
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES
EXCHANGE ACT OF 1934**

For the month of January 2023

Commission File Number: **001-39950**

Evaxion Biotech
(Translation of registrant's name into English)

Dr. Neergaards Vej 5f
DK-2970 Hoersholm
Denmark
(Address of 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 [X] 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):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

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):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

On January 19, 2023, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

[\(c\) Exhibit 99.1. Press release dated January 19, 2023](#)

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.

Evaxion Biotech
(Registrant)

Date: January 19, 2023

/s/ Katrine Hertz Mortensen
Katrine Hertz Mortensen
VP, Communications

Evaxion receives FDA fast-track designation for personalized cancer immunotherapy

COPENHAGEN, Denmark, Jan. 19, 2023 (GLOBE NEWSWIRE) -- Evaxion Biotech A/S (NASDAQ: EVAX) (“Evaxion” or the “Company”), a clinical-stage biotechnology company specializing in the development of AI-driven immunotherapies, today announced that the U.S. Food and Drug Administration (“FDA”) has granted fast track designation for the Company’s personalized cancer therapy, EVX-01, in combination with KEYTRUDA®.

In December 2023, Evaxion received FDA approval to proceed with its Phase 2b clinical trial, where EVX-01 is given in combination with KEYTRUDA® to patients with metastatic melanoma. On January 17, 2023, Evaxion furthermore received fast track designation for the vaccine candidate. The fast track is designed to expedite the FDA’s review of innovative, new drugs that demonstrate the potential to address an unmet medical need.

“We are extremely pleased that our cancer vaccine candidate EVX-01 has received the FDA fast track designation, as it enables a potentially faster approval of the vaccine. This is first and foremost to the benefit of the patients. And it is a great validation of our AI platform, PIONEER, and our drug development candidate,” says Per Norlén, CEO at Evaxion.

EVX-01 is a peptide-based cancer immunotherapy and is Evaxion’s most advanced clinical asset. Under the program, a unique drug is generated for each patient based on gene analysis of their tumors and on matching with their immune system. This process is made possible by the Company’s proprietary AI platform, PIONEER.

The ongoing Phase 2b study is conducted at clinical sites across the United States, Europe, and Australia. It is carried out in collaboration with Merck, supplying its PD-1 inhibitor KEYTRUDA®. The trial was initiated in Australia with the enrollment of the first patient in September 2022.

Read about EVX-01 Ph2b on clinicaltrials.gov: NCT05309421

About Evaxion

Evaxion Biotech A/S is a clinical-stage biotech company developing AI-powered immunotherapies. With our proprietary and scalable AI technology, we decode the human immune system to discover and develop novel immunotherapies for cancer, bacterial diseases, and viral infections. Evaxion has a broad pipeline of product candidates, including three personalized cancer immunotherapies. It is located in Hørsholm, Denmark, with 70 employees.

Source: Evaxion Biotech

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Forward-Looking Statements

This announcement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words “target,” “believe,” “expect,” “hope,” “aim,” “intend,” “may,” “might,” “anticipate,” “contemplate,” “continue,” “estimate,” “plan,” “potential,” “predict,” “project,” “will,” “can have,” “likely,” “should,” “would,” “could,” and other words and terms of similar meaning identify forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including, but not limited to, risks related to: our financial condition and need for additional capital; our development work; cost and success of our product development activities and preclinical and clinical trials; commercializing any approved pharmaceutical product developed using our AI platform technology, including the rate and degree of market acceptance of our product candidates; our dependence on third parties including for conduct of clinical testing and product manufacture; our inability to enter into partnerships; government regulation; protection of our intellectual property rights; employee matters and managing growth; our ADSs and ordinary shares, the impact of international economic, political, legal, compliance, social and business factors, including inflation, and the effects on our business from the worldwide COVID-19 pandemic and the ongoing conflict in the region surrounding Ukraine and Russia; and other uncertainties affecting our business operations and financial condition. For a further discussion of these risks, please refer to the risk factors included in our most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. We do not assume any obligation to update any forward-looking statements except as required by law.