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 November 2020

(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 November 8, 2020.

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 November 8, 2020

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: November 9, 2020

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

Exhibit 99.1

Stockholm, Sweden **November 8, 2020**

Calliditas Announces Positive Topline Results from Pivotal Phase 3 NefIgArd Trial

Calliditas Therapeutics AB (OMX Nasdaq: CALTX, NASDAQ: CALT) (”Calliditas”) today announced positive topline results from Part A of the global Phase 3 clinical trial NefIgArd, which investigated the effect of Nefecon® versus placebo in patients with primary IgA nephropathy (IgAN).

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 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. Collectively the efficacy data from 9 months treatment with 16 mg of Nefecon indicated a significant and beneficial effect on key factors correlated to the progression to end stage renal disease (ESRD) for IgAN patients. In addition, the trial showed that Nefecon was generally well-tolerated.

On the basis of these results, Calliditas plans to submit for accelerated approval with the US Food and Drug Administration (FDA) in Q1 2021 followed by a submission for conditional approval with the European Medicines Agency in H1 2021. Subject to approval by the FDA, Calliditas intends to commercialize Nefecon for IgAN by itself in the United States and through collaborations in other regions.

“We are delighted with this strong data set which confirms the results seen in the Phase 2b trial and provides further support for effectively treating IgAN at its origin. Calliditas has been a pioneer in IgAN for many years and we are excited to be the only company to have reported out a positive Phase 3 trial in this indication. This result brings hope to thousands of patients who today have no approved treatment alternatives.”, said CEO Renée Aguiar-Lucander.

Topline Results

The analysis included 199 patients diagnosed with primary IgA Nephropathy and who were on a background of optimised and stable renin-angiotensin system, or RAS inhibitor therapy. The patients were randomised in a 1:1 ratio into one of two treatment groups – Nefecon 16 mg/day or placebo – and treated orally for 9 months daily.

24-hour UPCR (proteinuria) Data

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.

eGFR Data

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.

Safety Profile

The results indicate that Nefecon was generally well-tolerated and were consistent with the known safety profile of Budesonide. The number of withdrawals in the trial was significantly less than what was seen in the Phase 2b NEFIGAN trial.

“I would like to thank all of the investigators, site staff and of course patients for their commitment and dedication to this important trial. I look forward to continuing this excellent work through completion of Part B of the trial,” said Calliditas CMO, Dr. Richard Philipson.

The NefIgArd trial is continuing on a blinded basis with patients continuing in the observational Part B of the trial for a 12 month follow up period post their completion of Part A. Calliditas is recruiting an additional 160 patients for inclusion in Part B during 2020 and aims to complete the recruitment in Q4 2020 or Q1 2021, depending on the impact of COVID-19.

Trial Design

The pivotal, global Phase 3 NefIgArd trial consists of two parts.

Part A, which is the basis for potential regulatory submissions and approvals, provides 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.

Patients with biopsy-confirmed primary IgA Nephropathy (IgAN), over or at 18 years of age and with a total urine protein of ≥ 1g / day, were eligible to take part in the trial. The inclusion criteria also required patients to have an eGFR of ≥ 35 mL/min * 1.73m2 and ≤ 90 ml/min * 1.73m2. In the lead up to the trial, the patients had to be on optimised and stable RAS treatment for at least 3 months, and remain on optimised stable RAS blockade throughout the trial.

Main exclusion criteria included secondary forms of IgAN, tuberculosis, kidney transplant, or treatment with high dose corticosteroids or immunosuppressants in the past 12 months.

Following screening, patients were randomized into either oral placebo or a once-daily 16 mg oral dose of Nefecon. After receiving 9 months of daily double-blind treatment, there was a two-week tapering, during which patients on drug received a once-daily 8mg oral dose of Nefecon and patients in the placebo arm continued to receive oral placebo. Following tapering, there was a 10-week follow-up where no trial drug was administered and during which blinding remained in place.

The primary endpoint for the trial is the effect of Nefecon on UPCR over 9 months compared to placebo, which is calculated from measured 24-hour urine samples. This is the same primary endpoint as the successful Phase 2b NEFIGAN trial. Secondary outcomes, assessed at various timepoints, include changes in eGFR, 24-hour urine protein excretion and urine albumin creatinine ratio (UACR).

Part B is designed to be a confirmatory post-market approval observational trial to confirm long-term renal protection. This trial consists of 360 patients, where recruitment of the 160 patients required, in addition to the 200 patients from Part A, is ongoing. Calliditas expects to complete recruitment of these patients in Q4 2020 or Q1 2021, depending on the impact of COVID-19.

Conference Call

The Company will host a live webcast for investors on 14.30 CET Monday 9th of November. Details will be distributed prior to the conference call.

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 November 8, 2020 at 12:45 p.m. CET.

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 the autoimmune renal disease IgA nephropathy, or IgAN, for which there is a high unmet medical need and there are no approved treatments. Calliditas is running a global Phase 3 trial within IgAN and, if approved, aims to commercialize Nefecon in the United States. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT). Visit www.calliditas.com for further information.

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 IgA nephropathy, as shown in a large Phase 2b trial, completed by the company. 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 the regulatory pathway for Nefecon, plans for submissions for marketing approvals, plans and strategies for commercialization of Nefecon, if approved, the conduct of Part B of the NefIgArd clinical trial, 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 regulatory filings submissions for Nefecon, the continuation of Part B of the NefIgArd study, Calliditas'' business, operations, 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 and other filings 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.