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 13, 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 ☐

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

On March 13, 2023, Calliditas Therapeutics AB (the "Registrant") announced the topline data from Part B of its NefIgArd trial for Nefecon. The press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information contained in this Form 6-K, including Exhibit 99.1, is hereby incorporated by reference into the Registrant's Registration Statement on Form F-3 (File No. 333-265881).

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated March 13, 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: March 13, 2023

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

Exhibit 99.1

Stockholm, Sweden **March 12, 2023**

Calliditas Announces Primary Endpoint Successfully Met in Phase 3 NefIgArd Trial Evaluating Nefecon® in IgA Nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced positive topline results from the global, randomized, double-blind, placebo-controlled Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon (TARPEYO®/Kinpeygo® (budesonide) delayed release capsules) versus placebo in patients with primary IgA nephropathy (IgAN).

- The trial met its primary endpoint with Nefecon demonstrating a highly statistically significant benefit over placebo (p value < 0.0001) in estimated glomerular filtration rate (eGFR) over the two-year period of 9-months of treatment with Nefecon or placebo and 15-months of follow-up off drug.
- Supportive 2-year total slope analyses were statistically significant and clinically meaningful reflecting a sustained treatment benefit.
- The eGFR benefit was observed across the entire study population, irrespective of urine protein-to-creatinine ratio (UPCR) baseline, which the company believes supports a regulatory filing for full approval in the study population.
- UPCR reductions observed were durable, reflecting a long lasting treatment effect during the 15-month follow-up period off treatment.

"This is truly a great outcome for IgAN patients. This reflects sustained impact on kidney function across the entire study population with a treatment which was specifically designed to treat IgAN by downregulating pathogenic IgA1 antibodies at their presumed source and we believe this dataset supports regulatory filing for full approval based on the Phase 3 study population," said CEO Renée Aguiar-Lucander.

"These data show the kidney function protection delivered by Nefecon and demonstrate that the approach offers patients a truly disease modifying treatment with sustained reductions in proteinuria over two years and continued eGFR benefit. Importantly Nefecon was well tolerated and together with the proteinuria and eGFR data mean that Nefecon has cemented its place as a key treatment option for patients with IgA nephropathy at risk of progressive kidney function loss," said Dr Jonathan Barratt, Mayer Professor of Renal Medicine at Leicester University.

"These data establish that there is an option for patients with IgA nephropathy to specifically target their illness and to safely slow and delay progression of their kidney disease. The sustained effects on proteinuria and on eGFR are impressive and clinically meaningful," said Richard Lafayette, Professor of Medicine (Nephrology) at Stanford University.

This data readout from Part B provides longer term data from the Phase 3 NefIgArd trial, which read out topline data on Part A in November 2020. An additional 29 Chinese patients, required for local Chinese regulatory purposes only, are expected to complete Part B in Q3, 2023. Based on the Part A data, Calliditas received accelerated approval from the U.S Food and Drug Administration (FDA) in December 2021 and conditional marketing authorization from the European Commission (EC) in July 2022, marking the first time a drug was approved for the treatment of IgAN in the US and the European Economic Area (EEA). Nefecon is being marketed by Calliditas in the US under the brand name TARPEYO®, and by STADA Arzneimittel AG in the EEA, Switzerland and the UK under the brand name Kinpeygo®.

“I am delighted with the positive outcome of the NefIgArd trial. This important milestone is the culmination of many years of hard work and dedication from so many people involved in the study. I would like to extend my thanks in particular to the investigators and site staff involved in the study, as well as of course the participating patients,” said Calliditas’ CMO, Dr. Richard Philipson.

On the basis of this data, Calliditas plans to file for full approval from the FDA, and support filing for full approval with EC and UK MHRA during 2023 for patients with primary IgAN based on the Phase 3 study population.

