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: September 27, 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 U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) for the treatment of Alport syndrome with setanaxib. Based on supportive pre-clinical work, Calliditas plans to initiate a randomized, placebo-controlled phase 2 clinical study in Alport syndrome with around 20 patients in the fourth quarter of 2023. 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 September 27, 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: September 27, 2023

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

Stockholm, Sweden **September 27, 2023**

Calliditas Therapeutics granted orphan drug designation by the FDA for the treatment of Alport syndrome with setanaxib

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the US Food and Drug Administration (FDA) has granted orphan drug designation (ODD) for the treatment of Alport syndrome with setanaxib.

Based on supportive pre-clinical work, Calliditas plans to initiate a randomized, placebo-controlled phase 2 clinical study in Alport syndrome with around 20 patients in the fourth quarter of 2023.

"We 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.

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, and thus the condition is 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). It is estimated that approximately 30,000 to 60,000 people in the United States (US) have this disorder, and it is a significant cause of chronic kidney disease (CKD), leading to ESRD in adolescents and young adults and accounting for 1.5% to 3.0% of children on renal replacement therapies in Europe and the US.[1]

Through its subsidiary Calliditas Therapeutics Suisse SA, which will sponsor the planned phase 2 clinical study of setanaxib in Alport syndrome, 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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About Calliditas
Calliditas Therapeutics is a biopharma company headquartered 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 is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT).
Visit Calliditas.com for further information.

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[1] Watson S, Padala SA, Hashmi MF, et al. Alport Syndrome. [Updated 2023 Aug 14]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470419/

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, regulatory submissions, commercialization efforts, business plans, and the prospects for setanaxib as a treatment for Alport syndrome. 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 the timing of Calliditas' planned clinical trial of setanaxib in Alport Syndrome, Calliditas' business, operations, clinical trials, supply chain, 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.