# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 6-K

**REPORT OF FOREIGN ISSUER**
**PURSUANT TO RULE 13a-16 OR 15d-16**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the month of August 2021**

**(Commission File No. 001-39308)**

# CALLIDITAS THERAPEUTICS AB
**(Translation of registrant's name into English)**

**Kungsbron 1, C8**
**SE-111 22**
**Stockholm, Sweden**
**(Address of registrant's principal executive office)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Enclosed hereto is a copy of an interim report and announcement published by Calliditas Therapeutics AB on August 19, 2021**.**

The information contained in this Form 6-K, including Exhibit 99.1, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

**EXHIBIT INDEX**

| Exhibit | Description |
|---|---|
| 99.1 | Company interim report dated August 19, 2021 |
| 99.2 | Company announcement dated August 19, 2021 |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**CALLIDITAS THERAPEUTICS AB**

Date: August 20, 2021

By: /s/ Fredrik Johansson
Fredrik Johansson
Chief Financial Officer

**CALLIDITAS THERAPEUTICS AB (publ)**

**Interim Report January 1 – June 30, 2021**

**Filing of Marketing Authorisation Application on accelerated basis with EMA**

**Key Figures**

**April 1 - June 30, 2021**

- No net sales were recognized for the three months ended June 30, 2021 and 2020, respectively.
- Operating loss amounted to SEK 159.4 million and SEK 66.6 million for the three months ended June 30, 2021 and 2020, respectively.
- Loss before income tax amounted to SEK 165.2 million and SEK 61.3 million for the three months ended June 30, 2021 and 2020, respectively.
- Loss per share before and after dilution amounted to SEK 3.20 and SEK 1.50 for the three months ended June 30, 2021 and 2020, respectively.
- Cash amounted to SEK 709.3 million and SEK 1,459.6 million as of June 30, 2021 and 2020, respectively.

**January 1 - June 30, 2021**

- No net sales were recognized for the six month ended June 30, 2021. Net sales amounted to SEK 0.5 million for the six months ended June 30, 2020.
- Operating loss amounted to SEK 310.2 million and SEK 138.9 million for the six months ended June 30, 2021 and 2020, respectively.
- Loss before income tax amounted to SEK 301.4 million and SEK 124.9 million for the six months ended June 30, 2021 and 2020, respectively.
- Loss per share before and after dilution amounted to SEK 5.71 and SEK 3.14 for the six months ended June 30, 2021 and 2020, respectively.

**Significant events during the period April 1 – June 30, 2021, in summary**

- In April 2021, Calliditas was granted accelerated assessment procedure by the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP) for Nefecon, reducing the maximum timeframe for review of the application for marketing authorization. If approved, Nefecon could be available to patients in Europe in first half of 2022.
- In April 2021, Calliditas announced that the FDA accepted the submission and granted Priority Review for the NDA for Nefecon. The FDA have set a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021. Subject to approval, this would enable commercialisation of Nefecon in the US in Q4, 2021.

- In May 2021, Calliditas announced that the company submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Nefecon.

**Significant events after the reporting period, in summary**

- In July 2021, Calliditas signed a loan facility of up to the EUR equivalent of $75 million with Kreos Capital.
- In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize Nefecon in the European Economic Area (EEA) member states, Switzerland and the UK valued at a total of EUR 97.5 million ($115m) in initial upfront and potential milestone payments, plus royalties.
- In August 2021, Calliditas received FDA fast track designation for setanaxib in PBC.
- In August 2021, Calliditas completed an accelerated book building procedure and resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of SEK 324.0 million before transaction costs.

**Investor presentation August 19, 14:30 CET**

Audio cast with teleconference, Q2 2021, August 19, 2021, 14:30 (Europe/Stockholm)

Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q2-2021

Teleconference: SE: +46850558356 UK: +443333009266 US: +16467224903

**CEO Statement**

**Execution, execution, execution.…**

Following the filing for accelerated approval with the FDA in Q1, we filed our submission for conditional approval with EMA in May. Both applications are being processed on an accelerated basis and we look forward to receiving first round of questions from EMA during Q3. In the U.S our target PDUFA date is September 15th, and it is an adrenaline filled and exciting time as we are getting closer to a potential approval of the first ever drug specifically developed for IgA nephropathy. However, as we all know, regulatory processes are complex and multifaceted, so we can only continue to work hard and prepare the organisation whilst we await the decision by the agency.

During the 2nd quarter we significantly ramped up our pre commercial activities in the US following the strengthening of the team announced in Q1. We have added significant internal resources as well as entered into some key partnerships, in order to ensure that we are well positioned to initiate commercialization in Q4, subject to a positive outcome of the FDA approval process. We have also continued to do work around pricing and reimbursement in the US, which will be completed in Q3 and form the basis for our decision related to pricing which will be communicated in conjunction with a potential approval. Other workstreams have focused on systems, processes and structures, which are required to be in place, tested and integrated in advance of commercial sales. All of these activities have been carried out in parallel with ongoing clinical, regulatory and CMC related activities related to the initiation of new clinical trials with setanaxib in the second half of this year, as well as the ongoing Phase 3 trial, NefIgArd, and interactions with the FDA. Focus in Q2 therefore has been on execution across all aspects of our business.

During Q2 we also explored avenues to non-dilutive financing by way of a competitive process in order to provide the company with access to additional capital in advance of, as well as post a potential regulatory approval. In parallel we also ran a successful competitive process focused on securing a strong European commercial partner for Nefecon. Both of these processes obviously required significant commitments across the organisation as discussions regarding fit, diligence and structuring were conducted with a number of parties. I applaud the commitment, focus and solutions orientation of each and every member of the organisation who worked tirelessly over the quarter to ensure that both of these processes were able to be successfully concluded in early Q3. The result of these processes which was announced in Q3 resulted in over $100m of non- dilutive capital potentially being available to the company, divided between approximately $50m available pre-approval with the remainder becoming available post FDA and EMA approvals and subsequent US commercialization. These processes, together with the accelerated book building procedure raising approximately gross $37m (SEK 324 million) which we completed in Q3, have significantly enhanced our financial strength after the close of Q2. We are delighted with the outcome and excited to welcome our new partners to the Calliditas team.

