

## Calliditas Q1 report, January – March 2024

### Calliditas Therapeutics AB (Nasdaq Stockholm: CALTX): Target market expansion following full approval in the US

JANUARY – MARCH 2024 (COMPARED TO JANUARY – MARCH 2023)

- Net sales amounted to SEK 295.5 million, of which TARPEYO® net sales amounted to SEK 278.3 million, for the three months ended March 31, 2024. For the three months ended March 31, 2023, net sales amounted to SEK 191.4 million, of which TARPEYO net sales amounted to SEK 185.7 million.
- Operating loss amounted to SEK 203.8 million and SEK 180.1 million for the three months ended March 31, 2024, and 2023, respectively.
- Loss per share before and after dilution amounted to SEK 4.59 and SEK 3.49 for the three months ended March 31, 2024, and 2023, respectively.
- Cash amounted to SEK 810.3 million and SEK 1,013.6 million as of March 31, 2024, and 2023, respectively.

**“In Q1 we generated another record quarter in terms of demand with 705 enrollments and 354 new prescribers. We are very excited over this positive trend, and we continue to see strong demand in Q2.” – CEO Renée Aguiar-Lucander.**

#### KEY TAKEAWAYS FROM Q1, 2024

- Calliditas had a record quarter with 705 enrollments, representing a 27% increase over Q4.
- In February, the United States Patent and Trademark Office (USPTO) issued patent no. 11896719, entitled “New Pharmaceutical Compositions”. This was Calliditas’ second patent for TARPEYO in the United States and provides product protection until 2043.
- In March, the FDA granted an orphan drug exclusivity period of seven years for TARPEYO®, expiring in December 2030, based on when the company obtained full approval with a new indication for this drug product.
- There was a negative impact on net TARPEYO revenues in the quarter of approximately USD 4.7 million due to a cyberattack on Change Health. The revenues we were not able to record in Q1 because of this technical issue are not lost, but are expected to roll forward over the next several months. This is not expected to have any impact on annual revenues.

#### KEY EVENTS AFTER THE REPORTING PERIOD

- Preliminary net sales from TARPEYO for the second quarter to date amounts to USD 25.5 million.
- Positive read out of the Nefecon Open label Phase 3 extension trial.
- Positive topline results from the setanaxib Phase 2 trial in head and neck cancer.
- Commercial launch of Nefecon in China by partner Everest Medicines.

#### KEY EVENTS UPCOMING 6 MONTHS

- European Commission decision regarding a potential full approval for Kinpeygo for Calliditas’ partner STADA.
- Full data read out of Phase 2 trial in Primary Biliary Cholangitis.
- Updated KDIGO guidelines expected in 2024.

Outlook for 2024: Unchanged

Calliditas expects continued revenue growth:

Total net sales from the Nefecon franchise, including milestones, are estimated to be USD 150-180 million for the year ending December 31, 2024.

Investor Presentation:

May 23, 2024 14:30 CET

Link to webcast: [Calliditas Therapeutics Q1 Report 2024 \(financialhearings.com\)](https://financialhearings.com)

To participate via conference call register via this link: [Call Access \(financialhearings.com\)](https://financialhearings.com)

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The information in the report 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 May 23, 2024, at 7:00 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](https://Calliditas.com) for further information.

**Forward-Looking Statements**

This Interim Report 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, business plans, revenue and other financial projections, 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 Interim Report 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 Interim Report, including, without limitation, any related to Calliditas' business, operations, commercialization of TARPEYO, Kinpeygo and Nefecon, clinical trials, supply chain, strategy, goals and anticipated timelines for development and potential approvals, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts, including 2024 total net sales guidance and cash runway and preliminary net sales for the second quarter of 2024 to date, 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 Interim Report represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.