
**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 2020

(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):

Share Purchase Agreement

On August 13, 2020, Calliditas Therapeutics AB (the “Company”) entered into a Share Purchase Agreement (the “Purchase Agreement”) with certain of the largest shareholders and management team (collectively, the “Sellers”) of Gentyotex SA, a French limited liability company (“Genkyotex”) to purchase a 62.7% interest in Genkyotex. Genkyotex’s ordinary shares, nominal value of €1.00 trade on Euronext Paris and Euronext Brussels under ISIN code FR0013399474 (the “Genkyotex Shares”). Genkyotex is a leader in NOX inhibition therapies, and its lead clinical candidate, Setanaxib (GKT831), is in development for Primary Biliary Cholangitis, a chronic orphan liver disease resulting from progressive destruction of the bile ducts in the liver.

Pursuant to the Purchase Agreement, the Company will purchase, in an off-market block trade, 7,236,515 ordinary shares from the Sellers at a purchase price of €2.80 per ordinary share (the “Transferred Shares”), with a total purchase price of €20.3 million (the “Acquisition”). This purchase price represents a 25% premium over Genkyotex’s volume weighted average price (“VWAP”) over the preceding month immediately prior to the date of the Purchase Agreement.

The Acquisition is expected to close in October 2020 and remains subject to customary conditions precedent, including the clearance from the French Minister of Economy and Finance regarding foreign investments into France. The Company expects to finance the Acquisition from its cash reserves.

The Purchase Agreement may be terminated upon the mutual consent of the company and Sellers’ agent at any time. In the event that the Acquisition does not close by November 1, 2020 (the “Longstop Date”), then the Purchase Agreement may be terminated at any time by the Sellers or the Company, provided that the Company may postpone the Longstop Date by up to 30 Business Days upon notice to the Sellers’ agent.

As soon as reasonably practicable after the completion of the Acquisition, the Company intends to file with the French Financial Market Authority (“AMF”) a mandatory cash simplified tender offer for the remaining Genkyotex Shares on the same terms as the Acquisition (the “Tender Offer”). In the event the Tender Offer is completed for all outstanding shares of Genkyotex, the total acquisition costs to the Company would be approximately €32.3 million. As additional consideration for the Transferred Shares, and contingent upon the consummation of the Tender Offer, the Company has agreed to grant the Sellers non-transferable contingent rights to receive additional cash payments of up to €55M (expressed in relation to 100% of the Genkyotex shares on a fully diluted basis) resulting from confirmed regulatory approvals and marketing authorizations of Setanaxib.

The following descriptions of the Purchase Agreement and Acquisition are not complete and are qualified in their entirety by reference the Purchase Agreement, a copy of which will be filed as an exhibit to the Company’s Annual Report on Form 20-F for the year ending December 31, 2020.

On August 13, 2020 the Company announced the entry into the Purchase Agreement, a copy of which is attached hereto as Exhibit 99.1, and is incorporated by reference herein.

Company Announcement and Interim Report

On August 13, 2020, the Company announced its unaudited first half-year results for 2020, which are further described in the Company’s Interim Report – January – June 2020, copies of which are attached hereto as Exhibits 99.2 and 99.3, respectively, and are incorporated by reference herein.

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Company announcement dated August 13, 2020
99.2	Company announcement dated August 13, 2020
99.3	Interim Report – January – June 2020

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 13, 2020

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



Stockholm, Sweden

August 13, 2020

Calliditas Announces Agreement to Acquire Controlling Interest in Genkyotex SA

Transaction adds late-stage orphan pipeline asset and platform in inflammation and fibrosis. Calliditas to acquire 62.7% of Genkyotex for €20.3M in cash at €2.80 per share in an off-market transaction. Following the closing of the control transaction a mandatory simplified cash tender offer on the same terms for the remaining outstanding shares would be launched. Total consideration for 100% of Genkyotex would amount to ~€32M, not including milestones of up to €55M payable upon regulatory approvals of setanaxib.

Calliditas Therapeutics AB (publ) (“Calliditas” or the Company) (Nasdaq OMX – CALTX; NASDAQ - CALT) announced today that the Company has reached an agreement to acquire a controlling interest in Genkyotex SA (“Genkyotex”) (Euronext Paris & Brussels: FR0013399474 – GKTX), a leader in NOX inhibition therapies.

Genkyotex’s lead clinical candidate, setanaxib (GKT831), is in development for Primary Biliary Cholangitis (PBC), a chronic orphan liver disease resulting from progressive destruction of the bile ducts in the liver. In a Phase 2 clinical trial, setanaxib demonstrated evidence of anti-fibrotic activity combined with a favorable tolerability profile, as well as a statistically significant impact on fatigue. In April 2020, Genkyotex completed an End of Phase 2 meeting with the US Food and Drug Administration (FDA) and in June 2020 obtained scientific advice from the European Medicine Agency’s (EMA) Scientific Advice Working Party (SAWP) that provide a path forward for the late stage development and potential registration of setanaxib in PBC.

“We believe this transaction represents an exciting expansion of our pipeline in orphan diseases related to inflammation and fibrosis”, says Calliditas’ CEO Renée Aguiar-Lucander. “We believe Genkyotex’s novel NOX inhibition technology may have broad clinical utility not just in PBC, but as a platform therapy with the potential to target other fibrotic indications, including Primary Sclerosing Cholangitis (PSC), selected kidney diseases and Idiopathic Pulmonary Fibrosis (IPF), in which an investigator led Phase 2 trial is expected to start recruitment later this year.”

“We look forward to leveraging our strong late stage clinical team, CMC and regulatory expertise as well as our learnings from our Phase 3 Nefecon program to navigate and execute an efficient path forward for setanaxib. We continue to deliver on our strategy focusing on adding late stage assets with an orphan focus and encouraging data in patients to build a company focused on delivering solution for patients with diseases with high unmet needs”, Ms. Aguiar-Lucander concludes.

