

## Calliditas Year-end report, January – December 2023

### Calliditas Therapeutics AB (Nasdaq Stockholm: CALTX)

#### 2023: Full approval for TARPEYO in the US; a year of successes

##### OCTOBER – DECEMBER 2023

(COMPARED TO OCTOBER – DECEMBER 2022)

- Net sales amounted to SEK 451.6 million, of which TARPEYO® net sales amounted to SEK 347.3 million, for the three months ended December 31, 2023. For the three months ended December 31, 2022, net sales amounted to SEK 429.0 million, of which TARPEYO net sales amounted to SEK 167.3 million.
- Operating income amounted to SEK 41.8 million and SEK 32.5 million for the three months ended December 31, 2023, and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 0.34 and SEK 0.07 for the three months ended December 31, 2023, and 2022, respectively.
- Cash amounted to SEK 973.7 million and SEK 1,249.1 million as of December 31, 2023, and 2022, respectively.

##### JANUARY – DECEMBER 2023

(COMPARED TO JANUARY – DECEMBER 2022)

- Net sales amounted to SEK 1,206.9 million, of which TARPEYO net sales amounted to SEK 1,075.8 million, for the year ended December 31, 2023. For the year ended December 31, 2022, net sales amounted to SEK 802.9 million, of which TARPEYO net sales amounted to SEK 372.2 million.
- Operating loss amounted to SEK 373.1 million and SEK 421.9 million for the year ended December 31, 2023, and 2022, respectively.
- Loss per share before and after dilution amounted to SEK 8.69 and SEK 7.78 for the year ended December 31, 2023, and 2022, respectively.
- For the year ended December 31, 2023, no dividend is proposed.

**“In December we were granted full approval by the FDA for TARPEYO – a crowning achievement after many years of striving to bring an approved disease modifying treatment to patients with primary IgAN.”**

CEO Renée Aguiar-Lucander

##### KEY TAKEAWAYS FROM Q4, 2023

- In November, Calliditas’ partner Everest Medicines announced that China’s National Medical Products Administration (NMPA) had approved Nefecon for the treatment of primary immunoglobulin A nephropathy (IgAN) in adults at risk of disease progression.
- In November, Calliditas announced the initiation of a Phase 2 clinical study to evaluate setanaxib in Alport syndrome.
- In December, Calliditas received approval (Notice of Allowance) regarding a US patent application for TARPEYO®. In the first quarter of 2024, notice was issued regarding the patent, which provides patent in the US through 2043.
- In December, the United States (US) Food and Drug Administration (FDA) granted Calliditas full approval of TARPEYO® for reduction of kidney loss in adult IgAN patients at risk of disease progression.

##### EXPECTED KEY EVENTS UPCOMING 6 MONTHS

- Read out of the Nefecon Open label Phase 3 extension trial, which will provide data on retreatment with Nefecon.
- The transfer of the Marketing Authorization Holder (MAH) approval to Everest Medicines and commercial launch of Nefecon in China.
- European Commission decision regarding a potential full approval for Kinpeygo for Calliditas’ partner STADA.
- Full data read out of the setanaxib Phase 2 trial in head and neck cancer.

## **OUTLOOK FOR 2024**

Calliditas expects continued revenue growth:

Total net sales are estimated to be USD 150-180 million for the year ending December 31, 2024

## **INVESTOR PRESENTATION**

February 21, 2024, 14:30 CET

Link to webcast: <https://ir.financialhearings.com/calliditas-therapeutics-q4-report-2023>

To participate via conference call register via this link:

<https://conference.financialhearings.com/teleconference/?id=50046870>

## **For further information, please contact:**

Åsa Hillsten, Head of IR & Sustainability, Calliditas

Tel.: +46 76 403 35 43, Email: [asa.hillsten@calliditas.com](mailto:asa.hillsten@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 person set out above, on February 21, 2024, at 07:00 a.m. CET.*

## **About Calliditas**

Calliditas Therapeutics is a biopharma company headquartered in Stockholm, Sweden, focused on identifying, developing, and commercializing novel treatments in orphan indications with significant unmet medical needs. 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 [Calliditas.com](http://Calliditas.com) for further 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 the development of Calliditas' pipeline. 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, intellectual property of the NEFECON franchise globally, competition from other companies, pipeline development, revenue and product sales projections or forecasts, 2024 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.