3,972) | (1,652) |
| **Cash flow from/(used in) financing activities** | | **(79,324)** | **(1,253)** | **768,558** | **198,835** |
| **Net increase/(decrease) in cash** | | **(372,003)** | **(46,979)** | **286,770** | **109,752** |
| **Cash at the beginning of the period** | | **1,396,869** | **805,075** | **753,540** | **646,175** |
| Net foreign exchange gains/(loss) on cash | | (28,562) | (4,556) | (44,006) | (2,387) |
| **Cash at the end of the period** | | **996,304** | **753,540** | **996,304** | **753,540** |

## Condensed Parent Company Statements of Income

| (SEK in thousands, except per share amounts) | Notes | Three Months Ended December 31, 2020 | Three Months Ended December 31, 2019 | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|---|---|---|
| Net sales | 4 | 400 | 46,586 | 874 | 184,829 |
| Research and development expenses | | (59,647) | (41,709) | (227,027) | (149,826) |
| Administrative and selling expenses | | (55,314) | (24,021) | (128,896) | (63,410) |
| Other operating income | | 1,513 | 870 | 2,482 | 4,385 |
| Other operating expenses | | - | - | - | (4,540) |
| **Operating loss** | | **(113,048)** | **(18,274)** | **(352,567)** | **(28,562)** |
| Net financial income/(expenses) | | (36,055) | (8,259) | (54,796) | (7,624) |
| **Loss before income tax** | | **(149,103)** | **(26,533)** | **(407,363)** | **(36,186)** |
| Income tax expense | | - | - | - | - |
| **Loss for the period** | | **(149,103)** | **(26,533)** | **(407,363)** | **(36,186)** |

## Condensed Parent Company Statements of Comprehensive Income

| (SEK in thousands) | Notes | Three Months Ended December 31, 2020 | Three Months Ended December 31, 2019 | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|---|---|---|
| **Loss for the period** | | **(149,103)** | **(26,533)** | **(407,363)** | **(36,186)** |
| Other comprehensive income/(loss) | | - | - | - | - |
| **Total comprehensive income/(loss)** | | **(149,103)** | **(26,533)** | **(407,363)** | **(36,186)** |

## Condensed Parent Company Balance Sheet

| (SEK in thousands) | Notes | December 31, 2020 | December 31, 2019 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Intangible assets | | 16,066 | 16,066 |
| Equipment | | 80 | 104 |
| Non-current financial assets | 7 | 298,683 | 2,040 |
| **Total non-current assets** | | **314,829** | **18,210** |
| | | | |
| **Current assets** | | | |
| Accounts receivable | | - | 46,586 |
| Other current assets | 8 | 25,488 | 21,005 |
| Cash | | 978,208 | 752,448 |
| **Total current assets** | | **1,003,696** | **820,039** |
| **TOTAL ASSETS** | | **1,318,525** | **838,249** |
| | | | |
| **SHAREHOLDERS' EQUITY AND LIABILITIES** | | | |
| ***Restricted Shareholders' equity*** | | | |
| Share capital | | 1,998 | 1,548 |
| Statutory reserve | | 3,092 | 3,092 |
| | | **5,090** | **4,640** |
| ***Non-restricted shareholders' equity*** | | | |
| Share premium reserve | | 2,116,721 | 1,268,334 |
| Retained earnings | | (479,379) | (448,989) |
| Net profit/(loss) for the period | | (407,363) | (36,186) |
| | | **1,229,979** | **783,159** |
| **Total shareholders' equity** | 9,10 | **1,235,069** | **787,799** |
| | | | |
| **Non-current liabilities** | | | |
| Provisions | 10 | 4,972 | 175 |
| Other non-current liabilities | | 105 | 50 |
| **Total non-current liabilities** | | **5,077** | **225** |
| | | | |
| **Current liabilities** | | | |
| Accounts payable | | 42,469 | 24,362 |
| Other current liabilities | | 5,123 | 1,332 |
| Accrued expenses and deferred revenue | | 30,787 | 24,531 |
| **Total current liabilities** | | **78,379** | **50,225** |
| **TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES** | | **1,318,525** | **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 year ended December 31, 2020 and December 31, 2019.