NefIgArd Topline Results
The analysis included 364 patients diagnosed with primary IgAN and who were on a background of optimized and stable renin-angiotensin system (RAS) inhibitor therapy. The patients were randomized in a 1:1 ratio into one of two treatment groups – Nefecon 16 mg/day orally or placebo – and treated for 9 months daily, and then monitored for 15 months off-drug.

eGFR Data
The key primary endpoint, eGFR over 2 years, was on average 5.05 mL/min/1.73 m^2 higher with Nefecon compared to placebo ($p<0.0001$). Mean change in eGFR over the 2-year period was -2.47 mL/min/1.73 m^2 for Nefecon 16 mg versus -7.52 mL/min/1.73 m^2 for placebo.

Safety Profile
The results indicate that Nefecon was generally well-tolerated and the safety profile was consistent with that observed in Part A of the trial.

Trial Design
The global clinical trial NefIgArd is an ongoing Phase 3, randomized, double-blind, placebo- controlled, multicenter study to evaluate the efficacy and safety of TARPEYO 16 mg once daily vs placebo in adult patients with primary IgAN as an addition to optimized RAS inhibitor therapy.

Part A of the study included a 9-month blinded treatment period and a 3-month follow-up period. The primary endpoint was UPCR, and eGFR was a secondary endpoint. Part B included a 12-month observational period off drug and assessed eGFR over the entire 2-year period for patients who were treated with the TARPEYO or placebo regimen in Part A in a total population of 360 patients.

The trial met its primary objective in Part A of demonstrating a statistically significant reduction in urine protein creatinine ratio (UPCR) or proteinuria after 9 months of treatment with 16 mg once daily of TARPEYO compared to placebo. Patients taking TARPEYO plus RAS inhibition (n=97) showed a statistically significant 34% reduction from baseline vs 5% with RASi alone (n=102) at 9 months, resulting in UPCR reduction of 31% (16% to 42%) p=0.0001.[3]

At 9 months, there was a 3.87 mL/min/1.73 m2 difference in eGFR absolute change with TARPEYO plus RASi vs RASi alone (-0.17 vs. -4.04).[4]

Topline data of the NefIgArd study were reported on March 12, 2023 in which the primary endpoint of eGFR was met as per above. The trial is expected to conclude in Q3 of 2023 when the final 29 patients in China (not required for global submission purposes) have completed 9 months of treatment and 15 months of observation.

Conference Call
The Company will host a live webcast for investors on Monday 13th March 2023 at 8 A.M. ET (13:00 CET).
Interested participants may register for the webcast here: https://lifescievents.com/event/calliditas-webcast/

Indication and important safety information
Indication: TARPEYO® (budesonide), named Kinpeygo in the EEA, a 4mg delayed release capsule, is a corticosteroid indicated in the US to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g and in the EEA for the treatment of IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/gram.

This indication is approved by the FDA in the US under an accelerated approval and as a conditional marketing authorisation by the European Commission for the EEA based on a reduction in proteinuria. It has not been established whether TARPEYO/Kinpeygo slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Important Safety Information
Contraindications: TARPEYO/Kinpeygo is contraindicated in patients with hypersensitivity to budesonide or any of the ingredients of TARPEYO/Kinpeygo. Serious hypersensitivity reactions, including anaphylaxis, have occurred with other budesonide formulations.

Warnings and Precautions
Hypercorticism and adrenal axis suppression: When corticosteroids are used chronically, systemic effects such as hypercorticism and adrenal suppression may occur. Corticosteroids can reduce the response of the hypothalamus-pituitary-adrenal (HPA) axis to stress. In situations where patients are subject to surgery or other stress situations, supplementation with a systemic corticosteroid is recommended. When discontinuing therapy [see Dosing and Administration] or switching between corticosteroids, monitor for signs of adrenal axis suppression.

