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: May 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 May 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 May 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: May 6, 2024

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

Exhibit 99.1

Stockholm, Sweden **May 6, 2024**

Calliditas announces positive topline results of Phase 2 head and neck cancer trial with lead NOX inhibitor candidate, setanaxib

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced data from the proof-of-concept Phase 2 trial evaluating setanaxib, its lead NOX enzyme inhibitor, in combination with pembrolizumab, in patients with squamous cell carcinoma of the head and neck (SCCHN). The analysis showed statistically significant improvements in progression-free survival (PFS), as well as in overall survival (OS), with statistically significant changes in tumor biology consistent with the mechanism of action of setanaxib.

The trial is a randomized, placebo-controlled, double-blind Phase 2 study investigating the effect of setanaxib 800mg twice daily in conjunction with pembrolizumab 200mg IV, administered every 3 weeks (a standard treatment regimen for SCCHN) with the full dataset reflecting all patients having had the opportunity to complete at least 15 weeks of treatment. The basis for the analysis consisted of a dataset of 55 patients with recurrent or metastatic SCCHN and moderate or high CAF-density tumors (Cancer Associated Fibroblasts). A tumor biopsy was taken prior to randomization and then again after at least 9 weeks of treatment.

The treatment groups were well-balanced with no clinically relevant differences between the groups observed at baseline. Patients treated with pembrolizumab and setanaxib showed statistically significant improvements in key secondary endpoints, such as progression-free survival, (PFS median 5 months versus 2.9 months; Hazard ratio= 0.58) and statistically significant improvement in overall survival (OS at 6 months 92% vs 68%; OS at 9 months 88% vs 58%; Hazard ratio=0.45) compared to patients treated with pembrolizumab and placebo. There was also an improvement in disease-control rate in setanaxib-treated patients, with 70% in the setanaxib arm showing a best response of at least stable disease compared to 52% in the placebo arm. No significant difference in the primary endpoint of best percentage change from baseline in tumor size was observed. Transcriptomic analysis of tumor biopsy samples showed a statistically significant increase in CD8+ T-cells in tumor tissue from patients treated with setanaxib, indicating an increase in tumor immunological activity consistent with the mechanism of action of setanaxib. The tolerability of setanaxib when given with pembrolizumab was generally good, with no new safety signals identified.

"It is very encouraging to see statistical significance on important clinical outcomes in this relatively small study, which provides an excellent basis for advancing setanaxib in this hard-to-treat population," said Kevin Harrington, Professor in Biological Cancer Therapies at The Institute of Cancer Research (ICR) London, Consultant Clinical Oncologist at The Royal Marsden NHS Foundation, London, and Investigator on the trial.

"This is a very exciting result which provides clinical evidence of the mode of action of setanaxib in line with our thesis of its anti-fibrotic effects, and with results beyond our expectations for a study of this size. It is exciting that we now have positive clinical evidence in support of our first in class NOX platform" said CEO Renée Aguiar-Lucander.

"I am delighted that we have seen statistical significance and clinically meaningful improvements in longer term outcomes of PFS and OS in this indication. I'd like to extend my thanks to investigators, clinical trial site staff, and most importantly patients, who have all contributed to this important study." said CMO Richard Philipson.

The company is conducting additional clinical trials with setanaxib and will read out its Phase 2 trial in PBC (primary biliary cholangitis) in Q3 of 2024 and is expecting the investigator led Phase 2 trial in IPF (idiopathic pulmonary fibrosis) to provide top line data in Q4 of 2024, subject to recruitment. There is also an ongoing Phase 2 proof of concept trial in Alport syndrome, which is expected to deliver top line data in 1H, 2025.

The company plans to arrange an R&D day in Stockholm later this month to provide additional details regarding the Phase 2 trial and other data supporting the mechanism of action of setanaxib. Further details will be provided by way of a press release.

For further information, please contact:

Åsa Hillsten, Head of IR & Sustainability, Calliditas
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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 May 6, 2024 at 08:00 a.m. CET.

About Head and Neck Cancer

Worldwide, head and neck cancer accounts for approximately 900,000 cases and over 400,000 deaths annually. In the United States, head and neck cancer accounts for approximately 71,100 cases annually and 16,100 deaths. In Europe, there were approximately 250,000 cases (an estimated 4 percent of the cancer incidence) and 63,500 deaths in 2012. Males are affected significantly more than females, with a ratio ranging from 2:1 to 4:1. as per UpToDate®. Recurrence of head and neck cancer, especially in advanced stages is common (50%+), with limited treatment alternatives.

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 Calliditas' strategy, commercialization efforts, business plans, regulatory submissions, clinical development plans, revenue and product sales projections or forecasts 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 and operations, the presumed mechanism of action of setanaxib, the safety and efficacy of setanaxib in SCCHN or other potential indications, anticipated timelines and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. The results of early clinical trials may not predict those of future, later-stage clinical trials. The clinical data presented herein involves a limited number of patients, and these results may not be replicated in larger clinical trials. 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.