**A glass half full**

There have been many harrowing scenes and deep personal losses experienced by many over the last 18 months due to the pandemic. In addition, healthcare workers across the globe have been carrying a heavy load, with any intermittent relief primarily reflecting the regional vaccination rate. On the other side, enormous scientific progress have been made over a very short time resulting in significant reductions in terms of hospitalisations and mortality.

One thing which strikes me however is the difference in how people, organisations and institutions interpret and react to this shift in statistics and the daily coverage of Covid 19. It has already since many months become a dominant force in daily news and on social media platforms, not to mention in conversations at home, in transit and at the workplace (for those who have had the opportunity to actually go to work). Despite a significantly reduced rate of hospitalisations and deaths as a percentage of the reported number of infections across Europe, primarily driven by high levels of vaccinations, the detailed focus remains. Covid-19, as any virus, has the potential ablity to mutate and hence clearly there can be no guarantee of a definitive, lasting solution, something which we humans are ill prepared to know how to deal with as uncertainty is difficult to manage. We prefer absolutes and well defined outcomes.

So therefore we continue to spend enormous amount of energy on worrying about what potentially will happen next, remaining transfixed by the pandemic. What else migth drive this? One reason is probably habit, which clearly is a very strong driver of human behaviour. Once a daily routine is established, we tend to seek the familiarity of looking up the same sites, reading the same news sources and performing the same rituals. Another, perhaps somewhat less attractive side of human nature is our fascination with disasters and tragedies.

According to the psychologist Dr. John Mayer, we are hardwired to stop and look at disasters. It is part of our survival process, which require us to analyse these kinds of situations and to assess whether or not it affects us directly and if we should react, by fleeing or fighting for example. Another reason for this behaviour according to psychiatrist Dr. David Henderson is that by continuing to stare at disasters and witness violence and destruction whether it is a movie or in real life, is a way for us to face our fears without risking immediate harm. We play out different scenarios in our head and try to reconcile the uncontrollable with our need to remain in control. Studies have concluded that we humans have a negative bias, meaning that we have a tendency to automatically give more attention to negative events and information than positive. It also shows that we learn more from our negative experiences than our positive ones. Also, looking at disasters stimulates our empathy and we are hard wired to be empathetic – it is a key psychosocial condition that makes us social human beings.

The other side of that coin however is that repeat exposure to disasters can drive anxiousness and fear, leading to illness and trauma. This therefore indicates that we should be careful and limit our exposure to avalanches of bad news and disasters or risk falling victim to an overload of anxiety and mental stress.

So as the pandemic seems to, at least for the moment, wane in terms of mortality and hospitalisations in Europe compared to the winter and early spring, perhaps we need to grasp the opportunity to also look at things which are full of hope, beauty or promise in our close environment. Maybe our minds, at least for a little while, need a bit less exposure to those who consistently look at the glass half empty, actively promoting a gloomy outlook, always at the ready to predict a turn for the worse and a looming disaster around the corner, and a little bit more to those who talk of achievements to date, building on our sucesses and striving for the light…a glass half full. Perhaps we need to turn down the daily noise and seek out positive thoughts at least for a while in order to build reserves for whatever might come in the future. This doesn't mean that we stop caring, or that we go into denial, but rather believe that, just as with a chronic disease, we can achieve more by taking one step at a time in a positive direction, rather than focus only on the negative and be defeated and defined by it.

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 downregulator of Iga1 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 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, and/or the leakiness of secretory galactose-deficient IgA antibodies into the blood. Nefecon's active ingredient, budesonide, has demonstrated efficacy and safety in other indications. After the active ingredient has been released and 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 thereby limits concerning side effects related to systemic immunosuppression.

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 Europe, Greater China, and Singapore, and – subject to approval by the FDA – we intend to commercialize Nefecon for IgAN on our own in the United States. In July 2021, Calliditas partnered with STADA to register and commercialize Nefecon in the European Economic Area (EEA) member states, Switzerland and the UK. The deal is valued at a total of EUR 97.5 million ($115m) in initial upfront and potential milestone payments, plus tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties. Calliditas has also out-licensed the development and commercialization of Nefecon in Greater China and Singapore to Everest Medicines.

### The NefIgArd study

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. On the basis of these results, we filed for regulatory approval with the FDA and the EMA in early 2021.

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, Calliditas submitted a New Drug Application (NDA) on March 15, 2021 to the United States Food and Drug Administration (FDA). We sought accelerated approval under Subpart H for the 505(b)(2) application, and also applied for priority review. On April, 28, 2021, Calliditas announced that the FDA had accepted the submission and granted Priority Review for Nefecon, setting a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021.

In April, Nefecon was also granted accelerated assessment procedure by the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP), reducing the maximum timeframe for review of the application to 150 days (excluding clock-stops). Calliditas submitted a Marketing Authorisation Application (MAA) for conditional approval to the EMA in May, 2021. If approved, Nefecon could be available to patients in Europe in first half of 2022.

The second part of the NefIgArd study, 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 the 200 patients previously enrolled in Part A. 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 ourselves in the United States as a treatment specifically designed to have a disease-modifying effect for IgAN by preserving kidney function and thereby delaying or 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. Also, recent clinical studies indicate that this treatment may not be associated with any benefit with regards to the underlying kidney function.