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 2020 Calliditas is also listed, in the form of ADSs, on The Nasdaq Global Select Market in the United States under the ticker "CALT".

The Year-End Report was approved by the Board of Directors (the "Board") for publication on February 18, 2021.

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

This Year-End Report has 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.

During the year, the Group has acquired a company (Genkyotex SA) that has defined benefit pension plans, which is recognized in the condensed consolidated statements of financial position under "Pension liabilities" and will be revalued due to actuarial changes.

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 29.

## 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 in addition to new variants of the virus. Calliditas has clinical trial sites in the global Phase 3 NefIgArd trial based in areas currently affected by this coronavirus and the future spread and mutation 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 NefIgArd trial. The extent to which the coronavirus impacts the operations and the NefIgArd 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 trials 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 and approvals 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 the 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 year ended December 31, 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 completed all performance obligations within the agreement as of the delivery of study-related drugs to Everest Medicines for the year ended December 31, 2020.

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

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| (SEK in thousands) | 2020 | 2019 | 2020 | 2019 |
| **Type of good or service** | | | | |
| Out-licensing | - | 46,586 | - | 184,829 |
| Provision of drugs | 400 | - | 874 | - |
| **Total** | **400** | **46,586** | **874** | **184,829** |

| | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| **Geographical markets** | | | | |
| China, Hong Kong, Macau, Taiwan and Singapore | 400 | 46,586 | 874 | 184,829 |
| **Total** | **400** | **46,586** | **874** | **184,829** |

## Note 5 Related-Party Transactions

During the reporting period, no significant related-party transactions have ocurred. For information about incentive programs please see Note 10.

## Note 6 Intangible Assets

| | December 31, | |
|---|---|---|
| **(SEK in thousands)** | **2020** | **2019** |
| Cost at opening balance | 16,066 | - |
| Business combinations | 460,253 | 16,066 |
| Exchange differences on translation | (14,952) | - |
| **Cost at closing balance** | **461,367** | **16,066** |
| | | |
| **Amortization at closing balance** | - | - |
| | | |
| **Net book value** | **461,367** | **16,066** |

Intangible assets consist of licenses and similar rights of SEK 414,115 thousand and goodwill of SEK 47,252 thousand.

### Business combinations:

The acquisition of Genkyotex SA resulted in the Group acquiring the rights to the NOX platform and SIIL agreement, as well as goodwill.

The net book value of the NOX platform amounts to SEK 370,092 thousand as of December 31, 2020. The estimated fair value of the NOX platform was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence.

The net book value of the SIIL agreement, which is an out-license agreement with Serum Institute of India (SIIL) for the use of a vaccine technology, amounts to SEK 27,957 thousand as of December 31, 2020. The estimated fair value of the SIIL agreement and extensions was determined using the discounted cash flow (DCF) method, adjusted for the likelihood of occurrence.

Goodwill amounts to SEK 47,252 thousand as of December 31, 2020 and for further information please see Note 7.

## Note 7 Business Combinations

In November 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 that it adds a late-stage orphan pipeline asset and platform in inflammation and fibrosis to the Groups 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 percent of the share capital and voting rights for SEK 204,867 thousand (EUR 19,747 thousand) in cash at EUR 2.73 per share. The acquisition date was November 3, 2020, when Calliditas acquired a controlling interest over

Genkyotex. The acquisition resulted in recognition of goodwill for SEK 48,839 thousand (EUR 4,708 thousand).

After the acquisition of the controlling interest, a mandatory simplified cash tender offer was launched of EUR 2.80 and non-transferable contingent rights, per share to the remaining shareholders in Genkyotex. In the final outcome after the acceptance period, 2,885,161 shares have been tendered into the offer, for which an acquisition price of SEK 82,172 thousand (EUR 8,078 thousand). As result Calliditas controls a total of 10,121,676 shares in Genkyotex, which corresponds to 86.2 percent of the share capital and the total number of votes in Genkyotex as of December 31, 2020. Purchase of non-controlling interests after the business combination have been recognized under financing activities in the condensed consolidated statements of cash flows.

