

Year-End Report, 2022

2022: Successful transformation into a commercial stage company

“2022 was a fantastic year for Calliditas as we launched TARPEYO® in the US, the first approved drug for IgA nephropathy and a medication with the potential to be disease modifying based on the early stabilization of eGFR in patients at risk of rapid disease progression. We achieved total revenues of SEK 802.9 million (\$79.3m) for the year of 2022, which represent an increase of 250% compared to 2021, whereof SEK 372.2 million (\$36.8m) was net sales of TARPEYO for the first 11 months of commercialization. We are immensely proud of this result, and we look forward to continuing to support the patient community with a drug which is designed to target the origin of the disease and thus help keep patients out of dialysis. We end the year with a very strong cash position of SEK 1,249 million (\$119.7m) which reflects a successful non-dilutive capital raising approach, and we believe that we are, based on our guidance for TARPEYO, funded to profitability and well prepared to capitalize on growth and opportunities in 2023.

In the fourth quarter, we continued to build on our commercial success in the US, seeing record average weekly patient enrollment numbers towards the end of the quarter, despite the Thanksgiving and Christmas holidays. The revenue impact of these enrollments is only partly reflected in Q4 revenues due to the requirement for insurance plan approvals for specialty products under the US healthcare system. Total Q4 revenues were SEK 429.0 million (appr. \$42.4m), out of which net sales from TARPEYO amounted to SEK 167.3 million (\$16.1m), resulting in an operating profit of SEK 32.5 million (appr. \$3.2m) and a positive cash flow from operating activities of SEK 230.0 million (appr. \$22.7m) for the fourth quarter. Prescribing nephrologists continue to grow bringing total unique prescribers to 642 for the year. New enrolments amounted to 310 in Q4, resulting in a total of 1,039 enrolments for the year.

In October, Kidney International published a peer reviewed article containing the details of Part A of our NeflgArd trial. We were delighted that, with the Phase 3 trial now approaching its completion, we were in a position to share this information. The data was very well received by nephrologists, as reflected by the high level of interest at the American Society of Nephrology's (ASN's) Kidney Week in Orlando in early November. We were very encouraged by the positive feedback from the many interactions during the conference and by the many discussions that took place about TARPEYO in various forums. It is clear from these interactions that as more eGFR data generally becomes available it will ultimately drive treatment decisions, as the goal of treating physicians is to protect kidney function rather than to address symptoms, and we are excited about being able to share long term eGFR data in 2023 as Part B top line data becomes available, which we hope to be able to announce around mid-March.

For the year of 2023, we estimate net sales from TARPEYO of between USD 120-150 million, reflecting continued market penetration now that the full Part A data is available, combined with the streamlining of market access, and increased peer to peer recommendations based on the early patient successes we are starting to hear about. We believe that strong topline data from the Part B from the NeflgArd trial could provide momentum to uptake as the long term eGFR data will provide additional insight into the potential for kidney protection and disease modification achieved by the TARPEYO treatment.

We also made progress with regards to our global Nefecon franchise. In early November our partner, Everest Medicines, received an acceptance of their New Drug Application (NDA) for approval of Nefecon in China, which was followed by a subsequent Priority Review decision recommendation by the Chinese NMPA in

December. In December we also entered into another important partnership deal related to our licensing of Nefecon for Japan and received an initial upfront payment of USD 20 million upon signing with Viatriis Pharmaceuticals Japan, who will develop Nefecon for patients in the Japanese market. We look forward to collaborating with our partners to bring Nefecon to patients as quickly as possible.”

CEO Renée Aguiar-Lucander

Summary of Q4 2022

October 1 - December 31 2022

- Net sales amounted to SEK 429.0 million, whereof TARPEYO® net sales amounted to SEK 167.3 million, for the three months ended December 31, 2022. For the three months ended December 31, 2021 net sales amounted to SEK 31.2 million and no TARPEYO net sales were recognized.
- Operating profit/(loss) amounted to SEK 32.5 million and (SEK 222.1 million) for the three months ended December 31, 2022 and 2021, respectively.
- Loss per share before and after dilution amounted to SEK 0.07 and SEK 4.19 for the three months ended December 31, 2022 and 2021, respectively.
- Cash amounted to SEK 1,249.1 million and SEK 955.5 million as of December 31, 2022 and 2021, respectively.

Significant events during Q4 2022, in summary

- In October 2022, Calliditas announced that Kidney International published the successful results from Part A of the NeflgArd pivotal Phase 3, randomized, double-blind, placebo-controlled, multicenter study, on the basis of which the accelerated approval by the FDA for TARPEYO and the conditional marketing authorization by the European Commission for Kinpeygo® in the USA and Europe (EEA), respectively.
- In November 2022, Calliditas announced that its partner in China Everest Medicine’s New Drug Application for Nefecon was accepted by the Chinese regulatory authority National Medical Products Administration (NMPA).
- In December 2022, Calliditas announced that it had entered into an exclusive license agreement with Viatriis Pharmaceuticals Japan Inc., to register and commercialize Nefecon for the treatment of IgAN in Japan. Under the terms of the agreement, Calliditas received an initial upfront payment of USD 20 million upon signing and is entitled to up to an additional USD 80 million in pre-defined development and commercialization milestones. Viatriis will also pay mid-teens percentage royalties on net sales.

Significant Events After the End of the Reporting Period, in Summary

- In February 2023, Calliditas announced that the MHRA of the United Kingdom has granted Conditional Marketing Authorization (CMA) for Kinpeygo for the treatment of IgAN. Calliditas will transfer the CMA to its partner STADA Arzneimittel AG, which have the right to commercialize Kinpeygo in the European Economic Area (EEA), Switzerland and the UK.

2023 outlook

- For 2023, Calliditas expects accelerated revenue growth in the U.S. where net sales from TARPEYO are estimated to be USD 120-150 million for the year ending December 31, 2023.

Investor Presentation February 23, 2023 14:30 CET

Audio cast with teleconference, Q4 2022

Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q4-2022>

Teleconference: <https://conference.financialhearings.com/teleconference/?id=5009654>

For further information, please contact:

Marie Galay, IR Manager, Calliditas

Tel.: +44 79 55 12 98 45, email: marie.galay@calliditas.com

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 February 23, 2023 at 07:00 a.m. CET.

About Calliditas

Calliditas Therapeutics is a commercial stage 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, developed under the name Nefecon, has been granted accelerated approval by the FDA under the trade name TARPEYO® and conditional marketing authorization by the European Commission under the trade name Kinpeygo®. Kinpeygo is being commercialized in the European Union Member States by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer with its NOX inhibitor product candidate, setanaxib. Calliditas' common shares are listed on Nasdaq Stockholm (ticker: CALTX) and its American Depositary Shares are listed on 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, commercialization efforts, business plans, regulatory submissions, clinical development plans, revenue and product sales projections or forecasts 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, continued and additional regulatory approvals for TARPEYO and Kinpeygo, market acceptance of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts and other risks identified in the section entitled "Risk Factors" in 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.