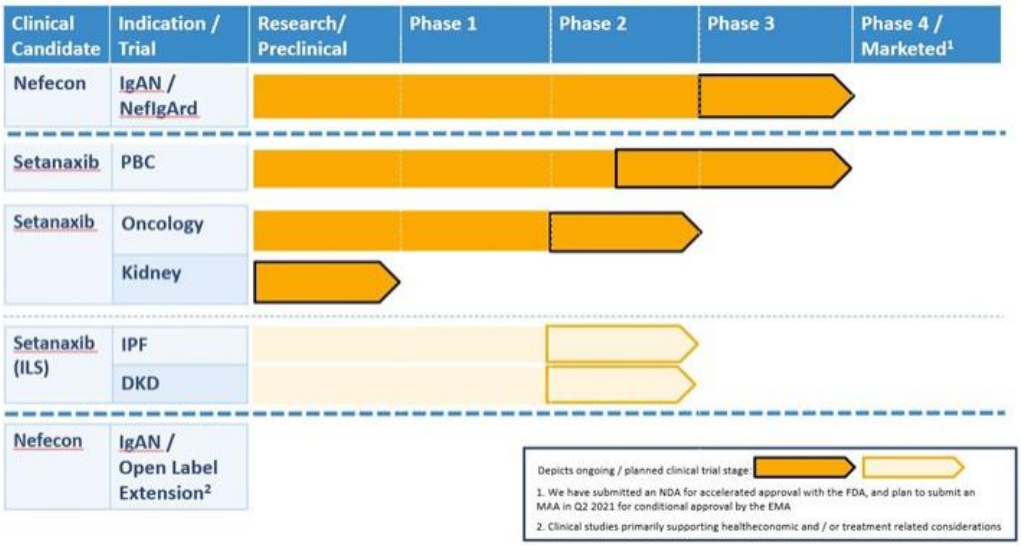
IgAN is an orphan disease that we estimate affects approximately 130,000 to 150,000 people in the United States and approximately 200,000 people in Europe. A significantly higher prevalence has been observed in Asia, including Greater China, where IgAN has historically been a leading cause of ESRD. We estimate that IgAN affects approximately two million people in Greater China. Calliditas estimates the U.S. target market opportunity for Nefecon to be approximately $4.5 billion to $5.0 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.

**Pipeline: A NOX Inhibitor Platform**

Through our recent acquisition of a controlling interest in Genkyotex, we have acquired access to a novel NOX inhibitor platform that includes the 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 GGT, 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, we plan 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.

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.

We also intend to explore oncology indications involving fibrotic components such as CAFs using setanaxib administered with checkpoint inhibitors to address tumour drug resistance related to fibroblasts. To this end, we plan 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.




*(ILS) Investigator lead studies

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 – June 30, 2021**

- 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. 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. 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.

- In March 2021, Calliditas announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Nefecon in patients with primary IgA Nephropathy. Calliditas is seeking accelerated approval under Subpart H for the 505(b)(2) application.

- In April 2021, Calliditas announced that its lead product candidate Nefecon, was granted accelerated assessment procedure by the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP). Accelerated assessment, reduces the maximum timeframe for review of the application for marketing authorization to 150 days (excluding clock-stops), for the EMA to review a marketing authorization application (MAA). If approved, Nefecon could be available to patients in Europe in the first half of 2022.

- In April 2021, Calliditas announced that the FDA accepted the submission and granted Priority Review for the NDA for Nefecon. The FDA have set a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021.

- In May 2021, Calliditas announced that the company submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Nefecon, a novel oral formulation targeting down regulation of IgA1 for the treatment of primary IgA Nephropathy (IgAN).

**Significant Events After the Reporting Period**

- In July 2021, Calliditas signed a loan agreement of up to the EUR equivalent of $75 million with Kreos Capital. The loan facility is divided into three tranches of $25 million each. Drawdown of the first $25 million tranche can be made until 31 December 2021 and will be available after the satisfaction of customary closing conditions. Drawdown of the second tranche of $25 million can be made until 30 June 2022 and will be available subject to accelerated approval of Nefecon by the U.S Food and Drug Administration (FDA). Drawdown of the third and final $25 million tranche can be made until 31 December 2022 and will be available subject to certain revenue milestones and coverage metrics.

- In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize Nefecon for the treatment of IgAN in the EEA member states, Switzerland and the UK valued at a total of EUR 97.5 million ($115m) in initial upfront and potential milestone payments, plus tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

- In August 2021, Calliditas received FDA fast track designation for setanaxib in PBC.

- In August 2021, Calliditas completed an accelerated book building procedure and resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of SEK 324.0 million before transaction costs.

## Financial Overview

### Key Figures

| (SEK in thousands, except share amounts or as otherwise indicated) | Three Months Ended June 30, | | Six Months Ended June 30, | | Year Ended December 31, |
|---|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 | 2020 |
| Net sales | — | — | — | 474 | 874 |
| Research and development expenses | (75,020) | (48,386) | (165,097) | (102,492) | (241,371) |
| Research and development expenses/ Total operating expenses in %[1] | 47 % | 73 % | 53 % | 74 % | 63 % |
| Operating loss | (159,398) | (66,562) | (310,179) | (138,888) | (379,720) |
| Loss before income tax for the period | (165,212) | (61,259) | (301,386) | (124,936) | (436,151) |
| Loss per share before and after dilution | (3.20) | (1.50) | (5.71) | (3.14) | (9.66) |
| Cash flow used in operating activities | (132,910) | (67,016) | (267,089) | (85,791) | (309,181) |

| (SEK in thousands, except share amounts or as otherwise indicated) | June 30, | | December 31, |
|---|---|---|---|
| | 2021 | 2020 | 2020 |
| Total registered shares at the end of period | 49,941,584 | 47,938,408 | 49,941,584 |
| Equity attributable to equity holders of the Parent Company at the end of the period | 937,842 | 1,425,116 | 1,210,491 |
| Equity ratio at the end of the period in %[1] | 76 % | 96 % | 80 % |
| Cash at the end of the period | 709,306 | 1,459,569 | 996,304 |

[1] Alternative performance measure, see definitions on page 27.

### January – June 2021

#### Revenue

No net sales were recognized for the three months ended June 30, 2021 and 2020, respectively. No net sales were recognized for the six months ended June 30, 2021. Net sales for the six months ended June 30, 2020 amounted to SEK 0.5 million and derived from the delivery of Nefecon to China as part of the license agreement with Everest Medicines. For additional information see Note 4.

#### Total Operating Expenses

Total operating expenses amounted to SEK 159.4 million and SEK 66.6 million for the three months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021 and 2020, total operating expenses amounted to SEK 310.2 million and SEK 139.4 million, respectively.

#### Research and Development Expenses

Research and development expenses amounted to SEK 75.0 million and SEK 48.4 million for the three months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021 and 2020, research and development expenses amounted to SEK 165.1 million and SEK 102.5 million, respectively. The increase of SEK 26.6 million for the second quarter and SEK 62.6 million for the six months ended June 30, 2021 is primarily due to increased cost of the NefIgArd studies and the preparation and product development for the upcoming setanaxib trials, compared to the same period last year

**Administrative and Selling Expenses**

Administrative and selling expenses amounted to SEK 84.4 million and SEK 18.8 million for the three months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021 and 2020, administrative and selling expenses amounted to SEK 143.2 million and SEK 36.8 million, respectively. The increase of SEK 65.6 million for the second quarter and SEK 106.4 million for the six months ended June 30, 2021 is mainly due to intensified commercial preparations and medical affairs activities in the US and an increased cost for administration, compared to the same period last year.