Patients with moderate to severe hepatic impairment (Child-Pugh Class B and C, respectively) could be at an increased risk of hypercorticism and adrenal axis suppression due to an increased systemic exposure to oral budesonide. Avoid use in patients with severe hepatic impairment (Child-Pugh Class C). Monitor for increased signs and/or symptoms of hypercorticism in patients with moderate hepatic impairment (Child-Pugh Class B).

Risks of Immunosuppression: Patients who are on drugs that suppress the immune system are more susceptible to infection than healthy individuals. Chicken pox and measles, for example, can have a more serious or even fatal course in susceptible patients or patients on immunosuppressive doses of corticosteroids. Avoid corticosteroid therapy in patients with active or quiescent tuberculosis infection; untreated fungal, bacterial, systemic viral, or parasitic infections; or ocular herpes simplex. Avoid exposure to active, easily transmitted infections (eg, chicken pox, measles). Corticosteroid therapy may decrease the immune response to some vaccines.

Other corticosteroid effects: TARPEYO is a systemically available corticosteroid and is expected to cause related adverse reactions. Monitor patients with hypertension, prediabetes, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataracts, a family history of diabetes or glaucoma, or with any other condition in which corticosteroids may have unwanted effects.

Adverse reactions: In clinical studies, the most common adverse reactions with TARPEYO (occurring in ≥5% of TARPEYO/Kinpeygo patients and ≥2% higher than placebo) were hypertension (16%), peripheral edema (14%), muscle spasms (13%), acne (11%), dermatitis (7%), weight increase (7%), dyspnea (6%), face edema (6%), dyspepsia (5%), fatigue (5%), and hirsutism (5%).

Drug interactions: Budesonide is a substrate for CYP3A4. Avoid use with potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine. Avoid ingestion of grapefruit juice with TARPEYO/Kinpeygo. Intake of grapefruit juice, which inhibits CYP3A4 activity, can increase the systemic exposure to budesonide.

Use in specific populations
Pregnancy: The available data from published case series, epidemiological studies, and reviews with oral budesonide use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with IgAN. Infants exposed to in utero corticosteroids, including budesonide, are at risk for hypoadrenalism.

Please see Full Prescribing Information for TARPEYO here.

About Primary Immunoglobulin A Nephropathy
Primary immunoglobulin A nephropathy (IgA nephropathy or IgAN or Berger's Disease) is a rare, progressive, chronic autoimmune disease that attacks the kidneys and occurs when galactose-deficient IgA1 are recognized by autoantibodies, creating IgA1 immune complexes that become deposited in the glomerular mesangium of the kidney.[5,6] This deposition in the kidney can lead to progressive kidney damage and potentially a clinical course resulting in end-stage renal disease. IgAN most often develops between late teens and late 30s.[6,7]

For further information, please contact:
Marie Galay, IR Manager, Calliditas
Tel.: +44 79 55 12 98 45, email: marie.galay@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 person set out above, on March 12, 2023 at 6:30 p.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 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 EEA, Switzerland, and the UK by Calliditas' partner, STADA Arzneimittel AG. Additionally, Calliditas is conducting a Phase 2b/3 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).

About TARPEYO/Kinpeygo
Calliditas has introduced TARPEYO/Kinpeygo, the first treatment to be approved for patients with IgAN.
TARPEYO/Kinpeygo is an oral, delayed release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. TARPEYO/Kinpeygo was designed as a 4 mg delayed release capsule and is enteric coated so that it would remain intact until it reaches the ileum. Each capsule contains coated beads of budesonide that target mucosal B-cells present in the ileum, including the Peyer's patches, which are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgAN. It is unclear to what extent TARPEYO's/Kinpeygo's efficacy is mediated via local effects in the ileum vs systemic effects.[1]

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, planned regulatory submissions, anticipated regulatory approvals and clinical development plans, timing and data readouts. 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 and additional regulatory approvals for TARPEYO and Kinpeygo, market acceptance of TARPEYO and Kinpeygo, competitive products, clinical trials, supply chain, strategy, goals and anticipated timelines 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.

References:

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