In addition to this there are potential future milestone payments relating to contingent consideration amounting to a maximum of EUR 55 000 thousand, subject to future regulatory approvals of setanaxib. The fair value of contingent consideration is measured at Level 3 of the IFRS value hierarchy. Contingent consideration is recognized as a financial liability in the condensed consolidated statements of financial position, which is revalued at fair value each reporting period. Any revaluation gains and losses are recognized in the condensed consolidated statements of income.

Acquisition costs during the financial year amounted to SEK 8,118 thousand, which are recognized under administrative and selling expenses in the condensed consolidated statements of income and under operating activities in the condensed consolidated statements of cash flows. Acquisition costs are expensed in the condensed consolidated statements of income when they occur.

Goodwill that has arisen in the Group through the acquisition represents future economic benefits that are neither individually identified, nor separately recorded. No recorded goodwill is expected to be tax deductible. Goodwill is allocated to the cash-generating unit, which is the full Group. Impairment testing on goodwill involves assessing whether the unit's recoverable amount is higher than the carrying amount. The cash flows have been based on financial forecasts covering 15 years. The impairment test has not indicated that there is a need to record any impairment losses.

There was no business combination for the year ended December 31, 2019.

**(SEK in thousands or as otherwise indicated)**

| Company | Operation | Acquisition date | Acquired ownership share as of December 31, 2020 | Sales during the holding period | Operating loss during the holding period | Sales for the year ended December 31, 2020 | Operating loss for the year ended December 31, 2020 |
|---|---|---|---|---|---|---|---|
| Genkyotex SA | Biopharmaceutical company specializing in NOX therapies | November 2020 | 86,2% | - | (20,698) | - | (143,447) |

**(SEK in thousands)**

| Purchase price | |
|---|---|
| Cash | 204,867 |
| Contingent consideration | 50,614 |
| **Total** | **255,481** |

Fair value of the 7,236,515 ordinary shares purchased as part of the purchase price for Genkyotex S.A. (SEK 204,867 thousand) was based on the agreed share price of EUR 2.73 per share. For the year ended December 31, 2020, acquisition costs amount to SEK 8,118 thousand, of which

SEK 7,020 thousand is attributable to the acquisition of the controlling interest. All costs are directly attributable to the acquisition of Genkyotex SA.

Contingent consideration, provided that future regulatory approvals or marketing authorizations regarding setanaxib are obtained, additional purchase price may arise. The contingent consideration has been computed in accordance with the present value method and the probability has been taken into account if and when the various milestones will occur. The calculations are based on a discount rate of 10.0 percent.

| (SEK in thousands) | December 31, |
|---|---|
| **Contingent consideration** | **2020** |
| Cost at opening balance | - |
| Additional contingent consideration | 50,614 |
| Exchange differences on translation | (1,645) |
| **Cost at closing balance** | **48,969** |

| (SEK in thousands) | Fair value |
|---|---|
| **The assets and liabilities recognized in conjunction with the acquisition are as follows:** | |
| Intangible assets: NOX Platform | 382,521 |
| Intangible assets: Other licenses | 28,893 |
| Non-current assets | 2,438 |
| Other current assets | 10,022 |
| Cash | 32,265 |
| Pension liabilities | (9,410) |
| Deferred tax liabilities | (82,683) |
| Other non-current liabilities | (643) |
| Other current liabilities | (20,677) |
| **Acquired identified assets** | **342,726** |
| Non-controlling interests | (136,084) |
| Goodwill | 48,839 |
| **Acquired net assets** | **255,481** |

| (SEK in thousands) | |
|---|---|
| Purchase price paid in cash (included in the Cash flow used in investing activities) | (204,867) |
| Cash equivalents in the acquired company (included in the Cash flow used in investing activities) | 32,265 |
| Acquisition costs attributable to the acquisition of subsidiaries (included in the Cash flow used in operating activities) | (7,020) |