**Other Operating Incomes/Expenses**

Other operating income amounted to SEK 0.4 million and SEK 0.6 million for the three months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021 and 2020, other operating income amounted to SEK 0.4 million and SEK 0.8 million, respectively.

Other operating expenses amounted to SEK 0.4 million for the three months ended June 30, 2021. No other operating expenses were recognized for the three months ended June 30, 2020. Other operating expenses amounted to SEK 2.3 million and SEK 0.8 million for the six months ended June 30, 2021 and 2020, respectively.

**Net Financial Income and Expenses**

Net financial income and (expenses) amounted to SEK (5.8) million and SEK 5.3 million for the three months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021 and 2020, net financial income and (expenses) amounted to SEK 8.8 million and SEK 14.0 million, respectively. The decrease of SEK 11.1 million for second quarter are primarily derived by unrealized foreign currency transaction losses on cash accounts and the decrease of SEK 5.2 million for the six months ended June 30, 2021 are primarily derived by decreased unrealized foreign currency transaction gains on cash accounts.

**Tax**

Deferred tax assets of SEK 11.4 million have been recognized in the six months ended June 30, 2021 due to future temporary differences that such losses can be used to offset and are related to Genkyotex. The Groups tax losses accumulated have otherwise not been valued and not 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 June 30, 2021 and 2020 the Group had a net loss of SEK 163.1 million and SEK 61.3 million, respectively and corresponding loss per share before and after dilution amounted to SEK 3.20 and SEK 1.50 for the three months ended, respectively.

For the six months ended June 30, 2021 and 2020 the Group had a net loss of SEK 289.9 million and SEK 125.0 million, respectively and the corresponding loss per share before and after dilution amounted to SEK 5.71 and SEK 3.14, respectively.

The decrease in the result for the periods is mainly due to the increased activities in R&D and the pre-commercial activities in the US.

**Cash Flow and Cash Position**

Cash flow used in operating activities amounted to SEK 132.9 million and SEK 67.0 million for the three months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021 and 2020, cash flow used in operating activities amounted to SEK 267.1 million and SEK 85.8 million, respectively. The cash flow used in operating activities during these periods is according to plan and is 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 18.6 million for the three months ended June 30, 2021. For the six months ended June 30, 2021, cash flow used in investing activities amounted to SEK 18.8. The cash flow used in investing activities amounted for both the three month period and six month period ending June 30, 2021, are mainly derived from a EUR 1.5 million milestone payment for the Budenofalk license. The Group had non-material cash flows used in investing activities for both the three months ended and the six months ended June 30, 2020.

Cash flow from/(used in) in financing activities amounted to SEK (0.7) million and SEK 791.2 million for the three months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021 and 2020, cash flow from/(used in) financing activities amounted to SEK (10.3) million and SEK 777.7 million, respectively. The cash used in financing activities for the six months ending June 30, 2021 are related to purchase of minority shares in Genkyotex.

Net increase/(decrease) in cash amounted to SEK (152.2) million and SEK 724.2 million for the three months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021 and 2020, net increase/(decrease) in cash amounted to SEK (296.2) million and SEK 691.9 million, respectively. Cash amounted to SEK 709.3 million and SEK 1,459.6 million as of June 30, 2021 and 2020, respectively.

**Changes in Shareholders' Equity and Number of Shares**

Equity attributable to equity holders of the Parent Company amounted to SEK 937.8 million and SEK 1,425.1 million as of June 30, 2021 and 2020, respectively. The number of shares amounted to 49,941,584 and 47,938,408 as of June 30, 2021 and 2020, respectively. The increase in number of shares between the periods is due to the exercise of the partial over-allotment option from the IPO of 0.7 million new common shares in July 2020 and the exercise of the Warrant Program 2017/2020 of 1.3 million new common shares.

**Employees**

The number of employees were 54 and 21 employees as of June 30, 2021 and 2020, respectively. The total number of full-time equivalent (FTE), including the consultants, were 61 and 30 people as of June 30, 2021 and 2020, respectively. The average number of employees were 44 and 20 employees for the three months ended June 30, 2021 and 2020, respectively and 40 and 18 for the six months ended June 30, 2021 and 2020, respectively.

**Incentive Programs**

For the three months ended June 30, 2021, an allocation of 510,000 employee stock options have been made for the ESOP 2021 program and an allocation of 26,968 share awards have been made for the Board LTIP 2021 program. 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.

**Declaration by the Board of Directors**

The Board of Directors and CEO declare that the interim report for the six months ended June 30, 2021 gives a fair view of the business development, financial position and result of operation of the Parent Company and the Group and describes significant risks and uncertainties that the Parent Company and its subsidiaries are facing.

Stockholm August 19, 2021

Board of Directors

| | | |
|---|---|---|
| Elmar Schnee | Lennart Hansson | Hilde Furberg |
| *Chairman of the Board* | *Board member* | *Board member* |
| Diane Parks | Molly Henderson | Renée Aguiar-Lucander |
| *Board member* | *Board member* | *CEO* |

**Financial Statements**

**Condensed Consolidated Statements of Income**

| (SEK in thousands, except per share amounts) | Notes | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Year Ended December 31, 2020 |
|---|---|---|---|---|---|---|
| Net sales | 4. | — | — | — | 474 | 874 |
| Research and development expenses | | (75,020) | (48,386) | (165,097) | (102,492) | (241,371) |
| Administrative and selling expenses | | (84,372) | (18,797) | (143,151) | (36,806) | (141,724) |
| Other operating income | | 383 | 621 | 383 | 782 | 2,501 |
| Other operating expenses | | (390) | — | (2,315) | (846) | — |
| **Operating loss** | | **(159,398)** | **(66,562)** | **(310,179)** | **(138,888)** | **(379,720)** |
| Net financial income/(expenses) | | (5,814) | 5,303 | 8,793 | 13,952 | (56,431) |
| **Loss before income tax** | | **(165,212)** | **(61,259)** | **(301,386)** | **(124,936)** | **(436,151)** |
| Income tax | | 2,140 | (67) | 11,445 | (105) | (360) |
| **Loss for the period** | | **(163,071)** | **(61,326)** | **(289,940)** | **(125,041)** | **(436,511)** |
| Attributable to: | | | | | | |
| Equity holders of the Parent Company | | (159,840) | (61,326) | (285,295) | (125,041) | (433,494) |
| Non-controlling interests | | (3,232) | — | (4,646) | — | (3,017) |
| | | **(163,071)** | **(61,326)** | **(289,940)** | **(125,041)** | **(436,511)** |
| Loss per share before and after dilution | | (3.20) | (1.50) | (5.71) | (3.14) | (9.66) |