Calliditas has agreed to acquire through an off-market block trade 7,236,515 ordinary shares of Genkyotex representing 62.7% of the share capital and voting rights of Genkyotex¹ from Genkyotex’s largest shareholders and management team (the “Block Sellers”)² for a total consideration of €20.3M payable in cash at closing (€2.80 per ordinary share) representing a 25% premium over Genkyotex’s volume weighted average price (VWAP) over the preceding month immediately prior to this announcement and non-transferable contingent rights to receive additional cash payments on confirmation of regulatory approvals or marketing authorizations of setanaxib, as described below. The off-market block trade is expected to close in early October 2020 and remains subject to customary conditions precedent, including the clearance from the French Minister of Economy and Finance regarding foreign investments into France. Calliditas will finance the block trade from its cash reserves.

¹ Based on the total number of issued shares and voting rights of Genkyotex on the date of this press release (11,548,562)

² The Block Sellers are Andera Partners (25,3%), Eclosion 2 (12,1%), Vesalius Biocapital (9,4%), Neomed Inovation (8,1%), N5 Investments (0,6%), Wellington Partners (4,2%), Elias Papatheodorou (1,3%), Philippe Wiesel (1%) and Alexandre Grassin (0,6%).

Calliditas is seeking to acquire all outstanding Genkyotex shares and, as soon as reasonably practicable after and subject to completion of the off-market block trade, in compliance with French and Belgian securities law, Calliditas will file with the French Financial Market Authority (*Autorité des Marchés Financiers* – the “AMF”) a mandatory simplified cash tender offer for the remaining Genkyotex shares on the same terms as the block trade, €2.80 per share in cash and non-transferable contingent rights as further described below. The tender offer will be followed by a squeeze-out of the non-tendered shares under the same terms (including the contingent rights) if the legal requirements are met. Total acquisition cost would in such case amount to approximately €32.3M with total contingent rights amounting to a maximum of €55M, subject to future regulatory approvals of setanaxib.

The Block Sellers and the Genkyotex shareholders who tender their shares in the centralized tender offer will be eligible to the following additional cash payments (expressed in relation to 100% of the Genkyotex shares on a fully diluted basis) on confirmation of regulatory approvals or marketing authorizations of setanaxib no later than within ten years of the closing of the tender offer:

- €30M on approval of setanaxib for a first indication by the FDA;
- €15M on approval of setanaxib for a first indication by the European Commission (EC); and
- €10M on approval of setanaxib by the FDA or the EC for either IPF or type 1 diabetes (unless such milestone already has been paid out for such indication by the FDA or the EC as per above).

Bryan Garnier & Co acted as financial advisor to Calliditas in this transaction. Latham & Watkins LLP and Vinge acted as legal advisers to Calliditas.

For further information, please contact:

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Mikael Widell, Investor Relations, Calliditas

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The information in the press release is information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was sent for publication, through the agency of the contact persons set out above, on August 13, 2020 at 07:00 a.m. CET.

This press release does not constitute an offer to purchase, or a solicitation of an offer to sell, any securities of Genkyotex. The documentation relating to the tender offer which, if filed, will state the terms and conditions of the tender offer, will be submitted to the review of the AMF. Investors and shareholders are strongly advised to read the documentation relating to the tender offer when it becomes available, if the offer is filed, as well as any amendments and supplements to those documents as they will contain important information about Calliditas, Genkyotex and the proposed transaction.

The transaction is notably subject to the obtaining of required regulatory authorizations and other customary conditions. The tender offer would only be filed with the AMF after such conditions have been fulfilled and the off-market block trade has been closed.

This press release must not be published, broadcast or distributed, directly or indirectly, in any country in which the distribution of this information is subject to legal restrictions. The tender offer will not be open to the public in jurisdictions in which its launch is subject to legal restrictions. The publication, broadcasting or distribution of this press release in certain countries may be subject to legal or regulatory restrictions. Therefore, persons located in countries where this press release is published, broadcasted or distributed must inform themselves about and comply with such restrictions. Calliditas disclaims any responsibility for any violation of such restrictions.



About Calliditas

Calliditas Therapeutics is a specialty pharmaceutical 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 the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. Calliditas is running a global Phase 3 study within IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. 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, inflammation, pain processing, cancer development, and neurodegeneration. Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, setanaxib (GKT831), a NOX1 and NOX4 inhibitor has shown evidence of anti-fibrotic activity in a Phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease). Based on its positive Phase II results, a phase 3 trial with setanaxib in PBC is being planned. Setanaxib is also being evaluated in an investigator-initiated Phase II clinical trial in Type 1 Diabetes and Kidney Disease (DKD). A grant from the United States National Institutes of Health (NIH) of \$8.9 million was awarded to Professor Victor Thannickal at the University of Alabama at Birmingham (UAB) to fund a multi-year research program evaluating the role of NOX enzymes in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs. The core component of this program is a Phase 2 trial with setanaxib in patients with IPF scheduled to recruit patients in the course of 2020. This product candidate may also be active in other fibrotic indications.

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.



Stockholm, Sweden

Aug 13, 2020

Interim Report Q2, 2020

Successful capital raise on NASDAQ

“In June we successfully closed a \$90m U.S. IPO on NASDAQ, which including the greenshoe that was exercised in July resulted in gross proceeds of \$97m in total. This successful and pioneering transaction, which was the first time a Swedish life science company raised capital on NASDAQ Global Select in an IPO, secured the funding we believe will be necessary to fully complete our Phase 3 study and, if approved, commercially launch the product in the U.S. The U.S. IPO also gave us added flexibility to pursue additional development initiatives related either to our existing pipeline or potential external additions.

In Q2 as we were faced with some extreme circumstances due to COVID-19, we pulled out all the stops to ensure that any impact on the NeflgArd clinical trial was mitigated and any serious disruption kept to a minimum. Special task forces were created, communication and collaboration with our global network of national coordinators were intensified and every detail of every part of the trial was reviewed, assessed and where needed, mitigating solutions were implemented. As a result, the trial remains on plan to report top line data in Q4 as the first Phase 3 clinical trial in IgA nephropathy to do so on a global basis. We are excited and proud to be in this position under these extreme circumstances.”