## Note 8 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 consisted of currency options. As of December 31, 2020, there were no currency options outstanding since they had expired and as of December 31, 2019, currency options amounted to SEK 399 thousand. Currency options were recognized as "Other current assets" and valued at fair value based on calculation using the Black-Scholes option pricing model (Level 2) as of December 30, 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 9 Equity

| (SEK in thousands, except per share amounts and number of shares) | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Total registered shares at the beginning of period | 38,707,638 | 35,202,347 |
| New issue of shares during the period | 11,233,946 | 3,505,291 |
| **Total registered shares at the end of period** | **49,941,584** | **38,707,638** |
| | | |
| Share capital at the end of period | 1,998 | 1,548 |
| | | |
| Equity attributable to equity holders of the Parent Company | 1,210,491 | 788,071 |
| Non-controlling interests | 45,809 | - |
| **Equity at the end of period** | **1,256,300** | **788,071** |

| (SEK in thousands, except per share amounts and number of shares) | Three Months Ended December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | | | | |
| Loss per share before and after dilution | (3.41) | (0.60) | (9.66) | (0.88) |
| Weighted-average number of shares outstanding for the period, before and after dilution | 49,941,584 | 38,707,638 | 44,873,448 | 36,940,587 |

Reserves for translation from foreign operations amounted to (SEK 9,352 thousand) and (SEK 11 thousand), which are included in equity as of December 31, 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 partial exercise of the 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 10 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 51,399 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 December 31, 2020 |
|---|---|---|---|---|
| **Incentive programs** | | | | |
| Warrant program 2018/2022 | 856,586 | - | - | 856,586 |
| Warrant program 2019/2022 | 422,500 | - | - | 422,500 |
| Board LTIP 2019 | - | - | 51,399 | 51,399 |
| Board LTIP 2020 | - | - | 31,371 | 31,371 |
| ESOP 2020 | - | 1,089,000 | - | 1,089,000 |
| **Total outstanding as of December 31, 2020** | **1,279,086** | **1,089,000** | **82,770** | **2,450,856** |

| | Warrants Outstanding | Share Awards Outstanding | Total Outstanding as of December 31, 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 December 31, 2019** | **2,575,586** | **57,032** | **2,632,618** |

### Incentive Programs in Subsidiaries

In Genkyotex SA, a subsidiary of Calliditas, incentive programs issued to external parties and former employees prior to Calliditas acquisition remains in the form of both warrants and stock options, which at maximum will represent 70,761 shares in Genkyotex SA, equivalent to 0.6 percent of the outstanding shares in Genkyotex SA.

# 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. |
| Equity at the end of the period | 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 equity attributable to equity holders of the Parent Company 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 December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| **(SEK in thousands or as otherwise indicated)** | **2020** | **2019** | **2020** | **2019** |
| ***Research and development expenses/Total operating expenses in %*** | | | | |
| Research and development expenses | (73,992) | (41,709) | (241,371) | (149,826) |
| Administrative and selling expenses | (63,881) | (23,790) | (141,724) | (62,882) |
| Other operating income/expenses | 1,532 | 870 | 2,501 | (140) |
| **Total operating expenses** | **(136,341)** | **(64,629)** | **(380,594)** | **(212,848)** |
| Research and development expenses/Total operating expenses in % | **54%** | **65%** | **63%** | **70%** |

| | December 31, | |
|---|---|---|
| **(SEK in thousands or as otherwise indicated)** | **2020** | **2019** |
| ***Equity ratio at the end of the period in %*** | | |
| Equity attributable to equity holders of the Parent Company at the end of the period | 1,210,491 | 788,071 |
| Total assets at the end of the period | 1,506,450 | 845,200 |
| **Equity ratio at the end of the period in %** | **80%** | **93%** |

## Financial Calendar

| | |
|---|---|
| Publication for the Annual Report 2020 | April 27, 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 |
| Year-end Report for the period January 1 – December 31, 2021 | February 24, 2022 |

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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 for development and potential approvals, 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.