## Condensed Consolidated Statements of Comprehensive Income

| (SEK in thousands) | Notes | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Year Ended December 31, 2020 |
|---|---|---|---|---|---|---|
| Loss for the period | | (163,071) | (61,326) | (289,940) | (125,041) | (436,511) |
| **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 | | (4,151) | (49) | 2,515 | 2 | (9,352) |
| **Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods** | | **(4,151)** | **(49)** | **2,515** | **2** | **(9,352)** |
| *Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:* | | | | | | |
| Remeasurement gain on defined benefit plans | | 109 | — | 1,525 | — | 1,216 |
| **Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods** | | **109** | **—** | **1,525** | **—** | **1,216** |
| **Other comprehensive income/(loss) for the period** | | **(4,042)** | **(49)** | **4,040** | **2** | **(8,137)** |
| **Total comprehensive loss for the period** | | **(167,114)** | **(61,375)** | **(285,901)** | **(125,039)** | **(444,648)** |
| Attributable to: | | | | | | |
| Equity holders of the Parent Company | | (163,377) | (61,375) | (281,695) | (125,039) | (438,343) |
| Non-controlling interests | | (3,736) | — | (4,205) | — | (6,305) |
| | | **(167,114)** | **(61,375)** | **(285,901)** | **(125,039)** | **(444,648)** |

## Condensed Consolidated Statements of Financial Position

| (SEK in thousands) | Notes | June 30, 2021 | June 30, 2020 | December 31, 2020 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| Intangible assets | 6 | 481,310 | 16,066 | 461,367 |
| Equipment | | 1,078 | 93 | 163 |
| Right-of-use assets | | 7,759 | 4,782 | 5,244 |
| Non-current financial assets | | 3,942 | 1,938 | 2,225 |
| Deferred tax assets | | 885 | 197 | 600 |
| **Total non-current assets** | | **494,973** | **23,076** | **469,599** |
| | | | | |
| **Current assets** | | | | |
| Other current assets | 8 | 27,276 | 4,267 | 40,547 |
| Cash | | 709,306 | 1,459,569 | 996,304 |
| **Total current assets** | | **736,582** | **1,463,836** | **1,036,851** |
| | | | | |
| **TOTAL ASSETS** | | **1,231,555** | **1,486,912** | **1,506,450** |
| | | | | |
| **EQUITY AND LIABILITIES** | | | | |
| **Equity** | | | | |
| Share capital | | 1,998 | 1,918 | 1,998 |
| Additional paid-in capital | | 2,141,445 | 2,036,378 | 2,133,179 |
| Retained earnings, including net loss for the period | | (1,205,601) | (613,180) | (924,686) |
| **Equity attributable to equity holders of the Parent Company** | | **937,842** | **1,425,116** | **1,210,491** |
| Non-controlling interests | | 32,860 | — | 45,809 |
| **Total equity** | 9,10 | **970,702** | **1,425,116** | **1,256,300** |
| | | | | |
| **Non-current liabilities** | | | | |
| Provisions | 10 | 60,945 | 603 | 55,361 |
| Pension Liabilities | | 5,520 | — | 8,296 |
| Deferred tax liabilities | 7 | 68,849 | — | 79,996 |
| Other non-current liabilities | | 3,478 | 1,671 | 878 |
| **Total non-current liabilities** | | **138,792** | **2,274** | **144,531** |
| | | | | |
| **Current liabilities** | | | | |
| Accounts payable | | 59,263 | 29,520 | 53,827 |
| Other current liabilities | | 8,991 | 5,161 | 10,406 |
| Accrued expenses and deferred revenue | | 53,806 | 24,841 | 41,386 |
| **Total current liabilities** | | **122,060** | **59,522** | **105,619** |
| **TOTAL EQUITY AND LIABILITIES** | | **1,231,555** | **1,486,912** | **1,506,450** |

## Condensed Consolidated Statements of Changes in Equity

| (SEK in thousands) | Notes | June, 30 2021 | June, 30 2020 | December 31, 2020 |
|---|---|---|---|---|
| **Opening balance equity attributable to equity holders of the Parent Company** | | **1,210,491** | **788,071** | **788,071** |
| Loss for the period | | (285,295) | (125,041) | (433,494) |
| Other comprehensive income/(loss) | | 3,599 | 2 | (4,849) |
| **Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company** | | **(281,695)** | **(125,039)** | **(438,343)** |
| **Transactions with owners:** | | | | |
| New share issue | | — | 827,999 | 891,388 |
| Cost attributable to new share issue | | (982) | (94,457) | (97,686) |
| Exercise of warrants | | — | 28,328 | 59,251 |
| Share-based payments | | 9,285 | 214 | 6,012 |
| Purchase of non-controlling interests | | 743 | — | 1,798 |
| **Total transactions with owners** | | **9,046** | **762,084** | **860,763** |
| **Closing balance equity attributable to equity holders of the Parent Company** | | **937,842** | **1,425,116** | **1,210,491** |
| **Opening balance equity attributable to non-controlling interests** | | **45,809** | **—** | **—** |
| Total comprehensive loss for the period | | (4,205) | — | (6,305) |
| Contribution from non-controlling interests | | 2,282 | — | — |
| Non-controlling interests from business combinations | | - | — | 136,084 |
| Purchase of non-controlling interests | | (11,026) | — | (83,970) |
| **Closing balance equity attributable to non-controlling interests** | | **32,860** | **—** | **45,809** |
| **Closing balance equity** | | **970,702** | **1,425,116** | **1,256,300** |

