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 March 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 March 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 March 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: March 15, 2021

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

Stockholm, Sweden **March 15, 2021**

Calliditas Announces Submission of New Drug Application to U.S. FDA for Nefecon in Patients with Primary IgA Nephropathy

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) ("Calliditas") today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Nefecon, a novel oral formulation targeting down regulation of IgA1 for the treatment of primary IgA Nephropathy (IgAN). Calliditas is seeking accelerated approval under Subpart H for the 505(b)(2) application.

"This is a key milestone in the company's development and we are looking forward to engaging with the agency. This is the first time a drug specifically designed for IgAN is being submitted for approval to the FDA and I believe that we are delivering a very robust data package based on the successful outcome of our pivotal Phase 3 trial and our large Phase 2b trial, which also met both the primary and key secondary endpoints. Calliditas has long been pioneering a treatment for IgAN based on precision and disease modification that focuses on the origin of the disease, with the hope of bringing help to thousands of patients, so today is truly a special day," said CEO Renée Aguiar-Lucander.

The NDA submission is based on positive data from Part A of the NefIgArd pivotal Phase 3 study, a randomized, double-blind, placebo-controlled, international multicenter study designed to evaluate the efficacy and safety of Nefecon compared to placebo in 200 adult patients with IgAN. As previously reported, the study achieved its primary endpoint of proteinuria reduction compared to placebo, as well as showing stabilisation of eGFR at 9 months. The NefIgArd trial also showed that Nefecon was generally well-tolerated with a safety profile in keeping with the Phase 2b results. The submission also includes clinical data from the Phase 2 NEFIGAN trial, which also met the same primary and secondary endpoints as the NefIgArd study. Calliditas is the only company which has achieved positive data in randomized, double-blind, placebo-controlled Phase 2b and Phase 3 clinical trials in IgAN.

Calliditas has applied for accelerated approval, which allows drugs targeting serious conditions that fill an unmet medical need to be approved based on a surrogate endpoint. The surrogate endpoint in the pivotal Phase 3 trial NefIgArd was reduction of proteinuria versus placebo, which is supported by the statistical framework based on the meta-analysis of clinical studies where an intervention was carried out in patients with IgAN, as updated by Thompson A et al, published in 2019[1]. A confirmatory study designed to provide data on long-term renal benefit is fully recruited and is expected to read out in early 2023.

If approved, Nefecon would become the first therapy specifically designed and approved for the treatment of IgAN, with the potential to be disease modifying. Subject to approval by the FDA, Calliditas intends to commercialize Nefecon for IgAN on its own in the United States.

For further information, please contact:
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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 March 15, 2021 at 07:30 a.m. CET.

1. Clin J Am Soc Nephrol. 2019;14:469-81.

About Calliditas
Calliditas Therapeutics is a specialty pharmaceutical 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 candidate, Nefecon, is a proprietary, novel oral formulation of budesonide, an established, highly potent local immunosuppressant, for the treatment of adults with the autoimmune renal disease primary IgA nephropathy (IgAN), for which there is a high unmet medical need and there are no approved treatments. Calliditas has recently read out topline data from Part A of its global Phase 3 study in IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is also planning to start clinical trials with NOX inhibitors in primary biliary cholangitis and head and neck cancer in 2H 2021. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

About the NefIgArd Study
The global Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon versus placebo in patients with primary IgA nephropathy (IgAN), consists of two parts.

Part A, which was designed to provide the basis for regulatory submissions and approvals, evaluates data on the efficacy and safety of Nefecon. The first patient in the NefIgArd trial was randomized by Calliditas in November 2018, and in December 2019, Calliditas announced the full recruitment of Part A, across approximately 146 sites in 19 countries. Calliditas read out topline data for Part A in November 2020. The trial met its primary objective of demonstrating a statistically significant reduction in urine protein creatinine ratio, UPCR or proteinuria, after 9 months of treatment with 16 mg of Nefecon compared to placebo, with significant continued improvement at 12 months. The primary endpoint analysis showed a 31% mean reduction in the 16 mg arm versus baseline, with placebo showing a 5% mean reduction versus baseline, resulting in a 27% mean reduction at 9 months (p=0.0005) of the 16 mg arm versus placebo. The trial also met the key secondary endpoint, showing a statistically significant difference in estimated glomerular filtration rate or eGFR after 9 months of treatment with Nefecon compared to placebo. The key secondary endpoint, eGFR, showed a treatment benefit of 7% versus placebo at 9 months, reflecting stabilisation in the treatment arm and a 7% decline of eGFR in the placebo arm (p=0.0029). This reflected an absolute decline of 4.04 ml/min/1.73m^2 in the placebo group over 9 months compared to a 0.17 ml/min/1.73m^2 decline in the treatment group. Nefecon was also generally well-tolerated, and the safety profile was in keeping with the Phase 2b results and consistent with the known safety profile of budesonide.

Part B of the NefIgArd study is designed to be a confirmatory post-market observational trial to confirm long-term renal protection and assess the difference in kidney function between treated and placebo patients as measured by eGFR over a two-year period from the start of dosing of each patient. The 360-patient population of the complete Phase 3 trial includes another 160 patients enrolled in addition to the 200 patients from Part A. The trial was fully recruited in January 2021, and aims to read out data in early 2023, after all patients have completed 2 years in the trial.

About Nefecon
Nefecon is a patented oral formulation of a potent and well-known active substance – budesonide – for targeted release. The formulation is designed to deliver the drug to the Peyer's patch region of the lower small intestine, where the disease originates, as per the predominant pathogenesis models. Nefecon is derived from the TARGIT technology, which allows for the substance to pass through the stomach and intestine without being absorbed, and to be released in a pulse like fashion only when it reaches the lower small intestine. The combination of dose and optimized release profile is required to be effective in patients with IgAN, as shown in a large Phase 2b trial, completed by Calliditas. In addition to its potent local effect, another advantage of using this active substance is that it has very low bioavailability, i.e. around 90% of it is inactivated in the liver before it reaches the systemic circulation. This means that a high concentration can be applied locally where needed but with only very limited systemic exposure and side effects.

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 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, the potential for FDA acceptance for filing and the success of its regulatory marketing application for Nefecon, 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.