
**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 22, 2022

(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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

Enclosed hereto is a copy of an announcement published by Calliditas Therapeutics AB on March 22, 2022.

The information contained in this Form 6-K, including Exhibit 99.1, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated March 22, 2022

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 22, 2022

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



Stockholm, Sweden

March 22, 2022

Calliditas provides a regulatory update on EMA process for Nefecon

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) today announced that the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) can be expected in Q2, 2022.

In its review of the marketing authorisation application (MAA) for NEFECON, the CHMP has informed us that they will issue an additional list of questions related to manufacturing related information which will result in the opinion from EMA slipping into the second quarter. The continued review does not relate to the safety or efficacy of NEFECON, and there are no plans for an oral explanation.

“Targeting an opinion in Q1 was ambitious in light of the fact that this is the first time the EMA has reviewed a drug for this indication,” said CEO Renée Aguiar-Lucander. “We are confident that we will be able to address the few remaining questions in a timely manner and we have been highly encouraged by our interactions to date with EMA, and look forward to continuing to work with them towards an approval.”

Calliditas submitted an MAA for NEFECON in May 2021. NEFECON was granted accelerated approval by the FDA in December of 2021 under the brand name TARPEYO™. For indication details please visit <https://www.tarpeyo.com/>.

For further information, please contact:

Marie Galay, IR Manager, Calliditas

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The information was sent for publication, through the agency of the contact persons set out above, on March 22, 2022, at 8:00 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, TARPEYO™ (budesonide) delayed release capsules, has been approved by the FDA and is the subject of a marketing authorization application (MAA) with the European Medicines Agency (EMA). Additionally, Calliditas is conducting a pivotal clinical trial with its NOX inhibitor product candidate setanaxib in primary biliary cholangitis and is initiating a head and neck cancer Phase 2 trial with 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 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 EMA review and approval for NEFECON, market acceptance of NEFECON/TARPEYO, safety or efficacy of NEFECON/TARPEYO, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, 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.
