

Interim Report Q1, 2022

Start of TARPEYO™ Commercial Launch in the US

“During the first quarter Calliditas launched its first commercial product, TARPEYO, in the US, supported by 40 experienced specialty sales executives who were trained and in the field in late January. Our commercial product was already available to ship to patients at the end of January, reflecting the great collaboration between our CMC group and our commercial team in the US.

Our transformation from a primarily R&D based company to a commercial stage, fully integrated business has been a journey, which first started 3 years ago when we brought onboard our first employee in the US. Under the guidance of a small but highly experienced senior team, we started to build our medical affairs and market access teams in preparation for a future regulatory approval.

With a fully integrated operation and a streamlined supply and distribution chain in place, the US organization had grown significantly and was by mid-2021 ready for the final step, onboarding of the sales force. When accelerated approval of TARPEYO was granted by the FDA, the entire organization was well prepared and ready. TARPEYO Touchpoints™ was available within hours and prescribers were able to access details regarding the product, the indication and could write prescriptions for appropriate patients. There was hope at last for IgAN patients in the US, as an approved product became available for the first time.

This is obviously just the very beginning of the journey, but we are very encouraged by the strong interest and early successes we have experienced, which have resulted in net product revenues of \$1.9M (SEK 18.0M) for the first couple of months of commercial availability, and we remain fully committed to continuing to build the TARPEYO franchise.”

CEO Renée Aguiar-Lucander

Summary of Q1 2022

January 1 - March 31, 2022

- Net sales amounted to SEK 49.7 million, whereof TARPEYO net sales amounted to SEK 18.0 million, for the three months ended March 31, 2022. No net sales were recorded for the three months ended March 31, 2021.
- Operating loss amounted to SEK 208.4 million and SEK 150.8 million for the three months ended March 31, 2022 and 2021, respectively.
- Loss per share before and after dilution amounted to SEK 3.95 and SEK 2.62 for the three months ended March 31, 2022 and 2021, respectively.
- Cash amounted to SEK 825.4 million and SEK 867.3 million as of March 31, 2022 and 2021, respectively.

Significant events during Q1 2022, in summary

- In January 2022, Calliditas announced commercial availability and initial sales of TARPEYO™ (budesonide) delayed release capsules, the first and only FDA approved treatment for IgA nephropathy, indicated for reduction of proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, generally considered a urine protein-to-creatinine ratio (UPCR) $\geq 1.5\text{g/g}$.

- In February 2022, Calliditas announced that the first patient had been randomized in the company's pivotal phase 2b/3 TRANSFORM study in patients with primary biliary cholangitis (PBC).
- In March 2022, Calliditas expanded its licensing agreement with Everest to extend the territory covered to include South Korea.

Significant events after the reporting period

- In May 2022, Calliditas announced that the first patient had been randomized in the company's proof-of-concept Phase 2 study in patients with squamous cell carcinoma of the head and neck (SCCHN) with the NOX 1 and 4 inhibitor setanaxib.

Investor Presentation May 18, 2022 14:30 CET

Audio cast with teleconference, Q1 2022

Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q1-2022>

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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 sent for publication, through the agency of the contact persons set out above, on May 18, 2022 at 7:00 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, TARPEYO™ (budesonide) delayed release capsules has been approved by the FDA and is the subject of a marketing authorization application (MAA) with the European Medicines Agency (EMA). Additionally, Calliditas is conducting two trials with its NOX inhibitor product candidate setanaxib: a pivotal Phase 2b/3 clinical trial in primary biliary cholangitis and a Phase 2 proof-of-concept trial in head and neck cancer. 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). Visit www.calliditas.com for more 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, commercialization efforts, business plans, regulatory submissions, clinical development 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, continued FDA approval for TARPEYO, market acceptance of TARPEYO, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, 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



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