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 September 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 September 16, 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 September 16, 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: September 16, 2021

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

Exhibit 99.1

Stockholm **September 16, 2021**

Updated regulatory timeline for review of MAA in Europe.

Calliditas Therapeutics AB (publ) (”Calliditas” or the ”Company”) (Nasdaq Stockholm – CALTX; Nasdaq – CALT), a biopharma company focused on identifying, developing and commercializing novel treatments in orphan indications, today announced that the European Medicine Agency’s (EMA) Committee for Human Medicinal Products (CHMP)) has decided to continue the assessment of the marketing authorization application (MAA) for Nefecon under standard procedure assessment timelines.

Calliditas was in April, 2021 granted an accelerated assessment procedure on its MAA for Nefecon in IgA Nephropathy and submitted the MAA in May of 2021. With the revised standard assessment timeline Calliditas estimates a potential impact of 3 months on the previously communicated timelines with an expected decision by EMA in the first quarter, 2022.

"This is the first time that EMA is assessing an application for conditional approval in IgA nephropathy and we acknowledge the need for an in depth review under standard assessment timelines. We look forward to engaging with the agency to achieve a potential approval for this very deserving patient population as soon as possible.” said Renée Aguiar-Lucander, CEO at Calliditas.

If approved, Nefecon could be available to patients in Europe in mid-2022 and would become the first therapy specifically designed and approved for the treatment of IgAN, and which has the potential to be disease modifying.

For further information, please contact:
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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 above, on September 16, 2021 at 14:30 (CEST).

About Calliditas

Calliditas Therapeutics is a 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 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 read out topline data from Part A of its global Phase 3 study in IgAN in November 2020 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. Calliditas is listed on Nasdaq Stockholm (ticker: CALTX) and the Nasdaq Global Select Market (ticker: CALT).

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 and timing of EMA approval 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.