Renée Aguiar-Lucander, CEO

Summary of Q2 2020

April 1 – June 30, 2020

- No net sales for the three months ended June 30, 2020 were recognized. For the three months ended June 30, 2019 net sales amounted to SEK 138.2 million.
- Operating profit/(loss) amounted to (SEK 66.6 million) and SEK 85.4 million for the three months ended June 30, 2020 and 2019, respectively.
- Profit/(loss) before income tax amounted to (SEK 61.3 million) and SEK 83.2 million for the three months ended June 30, 2020 and 2019, respectively.
- Earnings/(loss) per share before dilution amounted to (SEK 1.50) and SEK 2.36, and after dilution amounted to (SEK 1.50) and SEK 2.35 for the three months ended June 30, 2020 and 2019, respectively.
- Cash amounted to SEK 1,459.6 million and SEK 534.9 million as of June 30, 2020 and 2019, respectively.

Significant events during Q2 2020, in summary

- In April 2020, Calliditas appointed Dr. Richard Philipson as Chief Medical Officer (CMO).
 - In April 2020, Calliditas provided an update on its business activities and financial position on the evolving COVID-19 pandemic, focused on the continuity of the ongoing Phase 3 trial.
 - In June 2020, Calliditas completed an initial public offering on The Nasdaq Global Select Market in the United States for gross proceeds of approximately USD 90 million before deduction of issuance costs.
 - In June 2020, the Annual General Meeting of Calliditas was held and, among other things, the meeting decided on the election of Molly Henderson to the Board of Directors.
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Significant events after the end of reporting period, in summary

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

Investor Presentation August 13, 14:30 CET

Audio cast with teleconference, Q2 2020, August 13, 2020, 14:30 (Europe/Stockholm)

Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q2-2020>

Teleconference: SE: +46856642693 UK: +443333009264 US: +18335268383

Financial calendar

Interim report for the period January 1 – September 30, 2020

November 12, 2020

Year-end report for the period January 1 – December 31, 2020

February 18, 2021

Interim report for the period January 1 – March 31, 2021

May 13, 2021

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 13, 2020.

About Calliditas Therapeutics

Calliditas Therapeutics is a specialty pharmaceutical company based in Stockholm, Sweden. It is focused on developing high quality pharmaceutical products for patients with a significant unmet medical need in niche indications, in which the Company can partially or completely participate in the commercialization efforts. The Company is focused on the development and commercialization of the product candidate Nefecon, a unique two-step formulation optimized to combine a time lag effect with a concentrated release of the active substance budesonide, within a designated target area. This patented, locally acting formulation is intended for treatment of patients with the inflammatory renal disease IgA nephropathy (IgAN). Calliditas Therapeutics is running a global Phase 3 study within IgAN and aims to commercialize Nefecon in the US. The company is listed on Nasdaq Stockholm (ticker: CALTX). 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.



CALLIDITAS THERAPEUTICS AB (publ)

Interim Report January 1 – June 30, 2020

Successful capital raise on

NASDAQ

Key Figures

April 1 - June 30, 2020

- No net sales for the three months ended June 30, 2020 were recognized. For the three months ended June 30, 2019 net sales amounted to SEK 138.2 million.
- Operating profit/(loss) amounted to (SEK 66.6 million) and SEK 85.4 million for the three months ended June 30, 2020 and 2019, respectively.
- Profit/(loss) before income tax amounted to (SEK 61.3 million) and SEK 83.2 million for the three months ended June 30, 2020 and 2019, respectively.
- Earnings/(loss) per share before dilution amounted to (SEK 1.50) and SEK 2.36, and after dilution amounted to (SEK 1.50) and SEK 2.35 for the three months ended June 30, 2020 and 2019, respectively.
- Cash amounted to SEK 1,459.6 million and SEK 534.9 million as of June 30, 2020 and 2019, respectively.

January 1 - June 30, 2020

- Net sales amounted to SEK 0.5 million and SEK 138.2 million for the six months ended June 30, 2020 and 2019, respectively.
- Operating profit/(loss) amounted to (SEK 138.9 million) and SEK 42.7 million for the six months ended June 30, 2020 and 2019, respectively.
- Profit/(loss) before income tax amounted to (SEK 124.9 million) and SEK 40.6 million for the six months ended June 30, 2020 and 2019, respectively.
- Earnings/(loss) per share before and after dilution amounted to (SEK 3.14) and SEK 1.15 for the six months ended June 30, 2020 and 2019, respectively.

Significant Events During the Period April 1 – June 30, 2020, in summary

- In April 2020, Calliditas appointed Dr. Richard Philipson as Chief Medical Officer (CMO).
- In April 2020, Calliditas provided an update on its business activities and financial position on the evolving COVID-19 pandemic, focused on the continuity of the ongoing Phase 3 trial.
- In June 2020, Calliditas completed an initial public offering on The Nasdaq Global Select Market in the United States for gross proceeds of approximately USD 90 million (approximately SEK 828 million) before deduction of issuance costs.
- In June 2020, the Annual General Meeting of Calliditas was held and, among other things, the meeting decided on the election of Molly Henderson to the Board of Directors.

Significant Events After the Reporting Period, in summary

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

Investor Presentation August 13, 14:30 CET

Audio cast with teleconference, Q2 2020, August 13, 2020, 14:30 (Europe/Stockholm)

Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q2-2020>

Teleconference: SE: +46856642693 UK: +443333009264 US: +18335268383

CEO Statement

Successful capital raise on NASDAQ



On June 4, we successfully closed a \$90m U.S. IPO on NASDAQ. The roadshow was launched on Monday June 1st and over a couple of days resulted in a significantly over subscribed offering and an upsizing of the transaction from \$75m to \$90m, which including the greenshoe that was exercised resulted in gross proceeds of \$97m. This successful and pioneering transaction, which was the first time a Swedish life science company raised capital on NASDAQ Global Select in an IPO, secured the funding we believe will be necessary to fully complete our Phase 3 study and, if approved, commercially launch the product in the United States. The U.S. IPO also gave us added flexibility to pursue additional development initiatives related either to our existing pipeline or potential external additions. I would like to thank our existing shareholders as well as our advisors for their help and support in bringing this about. Most importantly, I would like to thank the members of the dedicated senior team at Calliditas, who all worked tirelessly to achieve this extraordinary feat and welcome our new American investors to Calliditas. I believe we are now well positioned to be successful in a volatile and unpredictable world.

