

## Calliditas Interim Report January – September 2023

### The Lancet publication of full Phase 3 data set

**In August we were excited to see the full data set from our Phase 3 clinical trial, NeflgArd, published in The Lancet and we are looking forward to a potential full approval of TARPEYO for treatment of IgA Nephropathy, for which the PDUFA date is December 20, 2023.**

### Financial Summary of Q3 2023

July 1 – September 30, 2023

- Net sales amounted to SEK 294.6 million, of which TARPEYO® net sales amounted to SEK 283.6 million, for the three months ended September 30, 2023. For the three months ended September 30, 2022, net sales amounted to SEK 260.1 million, of which TARPEYO® net sales amounted to SEK 123.4 million.
- Operating loss amounted to SEK 159.6 million and SEK 36.2 million for the three months ended September 30, 2023, and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 3.14 and SEK 0.17 for the three months ended September 30, 2023, and 2022, respectively.
- Cash amounted to SEK 786.9 million and SEK 736.2 million as of September 30, 2023, and 2022, respectively.

January 1 - September 30, 2023

- Net sales amounted to SEK 755.3 million, of which TARPEYO net sales amounted to SEK 728.5 million, for the nine months ended September 30, 2023. For the nine months ended September 30, 2022, net sales amounted to SEK 373.8 million, of which TARPEYO net sales amounted to SEK 205.0 million.
- Operating loss amounted to SEK 414.8 million and SEK 454.4 million for the nine months ended September 30, 2023, and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 8.34 and SEK 7.72 for the nine months ended September 30, 2023, and 2022, respectively.

*“The recent ASN meeting in Philadelphia provided us with numerous opportunities to meet and engage with nephrologists across the country, further cementing our belief that the strong long-term data from our Phase 3 trial, in combination with a potential full approval, will significantly impact how nephrologists view and use the product going forward.*

*We reconfirm our guidance for 2023 of USD 100 – 120m of net sales from TARPEYO and look forward to an exciting 2024.”* Renee Aguiar-Lucander, CEO

## Significant Events in Q3 2023, in Summary

- On July 13 Calliditas announced supportive interim data from Phase 2 head and neck cancer trial with lead NOX inhibitor candidate, setanaxib.
- On August 15 Calliditas announced full results from the NeflgArd Phase 3 trial published in The Lancet.
- On August 18 FDA granted priority review for full approval of TARPEYO® for the treatment of IgA Nephropathy.
- On September 27 Calliditas granted orphan drug designation by the FDA for the treatment of Alport syndrome with setanaxib.
- On September 28 STADA and Calliditas announced the filing for full marketing authorization of Kinpeygo® in the EU.
- On September 29 Calliditas presented Data from the NeflgArd Phase 3 trial at the 17th International Symposium on IgA Nephropathy (IIgANN) Tokyo 2023.

## Investor Presentation

Calliditas invites investors, analysts and press to a presentation of the Quarterly Report 2023 at 14:30 pm. on November 7. Calliditas' CEO Renee Aguiar-Lucander will present the report together with CFO Fredrik Johansson, CMO Richard Philipson and President North America Andrew Udell. The presentation will be given in English.

- Time: Tuesday 14:30 pm CET. on November 7
- Link to webcast <https://financialhearings.com/event/46414>
- To participate via conference call register via this link:

<https://conference.financialhearings.com/teleconference/?id=2001082>

After registration, you will receive a phone number and a conference ID to log in to the conference call. Via the telephone conference, there is an opportunity to ask oral questions.

### For further information, please contact:

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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 person set out above, on November 7, 2023, 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, 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 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, including 2023 revenue guidance, 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.