**Condensed Consolidated Statements of Cash Flows**

| (SEK in thousands) | Notes | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Year Ended December 31, 2020 |
|---|---|---|---|---|---|---|
| **Operating activities** | | | | | | |
| Operating loss | | (159,398) | (66,562) | (310,179) | (138,888) | (379,720) |
| Adjustment for non-cash-items | | 10,217 | 1,104 | 15,224 | 1,929 | 15,465 |
| Interest received | | — | — | — | — | 1,912 |
| Interest paid | | (55) | (78) | (209) | (261) | (393) |
| Income tax paid | | (993) | — | (993) | — | (528) |
| **Cash flow used in operating activities before changes in working capital** | | **(150,228)** | **(65,536)** | **(296,156)** | **(137,220)** | **(363,264)** |
| Cash flow from/(used in) changes in working capital | | 17,318 | (1,480) | 29,067 | 51,429 | 54,083 |
| **Cash flow used in operating activities** | | **(132,910)** | **(67,016)** | **(267,089)** | **(85,791)** | **(309,181)** |
| Cash flow used in investing activities | | (18,568) | (1) | (18,767) | (1) | (172,607) |
| **Cash flow used in investing activities** | | **(18,568)** | **(1)** | **(18,767)** | **(1)** | **(172,607)** |
| New share issue | | — | 828,000 | — | 828,000 | 891,388 |
| Costs attributable to new share issue | | — | (64,528) | (982) | (76,780) | (95,937) |
| Premiums from warrants issuance | | — | 28,328 | — | 28,328 | 59,251 |
| Purchase of non-controlling interests | | (366) | — | (10,283) | — | (82,172) |
| Contribution from non-controlling interests | | — | — | 2,282 | — | — |
| Repayment of loans | | (351) | (627) | (1,361) | (1,852) | (3,972) |
| **Cash flow from/(used in) financing activities** | | **(717)** | **791,173** | **(10,344)** | **777,696** | **768,558** |
| **Net increase /(decrease) in cash** | | **(152,195)** | **724,156** | **(296,200)** | **691,904** | **286,770** |
| **Cash at the beginning of the period** | | 867,346 | 728,574 | 996,304 | 753,540 | 753,540 |
| Net foreign exchange gains/(loss) on cash | | (5,845) | 6,839 | 9,202 | 14,125 | (44,006) |
| **Cash at the end of the period** | | **709,306** | **1,459,569** | **709,306** | **1,459,569** | **996,304** |

## Condensed Parent Company Statements of Income

| (SEK in thousands, except per share amounts) | Notes | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Year Ended December 31, 2020 |
|---|---|---|---|---|---|---|
| Net sales | 4 | — | — | — | 474 | 874 |
| Research and development expenses | | (59,223) | (48,386) | (131,373) | (102,492) | (227,027) |
| Administrative and selling expenses | | (79,829) | (19,126) | (134,382) | (37,346) | (128,896) |
| Other operating income | | 14,673 | 622 | 14,673 | 782 | 2,482 |
| Other operating expenses | | 784 | — | (453) | (845) | — |
| **Operating loss** | | **(123,595)** | **(66,890)** | **(251,535)** | **(139,427)** | **(352,567)** |
| Net financial income and expenses | | (5,820) | 5,385 | 9,306 | 14,239 | (54,796) |
| **Loss before income tax** | | **(129,415)** | **(61,505)** | **(242,229)** | **(125,188)** | **(407,363)** |
| Income tax expense | | — | — | — | — | — |
| **Loss for the period** | | **(129,415)** | **(61,505)** | **(242,229)** | **(125,188)** | **(407,363)** |

**Condensed Parent Company Statements of Comprehensive Income**

| (SEK in thousands) | Notes | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Year Ended December 31, 2020 |
|---|---|---|---|---|---|---|
| Loss for the period | | (129,415) | (61,505) | (242,229) | (125,188) | (407,363) |
| Other comprehensive income/(loss) | | — | — | — | — | — |
| **Total comprehensive loss** | | **(129,415)** | **(61,505)** | **(242,229)** | **(125,188)** | **(407,363)** |

**Condensed Parent Company Balance Sheet**

| (SEK in thousands) | Notes | June 30, 2021 | June 30, 2020 | December 31, 2020 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Subscribed but unpaid capital** | | **—** | **21,879** | **—** |
| **Non-current assets** | | | | |
| Intangible assets | 6 | 32,132 | 16,066 | 16,066 |
| Equipment | | 69 | 92 | 80 |
| Non-current financial assets | | 369,493 | 3,723 | 298,683 |
| **Total non-current assets** | | **401,693** | **19,881** | **314,829** |
| | | | | |
| **Current assets** | | | | |
| Other current assets | 8 | 26,646 | 4,842 | 25,488 |
| Cash | | 689,588 | 1,457,011 | 978,208 |
| **Total current assets** | | **716,233** | **1,461,853** | **1,003,696** |
| **TOTAL ASSETS** | | **1,117,926** | **1,503,613** | **1,318,525** |
| | | | | |
| **SHAREHOLDERS' EQUITY AND LIABILITIES** | | | | |
| ***Restricted Shareholders' equity*** | | | | |
| Share capital | | 1,998 | 1,918 | 1,998 |
| On-going issue of shares | | — | 47 | — |
| Statutory reserve | | 3,092 | 3,092 | 3,092 |
| | | **5,090** | **5,057** | **5,090** |
| ***Non-restricted shareholders' equity*** | | | | |
| Share premium reserve | | 2,116,721 | 2,051,868 | 2,116,721 |
| Retained earnings | | (877,494) | (485,164) | (479,379) |
| Net loss for the period | | (242,229) | (125,188) | (407,363) |
| | | **996,998** | **1,441,516** | **1,229,979** |
| **Total shareholders' equity** | 9,10 | **1,002,088** | **1,446,573** | **1,235,069** |
| | | | | |
| **Non-current liabilities** | | | | |
| Provisions | 10 | 5,946 | 603 | 4,972 |
| Other non-current liabilities | | 105 | 105 | 105 |
| **Total non-current liabilities** | | **6,051** | **708** | **5,077** |
| | | | | |
| **Current liabilities** | | | | |
| Accounts payable | | 50,462 | 29,143 | 42,469 |
| Other current liabilities | | 13,636 | 3,089 | 5,123 |
| Accrued expenses and deferred revenue | | 45,690 | 24,100 | 30,787 |
| **Total current liabilities** | | **109,787** | **56,332** | **78,379** |
| **TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES** | | **1,117,926** | **1,503,613** | **1,318,525** |

**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 six months ended June 30, 2021 and June 30, 2020.

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, in the form of ADSs, on the Nasdaq Global Select Market in the United States with the ticker "CALT".