The journey had been somewhat longer than what we had expected, due to the rapid and devastating blow from COVID-19 to the global economy towards the end of the first quarter. Capital raising both in Europe and the United States was significantly impacted in March and April, as reports of the global spread of the pandemic dominated the news outlets.

Across Europe hospitals were overwhelmed, non-urgent healthcare was put on hold, many hospitals closed down R&D and did not allow patient visits. Physicians moved out of their practices into their homes and were limited to seeing patients on-line. Much of the world shape shifted into a place only previously imagined in science fiction films; streets were empty, squares deserted, transportation came to a halt and social interaction rules were put in place by governments.

Under these extreme circumstances we pulled out all the stops to ensure that any impact on the NeflgArd clinical trial was mitigated and any serious disruption kept to a minimum. Special task forces were created, communication and collaboration with our global network of national coordinators were intensified and every detail of every part of the trial was reviewed, assessed and where needed, mitigating solutions were implemented. On a positive note, best practice was liberally shared globally, academic institutions co-operated with corporations to try to characterize the virus and human ingenuity and persistence thrived in many corners of this challenging new world. I cannot begin to tell you how immensely proud I am of every single member of the team, who all rose to the occasion and enabled the trial to continue to operate on plan with limited impact from this earthshattering event. Experience and expertise shared in a cross functional manner allowed for crucial collaboration to take place, resulting in identification of the very best solutions. Everyone in the company contributed to this amazing feat and everyone should be very proud of their achievements. As a result, the trial remains on plan to report top line data in Q4 as the first Phase 3 clinical trial in IgA nephropathy to do so on a global basis. We are excited and proud to be in this position under these extreme circumstances.

Healthcare in the eye of the storm

The pandemic has caused havoc with many aspects of our life and deeply impacted the society we live in. Many sectors have seen revenues go to virtually zero over just weeks. However, an area in which the virus has caused unparalleled investment is healthcare. There are presently over 700 preclinical and clinical programs ongoing related to COVID-19 globally according to Biocentury. This compares to around 200 programs in mid-April. Amongst these are the vaccine trials of which some have recently moved into Phase 3, providing the potential of having a vaccine against the virus. Governments and financial institutions around the globe have invested billions of dollars into many different areas to ensure access to drugs and to promote development of a potential cure. If one scans reports from banks who provide summary reports on capital raising the numbers become mind boggling. According to an RBC overview, over \$6bn of capital was raised in the United States in Q2 by biopharma companies going public. This compares to around \$2bn in Q2 last year and a quarterly average of around \$1.5bn over the last seven quarters. Also follow-ons have broken records in Q2 with over \$19bn being raised in the United States by biopharma compared to the quarterly average of \$5bn over the last seven quarters. The micro-cap biotech index in the United States is up over 85% YTD from the beginning of the quarter. The Europe Pharma/Biotech index is up around 16% over the same period. These numbers obviously do not include the billions of dollars which have been spent in the vaccine area or the approximately \$10bn of venture funding which according to EvaluatePharma has gone into private companies in the first half this year. I find it hard to come up with another example of such focused, multi-disciplinary and cross competency driven effort which has grown so rapidly and attracted so much capital over such a short period of time. The industry has also proven itself to be truly innovative and resilient; finding alternative ways of collaborating across institutions, partnering and sharing vital information in order to promote progress globally.

The virus is still with us however and even if some drugs have proven to be effective in treating some patients, we are far away from a true solution to the problem. It continues to rule the world, deciding where we can travel to, who we can socialise with and how we move around in our towns and neighbourhoods. It has also proven to be resilient and innovative, changing and shifting to ensure its own survival and ability to replicate. But there are now thousands of researchers and other healthcare professionals across the globe focusing on the problem on a daily basis and every day we learn something more about it, every day we increase our collective knowledge and understanding of the virus, incrementally adding yet another jigsaw piece into the puzzle, inching ever closer to a solution which will hopefully allow us to overcome the pandemic in due time and return to making our own decisions once again. In the meantime, let's all try to stay safe and continue to be vigilant in order to limit the spread of the virus, and thereby ultimately win the war.

Renée Aguiar-Lucander, CEO

Business Overview

Nefecon – an overview

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

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

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

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

The NefIgArd study

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

Part A is a pivotal efficacy and safety trial that we expect to form the basis for submissions of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA). The primary endpoint of Part A is the decrease in proteinuria in the first 200 randomized and dosed patients. In addition, a secondary endpoint of Part A is the difference in kidney function between treated and placebo patients as measured by eGFR over a nine-month period, which is also expected to be informative of the primary endpoint of Part B. Calliditas expects to report top-line results from Part A in the fourth quarter of 2020. If these data are positive, Calliditas intends to file marketing applications in the first half of 2021 for accelerated approval in the United States by the FDA and conditional approval in the European Union by the EMA.

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

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

IgA Nephropathy – an orphan disease with great unmet medical need

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

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

Despite a need for new therapies, there have been few new drugs developed for chronic kidney diseases during the last decade and there is no approved therapy for IgAN. Patients with IgAN are typically initially given antihypertensive medications, as recommended by the non-profit organization Kidney Disease: Improving Global Outcome (KDIGO). This treatment regimen initially attempts to manage the symptoms of IgAN by decreasing blood pressure and reducing proteinuria but does not address the underlying cause of IgAN. Over time, physicians attempt to control disease progression with a variety of off-label treatments, as a significant proportion of patients experience continued deterioration of kidney function, with no approved treatment options currently available.

