
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report: March 6, 2024

(Commission File No. 001-39308)

CALLIDITAS THERAPEUTICS AB

(Translation of registrant's name into English)

Kungsbron 1, D5

SE-111 22

Stockholm, Sweden

(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

Enclosed hereto is a copy of an announcement published by Calliditas Therapeutics AB on March 6, 2024.

The information contained in this Form 6-K, including Exhibit 99.1, is hereby incorporated by reference into the registrant's Registration Statements on Form F-3 (File No. 333-265881) and Form S-8 (File Nos. 333-240126 and 333-272594).

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated March 6, 2024

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CALLIDITAS THERAPEUTICS AB

Date: March 6, 2024

By: /s/ Fredrik Johansson
Fredrik Johansson
Chief Financial Officer



Stockholm, Sweden

March 6, 2024

Calliditas announces extended orphan drug exclusivity period for TARPEYO® in U.S.

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that the FDA has granted a new orphan drug exclusivity period of seven years for TARPEYO®, starting from Dec 20, 2023, when the company obtained full approval with a new indication. Orphan drug exclusivity for TARPEYO® will now run through December 20, 2030.

Under 21 CFR 316.31(b), orphan drug exclusivity is intended to protect “the approved indication or use of a designated drug.” Following full approval, TARPEYO® is now indicated “to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression”. This indication is different from the original accelerated approval indication both because it covers a broader range of patients with IgAN, and because it is based on a confirmed clinical benefit on kidney function for patients with IgAN, whereas the original indication was to reduce proteinuria related to their kidney disease.

“We are delighted to have another two years of market exclusivity for TARPEYO® in the US, reflecting the revised indication based on the long-term data generated,” said CEO Renée Aguiar-Lucander.

For further information, please contact:

Åsa Hillsten, Head of IR & Sustainability, Calliditas
Tel.: +46 76 403 35 43, Email: 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 persons set out above, on March 6, 2024 at 08:00 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 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.
