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

For the month of December 2021

(Commission File No. 001-39308)

CALLIDITAS THERAPEUTICS AB

(Translation of registrant's name into English)

Kungsbron 1, C8
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): ☐

Enclosed hereto is a copy of an announcement published by Calliditas Therapeutics AB on December 15, 2021**.**

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	Company announcement dated December 15, 2021

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: December 16, 2021

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

Exhibit 99.1

FDA grants Calliditas Therapeutics Accelerated Approval of TARPEYO™ (budesonide) to Reduce Proteinuria in IgA Nephropathy

- *TARPEYO (budesonide) delayed release capsules is the first and only treatment indicated to reduce proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g*[1]
- *TARPEYO (developed under the project name NEFECON) is the first and only FDA- approved treatment that was specifically designed for this condition*[1,2]
- *IgAN is a rare, progressive autoimmune disease, which has a high unmet need with more than 50% of patients potentially progressing to end-stage renal disease (ESRD)*[3]

Stockholm, December 15, 2021 – Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced that the US Food and Drug Administration (FDA) has approved TARPEYO (budesonide) delayed release capsules 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) ≥1.5g/g. This indication is approved under accelerated approval. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.[1]

This approval marks the successful transition for Calliditas to a commercial-stage biopharmaceutical company.

"We are very excited to bring the first and only FDA-approved treatment to reduce proteinuria in IgAN to market," said Renée Aguiar-Lucander, Chief Executive Officer of Calliditas. "TARPEYO represents an FDA approved product to help these patients who are at risk of rapid disease progression."

TARPEYO is approved under accelerated approval based on achieving its primary endpoint of reduction in proteinuria in Part A of the NeflgArd pivotal Phase 3 study, an ongoing, randomized, double-blind, placebo-controlled, multicenter study conducted to evaluate the efficacy and safety of TARPEYO 16 mg once daily vs placebo in adult patients with primary IgAN.[1] The effect of TARPEYO was assessed in patients with biopsy-proven IgAN, eGFR ≥35 mL/min/1.73 m^2, and proteinuria (defined as either ≥1 g/day or UPCR ≥0.8 g/g) who were on a stable dose of maximally-tolerated RAS inhibitor therapy.

Patients taking TARPEYO (n=97) showed a statistically significant 34% reduction in proteinuria from baseline vs 5% with RASi alone (n=102) at 9 months. The treatment effects for the primary endpoint of UPCR at 9 months were consistent across key subgroups, including key demographic and baseline disease characteristics.[1]

The most common adverse reactions (≥5%) in this study were hypertension, peripheral edema, muscle spasms, acne, dermatitis, weight increase, dyspnea, face edema, dyspepsia, fatigue, and hirsutism. Please see additional Important Safety Information below.

Richard Lafayette M.D., Professor of Medicine at Stanford University and the Director of the Stanford Glomerular Disease Center commented, "IgAN is a tough diagnosis for many patients, and it can progressively lead to the need for dialysis and/or kidney transplantation. The FDA approval of TARPEYO now offers disease-specific treatment for patients with this complicated disease."

Richard Philipson, Calliditas Chief Medical Officer added, “TARPEYO was developed to target a root cause of IgAN. The FDA’s approval of TARPEYO demonstrates our unwavering dedication to patients suffering from IgAN. We would like to thank the patients, researchers and clinical staff who participated in the studies of TARPEYO.”

Bonnie Schneider, Director and Co-Founder of the IGA Nephropathy Foundation of America commented,” It has been a difficult journey not only for our family but for all the IgA nephropathy patients we serve. Having this disease specific option has our community very excited.”

It is expected that TARPEYO will be available in the U.S. early in the first quarter of 2022. To assist patients and their healthcare providers who would prescribe TARPEYO, Calliditas is launching a comprehensive patient support program, TARPEYO Touchpoints™. This program offers services, assistance, and resources designed to help patients access treatment as easily as possible. To learn more visit TARPEYOTouchpoints.com or call 1-833-444-8277.

For access to additional materials related to this announcement, click here to locate the media kit.

Investor presentation December 16, 8:00 ET / 14:00 CET

Calliditas will host an audio cast with teleconference, with presentations from CEO Renée Aguiar-Lucander and Andrew Udell, President of North America, December 16, 8:00 ET / 14:00 CET.

Webcast: https://tv.streamfabriken.com/press-conference-audiocast-december-2021

Teleconference: SE: +46 856642651 PIN: 44920298# | UK: +44 3333000804 PIN: 44920298# | US: +1 6319131422 PIN: 44920298#

INDICATION and IMPORTANT SAFETY INFORMATION

Indication

TARPEYO™ (budesonide) delayed release capsules is a corticosteroid indicated 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.

This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO 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 is contraindicated in patients with hypersensitivity to budesonide or any of the ingredients of TARPEYO. 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 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. 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 TARPEYO

Calliditas has introduced TARPEYO, to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a UPCR≥1.5g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO 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.[1]

TARPEYO 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 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 IgA nephropathy. It is unclear to what extent TARPEYO's efficacy is mediated via local effects in the ileum vs systemic effects.[1]

About the NeflgArd Study

The global clinical trial NeflgArd 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 (N=360) as an addition to optimized RASi therapy.

The effect of TARPEYO was assessed in patients with biopsy-proven IgAN, eGFR ≥35 mL/min/1.73 m2, and proteinuria (defined as either ≥1 g/day or UPCR ≥0.8 g/g) who were on a stable dose of maximally-tolerated 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, a confirmatory validation study in which no TARPEYO treatment will be administered, will assess eGFR at two years.

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 RASi (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

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.[4,5] 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.[5,6]

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 www.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, business plans, regulatory submissions, 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 FDA approval for TARPEYO, market acceptance of 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.

The information in the press release is inside information that Calliditas is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons below, on December 15, 2021 at 3:45 pm ET.

For further information, please contact:

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1. TARPEYOTM (budesonide) [prescribing information]. Stockholm, SE: Calliditas Therapeutics AB; 2021
2. Fellstrom BC, Barratt J, Cook H, et al. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomised, placebo-controlled phase 2b trial. Lancet. May 27, 2017;389(10084):2117-2127. https://doi:10.1016/S0140-6736(17)30550-0
3. Hastings, M. C., Bursac, Z., Julian, B. A., Villa Baca, E., Featherston, J., Woodford, S. Y., Bailey, L., & Wyatt, R. J. (2018). Life Expectancy for Patients From the Southeastern United States With IgA Nephropathy. Kidney Int Rep, 3(1), 99-104. https://doi.org/10.1016/j. ekir.2017.08.008
4. Barratt, J., & Feehally, J. (2005). IgA nephropathy. J Am Soc Nephrol, 16(7), 2088-2097. https://doi.org/10.1681/ASN.2005020134
5. Barratt, J., Rovin, B. H., Cattran, D., et al. (2020). Why Target the Gut to Treat IgA Nephropathy? Kidney Int Rep, 5(10), 1620-1624. https://doi.org/10.1016/j.ekir.2020.08.009
6. Jarrick, S., Lundberg, S., Welander, A., et al. (2019). Mortality in IgA Nephropathy: A Nationwide Population-Based Cohort Study. J Am Soc Nephrol, 30(5), 866-876. https://doi.org/10.1681/ASN.2018101017