
**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: December 13, 2022

(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 December 13, 2022, Calliditas Therapeutics AB (the “Company”) announced that it has entered into an exclusive license agreement with Viatriis Pharmaceuticals Japan Inc., a subsidiary of Viatriis Inc. (“Viatriis”), to register and commercialize Nefecon[®], a specialty drug recently approved in Europe and the United States for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN), in Japan.

Under the terms of the agreement, the Company is entitled receive an initial upfront payment of US\$20 million upon signing and up to an additional US\$80 million in pre-defined development and commercialization milestones. Viatriis will also pay mid-teens percentage royalties on net sales.

FORWARD-LOOKING STATEMENTS

This Report on Form 6-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the Company’s strategy, business plans, regulatory submissions and focus, as well as the Company’s license agreement with Viatriis, the parties’ plans with respect to registration and commercialization of Nefecon, the terms of the collaboration and the intended benefits therefrom including with respect to potential milestone and royalty payments, the regulatory pathway and interactions for Nefecon, including the pursuit of Japanese marketing authorization and timing thereof. 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 Form 6-K 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 Form 6-K, including, without limitation, any related to the Company’s business, operations, the conduct of the Company’s license agreement with Viatriis, the potential for regulatory acceptance and the success and timeline of its regulatory marketing application in Japan, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other pharmaceutical companies, and other risks identified in the section entitled “Risk Factors” in the Company’s reports filed with the Securities and Exchange Commission. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company 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 Form 6-K represent the Company’s views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

INCORPORATION BY REFERENCE

The information contained in this Form 6-K, excluding Exhibit 99.1, is hereby incorporated by reference into the registrant's Registration Statement on Form F-3 (File No. 333-265881). Exhibit 99.1 is intended to be "furnished" and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly set forth by specific reference in such a filing.

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated December 13, 2022

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 13, 2022

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



Stockholm, Sweden

December 13, 2022

Calliditas Therapeutics announces license agreement with Viatris to register and commercialize specialty therapy for IgA nephropathy in Japan

Calliditas announces that it has entered into an agreement with Viatris to bring Nefecon[®], a specialty therapy focused on downregulating IgA1, to Japanese patients. The agreement, worth up to \$100M in upfront and milestone payments, combines Calliditas' specifically formulated drug candidate with Viatris' development, marketing and sales expertise.

Stockholm, Sweden; December 13, 2022 – Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”) announced today that they have entered into an exclusive license agreement with Viatris Pharmaceuticals Japan Inc., a subsidiary of Viatris Inc. (Nasdaq: VTRS) (“Viatris”), to register and commercialize Nefecon, a specialty drug recently approved in Europe and the US for the treatment of the chronic autoimmune kidney disease Immunoglobulin A Nephropathy (IgAN) in Japan.

Under the terms of the agreement, Calliditas is entitled receive an initial upfront payment of US\$20M upon signing and up to an additional US\$80M in pre-defined development and commercialization milestones. Viatris will also pay mid-teens percentage royalties on net sales.

IgAN, also known as Berger's disease, is a rare and serious progressive autoimmune disease in which up to 50% of patients end up at risk of developing end stage renal disease and thus requiring dialysis or a kidney transplant.

“We are excited to be entering into this license agreement with Viatris, through its Global Healthcare Gateway[®], to bring this IgAN therapy to patients in Japan, where there is a significant unmet medical need. We look forward to working in close collaboration to pursue a Japanese marketing authorization with the goal of bringing the first ever medication designed specifically to target the origin of the disease to Japanese IgAN patients as soon as possible,” said Renée Aguiar-Lucander, CEO of Calliditas.

Locust Walk acted as transaction advisor to Calliditas.

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 Calliditas contact person set out above, on December 13, 2022 at 8:00 a.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, 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 European Union Member States 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). 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, as well as Calliditas' license agreement with Viatriis, the parties' plans with respect to registration and commercialization of the specialty therapy, the terms of the collaboration and the intended benefits therefrom, the regulatory pathway and interactions for Nefecon, including the pursuit of Japanese marketing authorization and timing thereof. 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 conduct of Calliditas' license agreement with Viatriis, the potential for regulatory acceptance and the success and timeline of its regulatory marketing application in Japan, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other pharmaceutical 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.