These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on August 19, 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**

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, 2021, have had a significant impact on the Group's financial reporting. Significant accounting principles can be found on pages 45-49 of the Annual Report for 2020.

During 2020, Calliditas 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 27.

**Note 3 Risks and uncertainties in the Group and the Parent Company**

**Operational risks**

Research and drug development up to approved registration is subject to considerable risk and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to the technological risk such as the risk for 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 lack of approvals and price changes.

**COVID-19**

The COVID-19 virus has rapidly spread from an initial event and infections have been reported globally. Calliditas has clinical trial sites in the NefIgArd trial based in areas currently affected by this coronavirus. 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, or any planned trials for Nefecon or setanaxib, 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 impact of the coronavirus outbreak for Calliditas have been limited so far, but 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 risks**

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 and setanaxib 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 2020.

For more information and full disclosure regarding the operational- and financial risks, reference is made to the annual report for 2020 and the annual report on form 20-F, filed with the SEC in April 2021.

**Note 4 Revenue from Contracts with Customers**

The Group's revenues during 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 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.

No revenue was recognized for the three months and six months ended June, 30, 2021.

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

| (SEK in thousands) | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Year Ended December 31, 2020 |
|---|---|---|---|---|---|
| **Type of good or service** | | | | | |
| Provision of drugs | — | — | — | 474 | 874 |
| **Total** | **—** | **—** | **—** | **474** | **874** |
| | | | | | |
| **Geographical markets** | | | | | |
| China, Hong Kong, Macau, Taiwan and Singapore | — | — | — | 474 | 874 |
| **Total** | **—** | **—** | **—** | **474** | **874** |

**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 10.

**Note 6 Intangible Assets**

| (SEK in thousands) | June 30, 2021 | June 30, 2020 | December 31, 2020 |
|---|---|---|---|
| Cost at opening balance | 461,367 | 16,066 | 16,066 |
| Business Combinations | — | — | 460,253 |
| Acquisition license | 16,066 | — | — |
| Exchange difference on translation | 3,877 | — | (14,952) |
| **Cost at closing balance** | **481,310** | **16,066** | **461,367** |
| | | | |
| **Amortization at closing balance** | **—** | **—** | **—** |
| | | | |
| **Net book value** | **481,310** | **16,066** | **461,367** |

Intangible assets consist of licenses and similar rights of SEK 433,646 thousand and goodwill of SEK 47,663 thousand.

**Business combinations:**

The acquisition of Genkyotex SA in 2020 resulted in the Group acquiring the rights to the NOX platform and the SIIL agreement, as well as goodwill.

The net book value of the NOX platform amounts to SEK 373,314 thousand as of June 30, 2021. 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 28,201 thousand as of June 30, 2021. 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 47,663 thousand as of June 30, 2021.

**Note 7 Deferred Tax Liabilities**

| (SEK in thousands) | June 30, 2021 | June 30, 2020 | December 31, 2020 |
|---|---|---|---|
| Cost at opening balance | 79,996 | — | — |
| Business Combinations | — | — | 79,996 |
| Tax loss carried forward | (11,445) | — | — |
| Exchange difference on translation | 298 | — | — |
| **Cost at closing balance** | **68,849** | **—** | **79,996** |

Deferred tax assets of SEK 24.5 million have been offset against deferred tax liabilities in the statement of financial position as of June 30, 2021 due to future temporary differences that such losses can be used to offset.

**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. No currency options or derivates existed as of June 30, 2021. Currency options amounted to SEK 105 thousand as of June 30, 2020. 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 Shareholders' Equity**

| (SEK in thousands, except per share amounts and number of shares) | June 30, 2021 | June 30, 2020 | December 31, 2020 |
|---|---|---|---|
| Total registered shares at the beginning of period | 49,941,584 | 38,707,638 | 38,707,638 |
| New issue of shares during the period | — | 9,230,770 | 11,233,946 |
| **Total registered shares at the end of period** | **49,941,584** | **47,938,408** | **49,941,584** |
| Share capital at the end of period | 1,998 | 1,918 | 1,998 |
| Equity attributable to equity holders of the Parent Company | 937,842 | 1,425,116 | 1,210,491 |
| Non-controlling interests | 32,860 | — | 45,809 |
| **Equity at the end of period** | **970,702** | **1,425,116** | **1,256,300** |

| (SEK in thousands, except per share amounts and number of shares) | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Year Ended December 31, 2020 |
|---|---|---|---|---|---|
| Loss per share before and after dilution | (3.20) | (1.50) | (5.71) | (3.14) | (9.66) |
| Weighted-average number of shares outstanding for the period, before and after dilution | 49,941,584 | 40,915,681 | 49,941,584 | 39,817,759 | 44,873,448 |

Reserves for translation from foreign operations amounted to SEK 2,515 thousand and SEK 2 thousand, which are included in equity as of June 30, 2021 and 2020, respectively.

**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 can be exercised between October 1, 2022 and December 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the 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 some members of Calliditas' board. 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 ("AGM") to June 1, 2022.

**Board LTIP 2020**

This is a performance-based long-term incentive program for 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.

**Board LTIP 2021**

This is a performance-based long-term incentive program for Calliditas Board members. A total of 26,968 share awards were granted under the program during the second quarter of 2021. The share rights are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2021 Annual General Meeting to July 1, 2024.

