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: October 5, 2023

(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

Calliditas Therapeutics AB today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion on the company's application for orphan drug designation in the European Union (EU) for setanaxib in Alport syndrome. Enclosed hereto as Exhibit 99.1 is a copy of the announcement**.**

The information contained in this Form 6-K, excluding 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 October 5, 2023

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: October 5, 2023

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

Exhibit 99.1

Stockholm, Sweden **October 5, 2023**

European Medicines Agency Committee for Orphan Medicinal Products provides positive opinion on Calliditas' application for setanaxib in Alport syndrome

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has issued a positive opinion on the company's application for orphan drug designation in the European Union (EU) for setanaxib in Alport syndrome. The COMP opinion will now go to the European Commission, which is responsible for adopting the decision in relation to the application for orphan designation and adding it to the Community register of orphan medicinal products for human use.

The European Medicines Agency defines orphan drugs as medicinal products for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10,000 people in the European Union) or where the medicine is unlikely to generate sufficient profit to justify research and development costs. Companies that obtain orphan designation benefit from protocol assistance and market exclusivity once marketing authorization has been granted by the European Commission.

"We are pleased that the COMP has issued a positive opinion for orphan drug designation for setanaxib and are excited to start another clinical program in the renal space targeting an orphan indication where today there are no approved products," said CEO Renée Aguiar-Lucander.

Based on significant pre-clinical work, Calliditas targets initiation of a randomized, placebo-controlled Phase 2 clinical study evaluating setanaxib in Alport syndrome with around 20 patients in Q4 of 2023.

Alport syndrome is a genetic disorder arising from the mutations in the genes that code for type 4 collagen. The type 4 collagen alpha chains are primarily located in the kidneys, eyes, and cochlea. The condition is, thus, characterized by kidney disease, loss of hearing, and eye abnormalities. Eventually, patients present with proteinuria, hypertension, progressive loss of kidney function (gradual decline in GFR), and end-stage renal disease (ESRD).

Calliditas is currently investigating setanaxib in a Phase 2 proof-of-concept study in squamous cell carcinoma of the head and neck (SCCHN), as well as in a Phase 2b study in primary biliary cholangitis (PBC). Setanaxib is also being evaluated in an investigator-led study in idiopathic pulmonary fibrosis (IPF).

For further information, please contact:
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The information was sent for publication, through the agency of the contact persons set out above, on October 5, 2023 at 10:30 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 US 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, clinical development plans, business plans, and regulatory submissions. 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 (including as to the timing of the Company's planned clinical trial of setanaxib in Alport syndrome), strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts 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.