
**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: January 8, 2024

(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

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

Enclosed hereto are copies of announcements published by Calliditas Therapeutics AB on January 7, 2024 and January 8, 2024.

EXHIBIT INDEX

Exhibit Description

[99.1](#) [Press Release dated January 7, 2024](#)

[99.2](#) [Press Release dated January 8, 2024](#)

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: January 8, 2024

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

Stockholm, Sweden

January 7, 2024

Calliditas Therapeutics appoints Maria Törnsén as President North America

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”), a commercial biopharma company focused on rare diseases today announced that Maria Törnsén has been appointed to the position of President North America. Ms Törnsén will be responsible for all US based operations and will report to the CEO.

Maria Törnsén has broad commercial leadership experience having spent more than 20 years in the biopharma industry in senior commercial roles. Most recently Ms Törnsén held the position of Chief Commercial Officer at Passage Bio, prior to which she was SVP General Manager US at Sarepta Therapeutics. Prior to joining Sarepta she served as VP Global Therapeutic Area Head at Sanofi Genzyme and held several senior commercial roles at Shire including VP Head of US Sales. Ms Törnsén will replace Mr Andrew Udell, who has held the position since 2020.

“We are pleased to welcome Ms Törnsén to the executive management team as President of our US operations. She brings invaluable experience from building commercial organisations, driving growth and profitability in the area of rare diseases, which will be critical as we target the next step in our development.” said CEO Renée Aguiar- Lucander. “I also want to thank Mr Udell for his valuable contribution to the build-up of the US organisation and its early commercial success.”

“I am delighted to join Calliditas at this exciting time in the company’s history, with the recent full FDA approval of TARPEYO® and an innovative late-stage pipeline in rare diseases. I look forward to working with the Calliditas team to continue advancing the TARPEYO® launch and develop our capabilities to support further growth.” said Maria Törnsén.

Calliditas received full FDA approval of TARPEYO®(budesonide) delayed release capsules, a targeted treatment to reduce the loss of kidney function in patients with primary IgA nephropathy (IgAN) at risk of disease progression on December 20, 2023; the product has been granted conditional approval in Europe and China and is being commercialized by partners under the brand names of Kinpeygo and Nefecon, respectively. Calliditas is targeting top line read out of several Phase 2 clinical trials with setanaxib, its lead product candidate from its proprietary and novel NOX platform, in 2024.

For further information, please contact:

Åsa Hillsten, Head of IR & Sustainability, Calliditas
Tel.: +46 76 403 35 43, Email: asa.hillsten@calliditas.com

The information was sent for publication, through the agency of the contact persons set out above, on January 7, 2024 at 5:00 p.m. CET.

About Calliditas

Calliditas Therapeutics is a biopharma company headquartered in Stockholm, Sweden, focused on identifying, developing, and commercializing novel treatments in orphan indications with significant unmet medical needs.

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 Calliditas.com for further information.

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 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. Chickenpox 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 (e.g., 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 or cataracts, or with a family history of diabetes or glaucoma, or with any other condition where corticosteroids may have unwanted effects.

Adverse reactions: In clinical studies, the most common adverse reactions with TARPEYO (occurring in $\geq 5\%$ of TARPEYO treated patients, and $\geq 2\%$ higher than placebo) were peripheral edema (17%), hypertension (12%), muscle spasms (12%), acne (11%), headache (10%), upper respiratory tract infection (8%), face edema (8%), weight increased (7%), dyspepsia (7%), dermatitis (6%), arthralgia (6%), and white blood cell count increased (6%).

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**

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 development of Calliditas' pipeline. 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, clinical trials, intellectual property of the NEFECON franchise globally, competition from other companies, pipeline development, revenue and product sales projections or forecasts 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.



Stockholm, Sweden

January 8, 2024

Calliditas Therapeutics provides business update ahead of JP Morgan conference

Calliditas Therapeutics AB (Nasdaq: CALT, Nasdaq Stockholm: CALTX) (“Calliditas”), a commercial biopharma company focused on rare diseases today provided a business update for the fourth quarter of 2023 and certain preliminary, unaudited key financial information for the fourth quarter and full year 2023, as follows:

- Strong Q4 preliminary product revenue growth with net TARPEYO revenues of \$31 – 33m for the quarter, representing significant growth over Q3.
- Preliminary Net TARPEYO revenues of \$100 – 102m for 2023, representing over 170% year over year growth compared to 2022.
- Preliminary Total revenues reaching \$110 – 113m for 2023, as a result of milestone payments and royalty income from the Nefecon franchise outside the US.
- Record quarter in terms of enrollments with 555 new TARPEYO prescriptions in the 4th quarter.

The information above reflects our preliminary estimates with respect to such results based on currently available information. We have provided ranges, rather than specific amounts, for the preliminary results described above primarily because our financial closing procedures are not yet complete and, as a result, our final results may vary from the preliminary estimates.

“We are very pleased with the preliminary outcome of the 2023 fiscal year, generating product sales in excess of \$100 million in our second year of commercialisation. This is a very strong result and we are very excited about 2024 based on the recent full approval of TARPEYO in the US, strengthened product protection and the record growth seen in enrollments in Q4. This result, in combination with our successful debt refinancing and strengthening our US leadership team, puts us in an optimal position to drive growth and profitability in 2024 and build a high growth, durable franchise in the rare disease space.” said CEO Renée Aguiar-Lucander.

For further information, please contact:

Åsa Hillsten, Head of IR & Sustainability, Calliditas
Tel.: +46 76 403 35 43, Email: asa.hillsten@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 contact persons set out above, on January 8, 2024 at 8.15 am CET.

The above unaudited, estimated results for the quarter and year ended December 31, 2023 are preliminary financial information, remain subject to completion, and were prepared by management based upon estimates, a number of assumptions and currently available information, and are subject to revision based upon, among other things, quarter-end closing procedures and/or adjustments, the completion of our financial statements and other operational procedures. Our actual results could be materially different from this preliminary financial information, which should not be regarded as a representation by us as to our actual results for the quarter and year ended December 31, 2023. In addition, our independent registered public accounting firm has not audited, reviewed, compiled or performed any procedures with respect to this preliminary financial information and does not express an opinion or any other form of assurance with respect to this preliminary financial information. During the course of the preparation of our financial statements and related notes as of and for the quarter and year ended

December 31, 2023, we may identify items that would require us to make material adjustments to this preliminary financial information.

About Calliditas

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