Stockholm, Sweden **May 18, 2021**

Interim Report Q1, 2021

Filing of New Drug Application submission to the FDA

"Following the positive top line readout of our pivotal Phase 3 trial NefIgArd, which met both the primary and key secondary endpoints with results being statistically significant and clinically relevant we commenced the regulatory filing process which ultimately resulted in the timely filing of the submission to the FDA in Q1 as planned. In April, we received the response from the Food and Drug Administration (FDA) who accepted the submission and granted Priority Review for the New Drug Application (NDA) for Nefecon. The FDA have set a Prescription Drug User Fee Act (PDUFA) goal date of September 15, 2021. During Q1, we also submitted a request for accelerated assessment to the EMA, which was granted on April 23rd. These grants reflect the perceived unmet medical need in IgAN by regulators and, in my view, also the strength and overall quality of our dossier.

In Q1, we also reported positive data from the Phase 1 study of setanaxib, our lead compound in our NOX inhibition pipeline, paving the way for the use of higher dosing in the pivotal Phase 2/3 study in PBC. We also hosted an R&D day in January where we laid out the clinical development strategy for the year, presenting the plans for our PBC study as well as the Phase 2b proof of concept study in head and neck cancer, both slated to start in the second half of 2021. The substantial preclinical work that has been generated shows compelling data regarding setanaxib's impact on CAF (cancer associated fibroblasts), paving the way for a significantly improved reach of checkpoint inhibitors.

We also significantly built our US team during the quarter, adding a Head of Marketing, VP Medical Affairs and Head of Sales. We will continue to build our team in order to be ready to commercialize in Q4, if approved."

Renée Aguiar-Lucander, CEO

Summary of Q1 2021

January 1 – March 31, 2021

- No net sales for the three months ended March 31, 2021 were recognized. For the three months ended March 31, 2020 net sales amounted to SEK 0.5 million.
- Operating loss amounted to SEK 150.8 million and SEK 72.3 million for the three months ended March 31, 2021 and 2020, respectively.
- Loss before income tax amounted to SEK 136.2 million and SEK 63.7 million for the three months ended March 31, 2021 and 2020, respectively.
- Loss per share before and after dilution amounted to SEK 2.51 and SEK 1.65, for the three months ended March 31, 2021 and 2020, respectively.
- Cash amounted to SEK 867.3 million and SEK 728.6 million as of March 31, 2021 and 2020, respectively.

Significant events during Q1 2021, in summary

- In January 2021, Calliditas announced a positive readout of the Phase 1 study with setanaxib, which enables clinical trials with higher dosing levels.
- In January 2021, Calliditas shared the clinical development plan for setanaxib, including planned trials in Primary biliary cholangitis (PBC) and head and neck cancer, and additional data from Part A of NeflgArd study at its R&D Day.
- 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 (IgAN).

Significant events after the end of reporting period, in summary

- In April 2021, Calliditas was 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 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.

Investor presentation May 18, 14:30 CET
Audio cast with teleconference, Q1 2021, May 18, 2021, 14:30 (Europe/Stockholm)
Webcast: https://tv.streamfabriken.com/calliditas-therapeutics-q1-2021
Teleconference: SE: +46850558366 UK: + 443333009271 US: 18335268381

Financial calendar

Interim Report for the period January 1 – June 30, 2021	August 19, 2021
Interim Report for the period January 1 – September 30, 2021	November 18, 2021
Year-end Report for the period January 1 – December 31, 2021	February 24, 2022

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 May 18, 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.