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

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

Liver orphan indications

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

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

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

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

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

- In January 2020, EMA Paediatric Committee (PDCO) adopted a positive opinion on the Paediatric Investigation Plan (PIP) for Nefecon for the treatment of primary IgA nephropathy. With successful completion of the agreed PIP, Nefecon would be eligible for up to an additional two years of marketing exclusivity in the EU, on top of the ten-year EU market exclusivity after market approval.
- In March 2020, Calliditas held an Extra General Meeting where authorization for the Board of Directors to issue up to 11 million new shares for a potential equity offering and listing in the United States was approved. At the meeting the adoption of new articles of association and the adoption of a new incentive program were also approved.
- In April 2020, Calliditas announced that Dr. Richard Philipson had been appointed as Chief Medical Officer (CMO). He is a physician with 24 years of experience in the pharmaceutical industry with over 16 years at GSK and his most recent employment was as CMO at Trizell Ltd. Having worked in both large pharmaceutical companies and smaller biotech, Dr. Philipson has extensive experience in rare diseases, having brought several products from early development to the market.
- In April 2020, Calliditas anticipated that the COVID-19 pandemic will not significantly impact the ongoing clinical activities related to NeflgArd study. This was due to the facts that the Part A of the study was fully recruited in December 2019, that Nefecon is an oral formulation which patients are able to take at home, and that the trial is global and requires limited interaction among participants and the healthcare system. The overall impact of the COVID-19 pandemic on the study has been limited, and our estimated timeline for a read out of Part A in the fourth quarter of 2020 currently remains intact.
- In June 2020, Calliditas completed an initial public offering on The Nasdaq Global Select Market, 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 in the United States. 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.

Significant Events After the Reporting Period

- In July 2020, Calliditas announced the exercise of the partial over-allotment option from the IPO on The Nasdaq Global Select Market. Calliditas was thereby provided with additional gross proceeds of approximately USD 6.9 million (approximately SEK 63 million), which means that Calliditas has been provided with in total approximately USD 96.9 million (approximately SEK 891 million) in gross proceeds from the U.S. IPO before deduction of issuance costs.
- In August 2020, Calliditas announced it has reached an agreement to acquire a controlling interest in Genkyotex SA, a leader in NOX inhibition therapies. At closing Calliditas will acquire shares representing 62.7% of Genkyotex for EUR 20.3 million in cash at EUR 2.80 per share. The control transaction is expected to close in October 2020 and remains subject to customary conditions precedent. Following the closing of the control transaction a mandatory simplified cash tender offer on the same terms for the remaining outstanding shares would be launched.

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,
	2020	2019	2020	2019	2019
Net sales	-	138,243	474	138,243	184,829
Research and development expenses	(48,386)	(31,191)	(102,492)	(61,931)	(149,826)
Research and development expenses/ Total operating expenses in % ¹	73%	59%	74%	65%	70%
Operating profit/(loss)	(66,562)	85,386	(138,888)	42,662	(28,019)
Profit/(loss) before income tax for the period	(61,259)	83,167	(124,936)	40,611	(32,501)
Earnings/(loss) per share before dilution	(1.50)	2.36	(3.14)	1.15	(0.88)
Earnings/(loss) per share after dilution	(1.50)	2.35	(3.14)	1.15	(0.88)
Cash flow used in operating activities	(67,016)	(59,303)	(85,791)	(108,685)	(71,011)

(SEK in thousands, except share amounts or as otherwise indicated)	June 30,		December 31,
	2020	2019	2019
Total registered shares at the end of period	47,938,408	35,202,347	38,707,638
Equity at the end of the period	1,425,116	659,023	788,071
Equity ratio at the end of the period in % ¹	96%	93%	93%
Cash at the end of the period	1,459,569	534,863	753,540

¹ Alternative performance measure, see definitions on page 21

January – June 2020

Revenue

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

Operating Expenses

Total operating expenses amounted to SEK 66.6 million and SEK 52.9 million for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020 and 2019, total operating expenses amounted to SEK 139.4 million and SEK 95.6 million, respectively.

Research and Development Expenses

Research and development expenses amounted to SEK 48.4 million and SEK 31.2 million for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020 and 2019, research and development expenses amounted to SEK 102.5 million and SEK 61.9 million, respectively. The increase of SEK 17.2 million for the second quarter and SEK 40.6 million for the six months ended June 30, 2020 is both primarily due to the increased activity in the NefIgArd study and increased expenses for Nefecon product development compared to the same periods last year.

Administrative and Selling Expenses

Administrative and selling expenses amounted to SEK 18.8 million and SEK 19.0 million for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020 and 2019, administrative and selling expenses amounted to SEK 36.8 million and SEK 28.8 million, respectively. The increase of SEK 8.0 million for the six months ended June 30, 2020 and 2019 is primarily due to the increased activity and increase of headcount in the pre-commercial organization and to expenses for the preparation of the initial public offering and listing on The Nasdaq Global Select Market in the United States.

Other Operating Incomes and Expenses

Other operating income amounted to SEK 0.6 million for the three months ended June 30, 2020. For the six months ended June 30, 2020, other operating income amounted to SEK 0.8 million. No other operating income was recognized for the three months, and six months, ended June 30, 2019. The increase was primarily relating to favorable exchange rate development on operating receivables and liabilities.

No other operating expenses were recognized for the three months ended June 30, 2020. For the three months ended June 30, 2019 other operating expenses amounted to SEK 2.7 million. Other operating expenses amounted to SEK 0.8 million and SEK 4.9 million for the six months ended June 30, 2020 and 2019, respectively. The decreases for the periods primarily relate to a more favorable exchange rate development on operating liabilities.

Net Financial Income/(Expenses)

Net financial income/(expenses) amounted to SEK 5.3 million and (SEK 2.2 million) for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020 and 2019, net financial income/(expenses) amounted to SEK 14.0 million and (SEK 2.1 million), respectively. The increase of SEK 7.5 million for the three months ended June 30, 2020 and 2019 and the increase of SEK 16.1 million for the six months ended June 30, 2020 and 2019 are both primarily derived by unrealized foreign currency transaction gains on cash accounts.

