

Year-End Report, 2020

Positive Topline Results from Pivotal Phase 3 NeflgArd Trial

“On November 8, 2020, we announced positive topline readout of Part A of our Phase 3 pivotal trial, NeflgArd. The results were statistically significant and clinically relevant: proteinuria showed a 31% reduction versus baseline, a stronger effect than what was seen in the Phase 2b (27%), which is generally not expected when moving from Phase 2 to Phase 3. In addition, eGFR was stabilised in the treated patient population, which in the end is the true treatment goal. This potentially disease modifying effect is to our knowledge unique to Nefecon, which we find extremely exciting, and we look forward to our interactions with regulators during the year as we progress towards potential approval.

We also concluded the purchase of a controlling block in Genkyotex in Q4. This is a company we had followed and where we found the clinical data intriguing and their approach clearly differentiated. Genkyotex had positive interactions with the FDA in 2020, which resulted in an adaptive pivotal Phase 2/3 design in PBC and they also initiated a Phase 1 PK study to look into higher dosing, which read out positively in early 2021. We feel excited about taking on a pioneering role in the area of NOX inhibitors and to initiate studies in PBC, as well as on the basis of comprehensive and compelling animal-based data launch a proof of concept trial in head and neck cancer where today’s immunotherapy has limited reach.”

Renée Aguiar-Lucander, CEO

Summary of Q4 2020

October 1 – December 31, 2020

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

Significant events during Q4 2020, in summary

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

Significant events after the end of reporting period, in summary

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

Investor Presentation February 18, 14:30 CET

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

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

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

Financial calendar

Publication of the Annual Report 2020	April 27, 2021
Interim Report for the period January 1 – March 31, 2021	May 13, 2021
Interim Report for the period January 1 – June 30, 2021	August 19, 2021
Interim Report for the period January 1 – September 30, 2021	November 18, 2021
Year-end Report for the period January 1 – December 31, 2021	February 24, 2022

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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 submitted for publication, through the agency of the contact persons set out above, at 07:00 CET on February 18, 2021.

About Calliditas Therapeutics

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 also planning to conduct clinical trials with NOX inhibitors in PBC and oncology. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and The Nasdaq Global Select Market (ticker: CALT).

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.