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

FORM 6-K

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

For the month of December 2022

Commission File Number: 001-39950

Evaxion Biotech A/S
(Exact Name of Registrant as Specified in Its Charter)

Dr. Neergaards Vej 5f
DK-2970 Hoersholm
Denmark
(Address of principal executive offices)

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): ☐

INCORPORATION BY REFERENCE

This report on Form 6-K shall be deemed to be incorporated by reference in Evaxion Biotech A/S's registration statements on Form S-8 (File No. 333-255064), on Form F-3 (File No. 333-265132) and on Form F-1 (File No. 333-266050), including any prospectuses forming a part of such registration statements and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

FDA Indicates Phase 2b Study for EVX-01 May Proceed

As previously announced on September 21, 2022, Evaxion Biotech A/S (the "Company") reached an important milestone when it enrolled its first patient in Perth, Australia in the Company's global Phase 2b clinical trial of EVX-01, the Company's personalized, peptide-based cancer immunotherapy targeting melanoma, in combination with KEYTRUDA® an anti-PD-1 inhibitor developed by Merck &Co., Inc. ("Merck").

In November 2022, the Company submitted an Investigational New Drug Application ("IND") along with a Fast Track designation request to the U.S. Food and Drug Administration ("FDA") for the Phase 2b clinical trial of EVX-01 in combination with KEYTRUDA® for the treatment of patients with metastatic melanoma. On December 22, 2022, the FDA notified the Company that it had reviewed the Company's IND and determined that the Company may proceed with its Phase 2b trial. The Company anticipates a reply from the FDA on its Fast Track designation submission in the first quarter of 2023.

It is anticipated that the trial will be conducted globally at clinical sites across the United States, Europe, and Australia in collaboration with Merck, which is supplying the trial with its PD-1 inhibitor, KEYTRUDA®. Patients enrolled in the Phase 2b clinical trial will receive standard of care treatment along with KEYTRUDA® in combination with EVX-01, or in the event of progression, another standard of care treatment in combination with EVX-01. The Company is responsible for the conduct of the trial. The Company and Merck will continue to collaborate as the data mature. The Phase 2b clinical trial is a single arm trial evaluating the efficacy and safety of EVX-01 in combination with KEYTRUDA® (pembrolizumab) in adults with unresectable or metastatic melanoma. The trial will evaluate if EVX-01 improves the best overall response (BOR) in patients with an initial assessment of stable disease (SD) or partial response (PR) after initiating KEYTRUDA® treatment, as compared to historical outcomes with KEYTRUDA® alone in metastatic or unresectable melanoma.

The Company has received approval of its Clinical Trial Applications for the Phase 2b trial from regulatory authorities in Australia, Italy and France. The Company subsequently informed the French regulators that it currently does not intend to conduct the trial in France. In addition, the Company submitted a CTA in Spain and is awaiting approval by the Spanish regulatory authorities.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Evaxion Biotech A/S

Date: December 29, 2022

By: /s/ Bo Karmark
Bo Karmark
Chief Financial Officer