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 Groups 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 June 30, 2020 and 2019, profit/(loss) for the period amounted to (SEK 61.3 million) and SEK 83.2 million, and the corresponding earnings/(loss) per share before dilution amounted to (SEK 1.50) and SEK 2.36, and after dilution amounted to (SEK 1.50) and SEK 2.35, respectively.

For the six months ended June 30, 2020 and 2019, profit/(loss) for the period amounted to (SEK 125.0 million) and SEK 40.6 million, and the corresponding earnings/(loss) per share before and after dilution amounted to (SEK 3.14) and SEK 1.15, respectively. The decrease in the results for the periods for both the second quarter 2020 and the first six months of 2020, compared to the same periods 2019, were primarily derived from revenues from the out-licensing of Nefecon for China as part of the license agreement with Everest Medicines, which occurred in the second quarter 2019.

Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 67.0 million and SEK 59.3 million for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020 and 2019, cash flow used in operating activities amounted to SEK 85.8 million and SEK 108.7 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.

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. For both periods for the three months ended and six months ended June 30, 2019, cash flows used in the investing activities amounted to SEK 2.0 million and derived from a deposit for lease agreement, respectively.

Cash flow from/(used in) financing activities amounted to SEK 791.2 million and (SEK 0.1 million) for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020 and 2019, cash flow from/(used in) financing activities amounted to SEK 777.7 million and (SEK 0.3 million), respectively. The increase in cash flow from financing activities for both periods are primarily due to the initial public offering on The Nasdaq Global Select Market and exercise of the warrant program 2017/2020.

Net increase/(decrease) in cash amounted to SEK 724.2 million and (SEK 61.4 million) for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020 and 2019, net increase/(decrease) in cash amounted to SEK 691.9 million and (SEK 111.0 million), respectively. Cash amounted to SEK 1,459.6 million and SEK 534.9 million as of June 30, 2020 and 2019, respectively.

Changes in Shareholders' Equity and Number of Shares

Shareholders' equity amounted to SEK 1,425.1 million and SEK 659.0 million as of June 30, 2020 and 2019, respectively. The number of shares amounted to 47,938,408 and 35,202,347 as of June 30, 2020 and 2019, respectively. The increase in the number of shares between the periods is due the new share issuance of 3.5 million shares in July 2019 and 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.

Personnel

The number of employees were 21 and 14 employees as of June 30, 2020 and 2019, respectively. The total number of full-time equivalent (FTE), including the consultants, were 30 and 20 people as of June 30, 2020 and 2019, respectively. The average number of employees were 20 and 14 employees for the three months ended June 30, 2020 and 2019, respectively and 18 and 13 for the six months ended June 30, 2020 and 2019, respectively.

Incentive Programs

During the second quarter of 2020, the implementation of the LTIP 2020 share awards program for the Board of Directors were granted, following a resolution by the Annual General Meeting in June 2020. For more information, see Note 8.

Parent Company

Since the operations for the Parent Company are consistent with those of the Group in all material respects, the comments for the Group are also relevant for the Parent Company.

Auditor's Review

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

Declaration by the Board of Directors

The Board of Directors and CEO declare that the interim report for the six months ended June 30, 2020 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 13, 2020

Board of Directors

Elmar Schnee	Lennart Hansson	Hilde Furberg
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<i>Chairman of the Board</i>	<i>Board member</i>	<i>Board member</i>
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Diane Parks	Molly Henderson
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<i>Board member</i>	<i>Board member</i>
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Renée Aguiar-Lucander

CEO

Financial Statements

Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
		2020	2019	2020	2019	2019
Net sales	4	-	138,243	474	138,243	184,829
Research and development expenses		(48,386)	(31,191)	(102,492)	(61,931)	(149,826)
Administrative and selling expenses		(18,797)	(18,996)	(36,806)	(28,797)	(62,882)
Other operating income		621	-	782	-	4,385
Other operating expenses		-	(2,670)	(846)	(4,853)	(4,525)
Operating profit/(loss)		(66,562)	85,386	(138,888)	42,662	(28,019)
Net financial income/(expenses)		5,303	(2,219)	13,952	(2,051)	(4,482)
Profit/(loss) before income tax		(61,259)	83,167	(124,936)	40,611	(32,501)
Income tax expense		(67)	-	(105)	-	(77)
Profit/(loss) for the period attributable to shareholders of the Parent Company		(61,326)	83,167	(125,041)	40,611	(32,578)
Earnings/(loss) per share before dilution		(1.50)	2.36	(3.14)	1.15	(0.88)
Earnings/(loss) per share after dilution		(1.50)	2.35	(3.14)	1.15	(0.88)

Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Notes	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
		2020	2019	2020	2019	2019
Profit/(loss) for the period		(61,326)	83,167	(125,041)	40,611	(32,578)
Other comprehensive income						
<i>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:</i>						
Exchange differences on translation of foreign operations		(49)	(4)	2	(15)	(11)
Total other comprehensive income/ (loss)		(61,375)	83,163	(125,039)	40,596	(32,589)
Total comprehensive income/(loss) attributable to shareholders of the Parent Company		(61,375)	83,163	(125,039)	40,596	(32,589)

Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	June 30,		December 31,
		2020	2019	2019
ASSETS				
Non-current assets				
Intangible assets		16,066	-	16,066
Equipment		93	199	104
Right-of-use assets		4,782	7,214	5,959
Non-current financial assets		2,135	2,670	1,939
Total non-current assets		23,076	10,083	24,068
Current assets				
Accounts receivable		-	139,070	46,586
Other current assets	6	4,267	22,460	21,006
Cash		1,459,569	534,863	753,540
Total current assets		1,463,836	696,393	821,132
TOTAL ASSETS		1,486,912	706,476	845,200
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Share capital		1,918	1,408	1,548
Additional paid-in capital		2,036,378	1,072,571	1,274,664
Retained earnings, including net loss for the period		(613,180)	(414,956)	(488,141)
Total shareholders' equity attributable to shareholders of the Parent Company	7,8	1,425,116	659,023	788,071
Non-current liabilities				
Provisions	8	603	11	175
Other non-current liabilities		1,671	4,865	3,584
Total non-current liabilities		2,274	4,876	3,759
Current liabilities				
Accounts payable		29,520	32,481	24,384
Other current liabilities		5,161	3,313	3,471
Accrued expenses and deferred revenue		24,841	6,783	25,515
Total current liabilities		59,522	42,577	53,370
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,486,912	706,476	845,200

Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Notes	June 30,		December 31,
		2020	2019	2019
Opening shareholders' equity		788,071	618,175	618,175
Profit/(loss) for the period		(125,041)	40,611	(32,578)
Other comprehensive income/(loss)		2	(15)	(11)
Total comprehensive income/(loss) for the period		(125,039)	40,596	(32,589)
Transactions with owners:				
New share issue	7	827,999	-	210,317
Cost attributable to new share issue	7	(94,457)	-	(10,915)
Exercise of warrant	7	28,328	-	-
Premiums received from warrants		-	216	2,834
Share-based payments	8	214	36	249
Total transactions with owners		762,084	252	202,485
Closing shareholders' equity		1,425,116	659,023	788,071

Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Notes	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
		2020	2019	2020	2019	2019
Operating activities						
Operating profit/(loss)		(66,562)	85,386	(138,888)	42,662	(28,019)
Adjustment for non-cash-items		1,104	437	1,929	581	2,308
Interest received		-	-	-	-	926
Interest paid		(78)	(78)	(261)	(102)	(325)
Cash flow from/(used in) operating activities before changes in working capital		(65,536)	85,745	(137,220)	43,141	(25,110)
Cash flow from/(used in) changes in working capital		(1,480)	(145,048)	51,429	(151,826)	(45,901)
Cash flow used in operating activities		(67,016)	(59,303)	(85,791)	(108,685)	(71,011)
Cash flow used in investing activities		(1)	(2,006)	(1)	(2,006)	(18,072)
Cash flow used in investing activities		(1)	(2,006)	(1)	(2,006)	(18,072)
Cash flow from/(used in) financing activities		791,173	(138)	777,696	(267)	198,835
Cash flow from/(used in) financing activities		791,173	(138)	777,696	(267)	198,835
Net increase/(decrease) in cash		724,156	(61,447)	691,904	(110,958)	109,752
Cash at the beginning of the period		728,574	596,850	753,540	646,175	646,175
Net foreign exchange gains/(loss) on cash		6,839	(540)	14,125	(354)	(2,387)
Cash at the end of the period		1,459,569	534,863	1,459,569	534,863	753,540

Condensed Parent Company Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
		2020	2019	2020	2019	2019
Net sales	4	-	138,243	474	138,243	184,829
Research and development expenses		(48,386)	(31,191)	(102,492)	(61,931)	(149,826)
Administrative and selling expenses		(19,126)	(19,341)	(37,346)	(29,141)	(63,410)
Other operating income		622	-	782	-	4,385
Other operating expenses		-	(2,676)	(845)	(4,868)	(4,540)
Operating profit/(loss)		(66,890)	85,035	(139,427)	42,303	(28,562)
Net financial income/(expenses)		5,385	(2,155)	14,239	(1,979)	(7,624)
Profit/(loss) before income tax		(61,505)	82,880	(125,188)	40,324	(36,186)
Income tax expense		-	-	-	-	-
Profit/(loss) for the period		(61,505)	82,880	(125,188)	40,324	(36,186)

Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Notes	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
		2020	2019	2020	2019	2019
Profit/(loss) for the period		(61,505)	82,880	(125,188)	40,324	(36,186)
Other comprehensive income/(loss)		-	-	-	-	-
Total comprehensive income/(loss)		(61,505)	82,880	(125,188)	40,324	(36,186)

Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	June 30,		December 31,
		2020	2019	2019
ASSETS				
Subscribed but unpaid capital	7	21,879	-	-
Non-current assets				
Intangible assets		16,066	-	16,066
Equipment		92	199	104
Non-current financial assets		3,723	6,159	2,040
Total non-current assets		19,881	6,358	18,210
Current assets				
Accounts receivable		-	139,070	46,586
Other current assets	6	4,842	22,147	21,005
Cash		1,457,011	534,225	752,448
Total current assets		1,461,853	695,442	820,039
TOTAL ASSETS		1,503,613	701,800	838,249
SHAREHOLDERS' EQUITY AND LIABILITIES				
Restricted Shareholders' equity				
Share capital		1,918	1,408	1,548
On-going issue of shares		47	-	-
Statutory reserve		3,092	3,092	3,092
		5,057	4,500	4,640
Non-restricted shareholders' equity				
Share premium reserve		2,051,868	1,069,072	1,268,334
Retained earnings		(485,164)	(451,820)	(448,989)
Net profit/(loss) for the period		(125,188)	40,324	(36,186)
		1,441,516	657,576	783,159
Total shareholders' equity	7,8	1,446,573	662,076	787,799
Non-current liabilities				
Provisions	8	603	11	175
Other non-current liabilities		105	-	50
Total non-current liabilities		708	11	225
Current liabilities				
Accounts payable		29,143	32,135	24,362
Other current liabilities		3,089	938	1,332
Accrued expenses and deferred revenue		24,100	6,640	24,531
Total current liabilities		56,332	39,713	50,225
TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES		1,503,613	701,800	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 six months ended June 30, 2020 and June 30, 2019. All the Group’s significant business operations are conducted in the Parent Company.

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

These interim condensed consolidated financial statements were approved by the Board of Directors (the “Board”) for publication on August 13, 2020.

