United States securities and exchange commission logo

January 12, 2023

Hartmut Ehrlich, MD
Chief Executive Officer
Abivax SA
7-11 boulevard Haussmann
75009 Paris
France

Re: Abivax SA
Draft Registration Statement on Form F-1
Submitted on December 16, 2022
CIK No. 0001956827

Dear Hartmut Ehrlich:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1 submitted on December 16, 2022

Cover Page

1. Please disclose on your cover page whether your offering is contingent upon final approval of your Nasdaq listing. Please ensure the disclosure is consistent with your underwriting agreement.

Prospectus Summary, page 4

2. We note your disclosure that you hold a "position as a leader in the development of therapeutics for chronic inflammatory diseases." Given that you have a limited operating

history, no approved products, and no historical product revenues, please justify this claim or otherwise advise.

3. We note your footnote under your pipeline table on page 5 where you state your belief that you will be able to use the Phase 1 data generated in your UC trials for your Crohn's disease indication. Please update your footnote to clarify that the FDA or other regulators may require additional trials. In addition, it does not appear that you have initiated a Phase 2 trial for Crohn's disease. Please shorten your progress arrow

so it reflects the
current stage of development or otherwise advise.
4. We refer to the last row in your pipeline table where you refer to ABX711 for an unnamed
inflammatory condition indication. Please expand your disclosure in your Business
section to provide a more fulsome discussion of this program, including identifying the
specific indication. Alternatively, please explain to us why this program is sufficiently
material to your business to warrant inclusion in your pipeline table.
5. We note your disclosure on page 6 that obefazimod "showed a rapid onset of action and
consistent efficacy[,]" your disclosure on page 29 that the "products [you] are developing
are likely to provide a therapeutic response[,]" your disclosure on page 87 that obefazimod
has "demonstrated a favorable safety and tolerability profile[,]" and your disclosure on
page 88 noting that obefazimod has demonstrated "consistent efficacy[.]" Please revise
throughout to remove these and any other inferences regarding the safety and efficacy of
your product candidates. Given that the determination of a product's safety and efficacy is
solely within the FDA's authority and your product candidates have not yet completed
clinical trials, these inferences are not appropriate.
6. We note on page 13 that you intend to use the proceeds of the offering to "fund the
development of obefazimod for ulcerative colitis." Please disclose here and in your Use
of Proceeds section how far the proceeds from the offering will allow you to proceed with
the development of obefazimod for the treatment of ulcerative colitis.

Our Team and Investors, page 7

7. We note that you identify a "supported syndicate of leading life science investors" in your
company in this section, however, some of these investors do not appear to be among the
principal stockholders that are identified on page 167. Please relocate this disclosure from
your prospectus summary to your "Principal Stockholder" section. We note in this regard
that the identification of the pre-IPO investors in your prospectus summary may appear to
suggest that potential investors in your public offering consider investments made by the
pre-IPO investors as a factor in making an investment decision without knowing, among
other things, the amount of each pre-IPO investor s investment in total or on a per share
basis, their investment strategies or whether those investors will continue to hold their
shares in the future, as some of the pre-IPO investors may not be subject to the reporting
requirements of Section 16 of the Exchange Act, and investors in your public offering will
not necessarily know when some of the pre-IPO investors decide to sell any of their

shares. In addition to relocating this disclosure, please limit any textual description of
your pre-IPO investors in your "Principal Stockholders" section to the investors identified
in that table.

Risks Related to Product Development, Regulatory Approval and Commercialization, page 25

8. We note your disclosure that currently, "there are no similar immunological treatments
with marketing authorization granted by competent regulatory

authorities." Given your
disclosure on page 33 that the "current standard of care for treatment
of patients with mild
IBD involves the use of conventional anti-inflammatory therapies[,]"
please reconcile
these statements or otherwise advise.
The war between Ukraine and Russia may affect our business, industry and the
markets in which
we operate., page 42

9. We note your disclosure on page F-10 where you state you "[e]arly
terminated the Phase
2b maintenance study of obefazimod in moderate to severe UC in
Ukraine." Please
update your disclosure here or otherwise advise.
Risks Related to Legal and Compliance, page 49

10. We note your disclosure on page 58 that one of your CROs experienced a
data breach that
involved personal data being compromised. Please clarify if any of
your data was
compromised during this event and if so, please disclose any remedial
measures you have
taken since this event.
Business, page 83

11. We note your inclusion of Figure 4 on page 92. Please clarify where
you believe your
product candidate, if approved, would fit within the treatment
landscape described in
Figure 4 or otherwise advise.
Our Strengths, page 87

12. We note your disclosure here that your lead drug candidate is
"derisked" and "has the
potential to be a first-in-class therapy and alter the inflammatory
treatment paradigm."
Given the development stage of your product candidate and the length
of the drug
approval process, it is premature and inappropriate to speculate or
imply that your product
candidate will ultimately be approved or become first-in-class. Please
remove these
statements.
Clinical Trials, page 93

13. We note your disclosure that the primary endpoint in the induction
Phase 2a trial was
safety, assessed as the rate of treatment emergent adverse events.
Please revise your
disclosure to note the most common treatment emergent adverse events
that were

observed in the trial. Additionally, for each of the clinical trials
described in this section,
please disclose whether any serious adverse effects were observed.
Patents, page 114

14. We note your disclosure that all of your patents and patent
applications are "co-owned"
except for certain exceptions. Please disclose the identity or
identities of any co-owners
of the patents and patent applications described in this section.
Collaboration, Research and Development Agreements, page 118

15. We note your disclosure regarding the Evotec Master Services Agreement
entered into
with Evotec in September 2017, including your disclosure that "[you]
are required to pay
Evotec an agreed set of fees." Please revise to clarify your
disclosure to describe the
material terms of the agreement, including the (i) aggregate amounts
paid or received to
date under this agreement, (ii) whether there are any milestone
payments or royalties set
forth in this agreement and (iii) clarify what product candidate(s)
have been discovered
pursuant to this agreement or otherwise advise.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Principal Factors Affecting Our Results of Operations
Acquisition of Prosynergia, page 126

16. You acquired 100% of the share capital of Prosynergia on April 1, 2022 and based on your disclosure on page F-12 the acquisition did not meet the definition of a business under IFRS 3. Thus it appears you have accounted for the acquisition as an asset acquisition. You state on pages 122 and 126 that since January 1, 2022, you have prepared consolidated financial statements. You also state that on December 12, 2022, you completed a merger with Prosynergia and all of Prosynergia's assets and liabilities were transferred to you and Prosynergia was dissolved. Please address the following:

- The disclosure relating to you consolidating Prosynergia since January 1, 2022 conflicts with your disclosure on page F-72 which states that you consolidated Prosynergia since the date control was obtained, i.e. April 1, 2022. Please revise to clarify when you began consolidating Prospynergia.
- If consolidation began prior to the acquisition date and the acquisition was accounted for as an asset acquisition, please tell us the guidance you are relying on for your accounting treatment.
- Please clarify on pages 122 and 163 what you acquired on December 12, 2022. Your disclosure throughout the filing appears to indicate that you acquired 100% of the share capital of Prosynergia on April 1, 2022.
- Please clarify in Management's Discussion and Analysis on page 134 the effect the acquisition of Prosynergia had on your results of operations.

General

17. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Vanessa Robertson at 202-551-3649 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Joshua Gorsky at 202-551-7836 or Jason Drory at 202-551-8342 with any other questions.

Sincerely,

Division of Corporation Finance

Office of Life Sciences

cc: Patrick Lyons