**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 115% of 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.

**ESOP 2021**

In 2021, 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 115% of 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 June 30, 2021 |
|---|---|---|---|---|
| **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 |
| Board LTIP 2021 | — | — | 26,968 | 26,968 |
| ESOP 2020 | — | 1,485,000 | — | 1,485,000 |
| ESOP 2021 | — | 510,000 | — | 510,000 |
| **Total outstanding as of June 30, 2021** | **1,279,086** | **1,995,000** | **109,738** | **3,383,824** |

| | Warrants Outstanding | Share Awards Outstanding | Total Outstanding as of June 30, 2020 |
|---|---|---|---|
| **Incentive program** | | | |
| Warrant program 2017/2020 | 111,250 | | 111,250 |
| 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 |
| **Total outstanding as of June 30, 2020** | **1,390,336** | **88,403** | **1,478,739** |

**Definitions of Performance Measures 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 share before and after dilution. Diluted earnings per share is calculated by adjusting the weighted average number of common share outstanding to assume conversion of all dilutive potential common shares, 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 ratio at the end of the period | Equity position 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**

| (SEK in thousands or as otherwise indicated) | Three Months Ended June 30, 2021 | Three Months Ended June 30, 2020 | Six Months Ended June 30, 2021 | Six Months Ended June 30, 2020 | Year Ended December 31, 2020 |
|---|---|---|---|---|---|
| ***Research and development expenses/Total operating expenses in %*** | | | | | |
| Research and development expenses | (75,020) | (48,386) | (165,097) | (102,492) | (241,371) |
| Administrative and selling expenses | (84,372) | (18,797) | (143,151) | (36,806) | (141,724) |
| Other operating income/expenses | (6) | 621 | (1,931) | (64) | 2,501 |
| **Total operating expenses** | **(159,398)** | **(66,562)** | **(310,179)** | **(139,362)** | **(380,594)** |
| Research and development expenses/Total operating expenses in % | 47 % | 73 % | 53 % | 74 % | **63 %** |

| (SEK in thousands or as otherwise indicated) | June 30, 2021 | June 30, 2020 | December 31, 2020 |
|---|---|---|---|
| ***Equity ratio at the end of the period in %*** | | | |
| Equity attributable to equity holders of the Parent Company at the end of the period | 937,842 | 1,425,116 | 1,210,491 |
| Total assets at the end of the period | 1,231,555 | 1,486,912 | 1,506,450 |
| **Equity ratio at the end of the period in %** | **76 %** | **96 %** | **80 %** |

**Financial Calendar**

| | |
|---|---|
| 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 |

**Contact:**

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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 interim report 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 interim report, 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.

**Stockholm, Sweden**

**August 19, 2021**

# Interim Report Q2, 2021

**Filing of Marketing Authorisation Application on accelerated basis with EMA**

“Following the filing for accelerated approval with the FDA in Q1, we filed our submission for conditional approval with EMA in May. Both FDA and EMA applications are being processed on an accelerated basis and in the U.S our target PDUFA date is September 15th.

During the 2nd quarter we significantly ramped up our pre commercial activities in the US following the strengthening of the team announced in Q1. We have added significant internal resources as well as entered into some key partnerships, in order to ensure that we are well positioned to initiate commercialization in Q4, subject to a positive outcome of the FDA approval process.

During Q2 we also explored avenues to non-dilutive financing by way of a competitive process in order to provide the company with access to additional capital in advance of, as well as post a potential regulatory approval. In parallel we also ran a successful competitive process focused on securing a strong European commercial partner for Nefecon. The result of these processes which was announced in Q3 resulted in over $100m of non- dilutive capital potentially being available to the company, divided between approximately $50m available pre-approval with the remainder becoming available post FDA and EMA approvals and subsequent US commercialization. These processes, together with the accelerated book building procedure raising approximately gross $37m (SEK 324 million) which we completed in Q3, have significantly enhanced our financial strength after the close of Q2.”

*Renée Aguiar-Lucander, CEO*

**Summary of Q2 2021**

*April 1 – June 30, 2021*

- No net sales were recognized for the three months ended June 30, 2021 and 2020, respectively.
- Operating loss amounted to SEK 159.4 million and SEK 66.6 million for the three months ended June 30, 2021 and 2020, respectively.
- Loss before income tax amounted to SEK 165.2 million and SEK 61.3 million for the three months ended June 30, 2021 and 2020, respectively.
- Loss per share before and after dilution amounted to SEK 3.20 and SEK 1.50 for the three months ended June 30, 2021 and 2020, respectively.
- Cash amounted to SEK 709.3 million and SEK 1,459.6 million as of June 30, 2021 and 2020, respectively.

**Significant events during Q2 2021, in summary**

- In April 2021, Calliditas was granted accelerated assessment procedure by the European Medicine Agency's (EMA) Committee for Human Medicinal Products (CHMP) for Nefecon, reducing the maximum timeframe for review of the application for marketing authorization. If approved, Nefecon could be available to patients in Europe in first half of 2022.

- In April 2021, Calliditas announced that the FDA accepted the submission and granted Priority Review for the NDA for Nefecon. The FDA have set a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021. Subject to approval, this would enable commercialization of Nefecon in the US in Q4, 2021.

- In May 2021, Calliditas announced that the company submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for Nefecon.

**Significant events after the end of reporting period, in summary**

- In July 2021, Calliditas signed a loan facility of up to the EUR equivalent of $75 million with Kreos Capital.

- In July 2021, Calliditas and STADA Arzneimittel AG entered into a license agreement to register and commercialize Nefecon in the European Economic Area (EEA) member states, Switzerland and the UK valued at a total of 97.5 million EUR ($115m) in initial upfront and potential milestone payments, plus royalties.

- In August 2021, Calliditas received FDA fast track designation for setanaxib in PBC.

- In August 2021, Calliditas completed an accelerated book building procedure and resolved on a directed share issue in the amount of 2.4 million shares, raising proceeds of SEK 324.0 million before transaction costs.

**Investor presentation August 19, 14:30 CET**

Audio cast with teleconference, Q2 2021, August 19, 2021, 14:30 (Europe/Stockholm)
Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q2-2021
Teleconference: SE: +46850558356 UK: +443333009266 US: +16467224903

**Financial calendar**

| | |
|---|---|
| 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 |

## For further information, please contact:

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*The information was submitted for publication, through the agency of the contact persons set out above, at 07:00 CET on August 19, 2021.*

## About Calliditas Therapeutics

Calliditas Therapeutics is a biopharma company based in Stockholm, Sweden 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 proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of adults with the autoimmune renal disease primary IgA

nephropathy (IgAN), for which there is a high unmet medical need and there are no approved treatments. Calliditas has recently read out topline data from Part A of its global Phase 3 study in IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is also planning to start clinical trials with NOX inhibitors in primary biliary cholangitis and head and neck cancer. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

## Forward-Looking Statements

This press release 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 press release represent Calliditas'' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.