

Interim Report Q3, 2022

Conditional Marketing Authorization in EU Granted for Kinpeygo®

“On July 15th the European Commission issued the conditional marketing authorization for Kinpeygo, which marked the first time that any drug has achieved approval for this rare disease in EU. We immediately started the process of transferring the market authorization to our European partner, STADA Arzneimittel AG, in order to enable a launch in Europe as quickly as possible. STADA is initially launching the product in Germany, with other European countries to follow over time.

With approval and commercial efforts now ongoing in both the US and Europe, we are looking forward to the regulatory process in China, where our partner, Everest Medicines, expects to receive NDA acceptance notice from NMPA this quarter. We are excited to support Everest as they work with regulators in China, who are expected to reach a decision regarding a potential approval in the second half of next year. If Nefecon is approved, this would be the first and only approved medication for the by Everest estimated 5m biopsy-proven IgAN patients in China.

In the US, we continue to build on our early commercial success. Net sales from TARPEYO grew by 94% when compared to Q2, resulting in net sales from TARPEYO of SEK 123.4 million (\$12.1m) for Q3. There is a growing number of nephrologists choosing to prescribe TARPEYO, with 166 new prescribers added in Q3, bringing total unique prescribers to 480 at the end of the quarter. We continue to see a continuous build of interest which mirrors the natural cadence of nephrology visits, which aligns with our expectations regarding this fairly silent, progressive disease. We expect to achieve net sales from TARPEYO for the year of between \$35 – 40m, which aligns with our internal plans for 2022. We also expect to see significant continued growth in 2023 as nephrologists become more familiar with the clinical data, access becomes more streamlined, and as topline data from the Part B of the NefIgArd trial becomes available.

We were delighted to be able to have the Part A data published in Kidney International in October, 2022, as regulators also posted their review assessments. This data set, showing increasing reduction of proteinuria across the entire patient population during the 9 months on drug as well as significant continued reduction of proteinuria across the entire study population in the following 3 months when no drug was administered, showing a highly differentiated profile. The significance of this data was further confirmed by countless interactions at the American Society of Nephrology (ASN) Kidney Week in early November, where we had the opportunity to engage not only with KOLs but with the broader nephrology community treating IgAN patients.”

CEO Renée Aguiar-Lucander

Summary of Q3 2022

July 1 - September 30

- Net sales amounted to SEK 260.1 million, whereof TARPEYO® net sales amounted to SEK 123.4 million, for the three months ended September 30, 2022. For the three months ended September 30, 2021 net sales amounted to SEK 198.2 million and no TARPEYO net sales were recognized.
- Operating profit/(loss) amounted to (SEK 36.2 million) and SEK 7.9 million for the three months ended September 30, 2022 and 2021, respectively.
- Earnings/(loss) per share before and after dilution amounted to (SEK 0.17) and SEK 0.21 for the three months ended September 30, 2022 and 2021, respectively.

- Cash amounted to SEK 736.2 million and SEK 1,163.8 million as of September 30, 2022 and 2021, respectively.

Significant events during Q3 2022, in summary

- In July 2022, Calliditas announced that the European Commission (EC) granted conditional marketing authorization for Kinpeygo for the treatment of IgA nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/gram. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in EU. Kinpeygo will be marketed in the European Economic Area (EEA) exclusively by STADA Arzneimittel AG. Subsequently, in September 2022, Calliditas transferred its Market Authorization for Kinpeygo to its European commercial partner, STADA Arzneimittel AG, who will initially launch in Germany, with additional European countries to follow.

Investor Presentation November 14, 2022 14:00 CET

Audio cast with teleconference, Q3 2022

Webcast: <https://ir.financialhearings.com/calliditas-therapeutics-q3-2022>

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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 November 14, 2022 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-



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