



DIVISION OF  
CORPORATION FINANCE

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

May 17, 2024

Christian Kanstrup  
Chief Executive Officer  
Evaxion Biotech A/S  
Dr. Neergaards Vej 5F  
2970 Hørsholm  
Denmark

**Re: Evaxion Biotech A/S**  
**Registration Statement on Form F-1**  
**Filed May 6, 2024**  
**File No. 333-279153**

Dear Christian Kanstrup:

We have conducted a limited review of your registration statement and have the following comment.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to this letter, we may have additional comments.

Registration Statement on Form F-1 filed May 6, 2024

General

1. We note certain statements regarding safety and efficacy in your business overview that is incorporated into your prospectus by reference to your most recent annual report on Form 20-F for the year ended December 31, 2023. For example only and without limitation, you state in the "Business overview" section that is incorporated into your prospectus by reference to your Form 20-F that:
  - "In addition, the data showed induction of neoantigen-specific T cells in 100% of patients and a favorable safety profile." (page 95)
  - "Our five AI models...have allowed us to generate numerous pipeline candidates within both cancer and infectious diseases, all with first-in-class potential." (page 97)
  - "The initial data demonstrated that the EVX-01 treatment appeared safe and well tolerated." (page 115)

- "Final data from a first-in-human Phase 1/2a clinical trial...substantiated a promising safety profile...as well as indicated encouraging clinical outcome data of our first-generation neoantigen DNA therapy." (page 116)
- "EVX-B2 was developed using our, proprietary AI model EDEN for B-cell antigen discovery, to identify novel and, we believe, highly efficacious B-cell antigen vaccine targets." (page 135)
- "GLA-SE was identified to have the highest adjuvating capacity on the antigens, resulting in a formulation with high immunogenicity and protective efficacy *in vivo* and *in vitro*." (page 136)
- "EVX-B2 demonstrates broad protection in a bactericidal assay using a panel of 50 different relevant clinical isolates with >50% bactericidal killing recognized as efficacy." (page 139)

Although we do not object to disclosure regarding the objective results of a product candidate study, safety and efficacy determinations are solely within the authority of the FDA. Therefore, please revise your registration statement to remove any statements regarding safety or efficacy determinations from the "Business overview" disclosures required by Part I, Item 4.a of Form F-1. In addition, please remove references to your product candidates potentially being "first-in-class" as these descriptions imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing marketing approval.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

Please contact Jessica Dickerson at 202-551-8013 or Jason Drory at 202-551-8342 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Michael D. Baird, Esq.