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

Note 2 Accounting Policies

These interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard No. 34 (IAS 34), “Interim Financial Reporting”. The Parent Company applies the Swedish Financial Reporting Board recommendation RFR2, Accounting for legal entities. None of the new or amended standards and interpretations that became effective January 1, 2020, have had a significant impact on the Group’s financial reporting. Relevant accounting principles can be found on pages 38-42 of the Annual Report for 2019.

The ESMA (European Securities and Markets Authority) guidelines on alternative key performance ratios are applied, which means disclosure requirements regarding financial measures that are not defined in accordance with IFRS. For key ratios not defined by IFRS, see the Definitions and reconciliations of alternative performance measures on page 21.

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, now known as COVID-19, has rapidly spread from an initial event in Wuhan, China, and infections have been reported globally. Calliditas has clinical trial sites in the global Phase 3 NefIgArd trial based in areas currently affected by this coronavirus and the future spread of the virus and its impact on global markets, the supply chain, and research sites remains unknown. Calliditas has not yet experienced any major disturbances in the 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 trial as a result of disruptions, such as travel bans, quarantines, and inability of patients to access the trial sites and provide samples as well as interruptions in the supply chain, which could result in delays and impact on the data integrity of the trial.

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

Financial Risk Management

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

The Group is primarily affected by foreign exchange risk, since the development costs for Nefecon are mainly paid in USD and EUR. 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 six months ended June 30, 2020 consisted of revenues for the delivery of study-related drugs within the framework of the out-licensing of Nefecon in connection with the agreement with Everest Medicines to Greater China and Singapore.

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

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

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

Note 5 Related-Party Transactions

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

Note 6 Financial Instruments

The Groups' financial assets comprise of long-term receivables, derivatives, other current receivables and cash, all of which, except derivatives, are recognized at amortized cost. Derivatives are recognized at fair value through profit or loss, which consist of currency options amounting to SEK 105 thousand and SEK 1,496 thousand as of June 30, 2020 and 2019, respectively. Currency options are presented as "Other current assets" and valued at fair value based on calculation using the Black-Scholes option pricing model (Level 2) for the six months ended June 30, 2020 and 2019. The Group's financial liabilities comprise of accounts payable and other current liabilities, which are recognized at amortized cost. The carrying amount is an approximation of the fair value.

Note 7 Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	June 30,		December 31,
	2020	2019	2019
Total registered shares at the beginning of period	38,707,638	35,202,347	35,202,347
New issue of shares during the period	9,230,770	-	3,505,291
Total registered shares at the end of period	47,938,408	35,202,347	38,707,638
Share capital at the end of period	1,918	1,408	1,548
Shareholders' Equity at the end of period	1,425,116	659,023	788,071

(SEK in thousands, except per share amounts and number of shares)	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2020	2019	2020	2019	2019
Earnings/(loss) per share before dilution	(1.50)	2.36	(3.14)	1.15	(0.88)
Earnings/(loss) per share after dilution ¹	(1.50)	2.35	(3.14)	1.15	(0.88)
Weighted-average number of shares outstanding for the period, before dilution	40,915,681	35,202,347	39,817,759	35,202,347	36,940,587
Weighted-average number of shares outstanding for the period, after dilution ¹	40,915,681	35,436,980	39,817,759	35,335,047	36,940,587

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

Reserves for translation from foreign operations amounted to SEK 2 thousand and (SEK -15 thousand), which are included in equity as of June 30, 2020 and 2019, respectively.

As of June 5, 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.

As of June 30, 2020, there was an on-going issue of shares of 1,185,250 common shares under registration, which referred to the exercise of the Warrant Program 2017/2020. The part relating to “Subscribed but unpaid capital” of 516,500 common shares is not recognized in the Group but is only presented in the Parent Company. Regarding the calculation of the weighted-average number of shares outstanding for the period, shares in on-going issue of shares have been taken into account, whereby subscribed but unpaid shares have not been included.

Note 8 Incentive Programs

Warrant Program 2017/2020

Warrants representing 1,185,250 common shares, from Warrant Program 2017/2020, with the right to exercise up until June 30, 2020, have been subscribed for before the end of the period. Remaining warrants representing 111,250 common shares in Warrant Program 2017/2020 may be exercised until August 30, 2020.

Warrant Program 2018/2022

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

Warrant Program 2019/2022

The warrants in the Warrant Program 2019/2022 may be exercised between October 1, 2022 and December 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the Parent Company at a subscription price of SEK 74.50 per share. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model.

Board LTIP 2019

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

Board LTIP 2020

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

Summary of Outstanding Incentive Programs

	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 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.
Shareholders' equity at the end of the period	Shareholders' equity at the end of respective period. The measure is extracted from the statements of financial position.
Cash at the end of the period	Cash at the end of respective period. The measure is extracted from the statements of financial position.

Definitions of Alternative Performance Measures

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

Reconciliations of Alternative Performance Measures

(SEK in thousands or as otherwise indicated)	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2020	2019	2020	2019	2019
Research and development expenses/Total operating expenses in %					
Research and development expenses	(48,386)	(31,191)	(102,492)	(61,931)	(149,826)
Administrative and selling expenses	(18,797)	(18,996)	(36,806)	(28,797)	(62,882)
Other operating income/expenses	621	(2,670)	(64)	(4,853)	(140)
Total operating expenses	(66,562)	(52,857)	(139,362)	(95,581)	(212,848)
Research and development expenses/Total operating expenses in %	73%	59%	74%	65%	70%

(SEK in thousands or as otherwise indicated)	June 30,		December 31,
	2020	2019	2019
Equity ratio at the end of the period in %			
Total shareholders' equity at the end of the period	1,425,116	659,023	788,071
Total assets at the end of the period	1,486,912	706,476	845,200
Equity ratio at the end of the period in %	96%	93%	93%

Financial Calendar

Interim report for the period January 1 – September 30, 2020 November 12, 2020

Year-end report for the period January 1 – December 31, 2020 February 18, 2021

Interim report for the period January 1 – March 31, 2021 May 13, 2021



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Forward-Looking Statements

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

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.