# Cooley

Divakar Gupta +1 212 479 6474 dgupta@cooley.com

July 28, 2023

U.S. Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549 Attention: Vanessa Robertson Mary Mast Joshua Gorsky Jason Drory

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

Ladies and Gentlemen:

On behalf of Abivax SA (the "*Company*"), we are providing this letter in response to the comments of the staff (the "*Staff*") of the U.S. Securities and Exchange Commission (the "*Commission*") Division of Corporation Finance contained in its letter, dated January 12, 2023 (the "*Comment Letter*"), relating to the Company's Draft Registration Statement on Form F-1, confidentially submitted on December 16, 2022 (the "*Draft Registration Statement*").

The Company is concurrently confidentially submitting Amendment No. 1 to the Draft Registration Statement (the "*Amended Draft Registration Statement*"), which reflects changes made in response to certain of the comments contained in the Comment Letter.

The numbering of the paragraphs below corresponds to the numbering of the comments contained in the Comment Letter, which, for your convenience, we have incorporated into this response letter in italics. Page references in the text of this response letter correspond to the page numbers of the Amended Draft Registration Statement. Capitalized terms used but not otherwise defined in this letter shall have the meanings set forth in the Amended Draft Registration Statement.



July 28, 2023 Page Two

# Draft Registration Statement on Form F-1 submitted 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.

The Company respectfully acknowledges the Staff's comment and has revised the cover page to state "There is no assurance that such application will be approved, and if our application is not approved, this offering will not be completed."

## Prospectus Summary

# Overview, 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.

In response to the Staff's comment, the Company has amended the disclosure on pages 4 and 117 to instead refer to the Company's "advanced position in the development of therapeutics for IBD and other chronic inflammatory diseases". The Company notes that such claim is supported by the Company's lead drug candidate, obefazimod, which is in Phase 3 clinical trials for the treatment of adults with moderately to severely active ulcerative colitis.

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.

In response to the Staff's comment, the Company has amended the pipeline chart on pages 3, 114 and 121, as requested.

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.



#### July 28, 2023 Page Three

In response to the Staff's comment, the Company has amended its pipeline chart to remove its reference to ABX711.

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.

In response to the Staff's comment, the Company has revised the disclosure to remove any inferences regarding the safety and efficacy of its drug candidate.

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.

In response to the Staff's comment, the Company notes that it will include disclosure regarding how far the proceeds from the offering will allow for continued development of obefazimod for ulcerative colitis in a subsequent amendment when it has more information about the potential size of the offering.

# 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



July 28, 2023 Page Four

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.

In response to the Staff's comment, the Company has removed the reference to, and description of, its "supported syndicate of leading life science investors" (see pages 7 and 121) and has limited any textual description of pre-IPO investors in the "Principal Shareholders" section to those investors identified in the table on page 182.

## 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.

In response to the Staff's comment, the Company has amended the disclosure on page 25 to state "To our knowledge, currently, there are no similar immunological treatments with a mechanism of action based on the upregulation on a single microRNA miR-124, with marketing authorization granted by competent regulatory authorities."

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.

In response to the Staff's comment, the Company has updated its disclosure on pages 47, 93 and F-10.

## 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.

In response to the Staff's comment, the Company has amended its disclosure on page 64.



July 28, 2023 Page Five

#### 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.

In response to the Staff's comment, the Company has included disclosure on pages 5, 6, 118, 119 and 125 to clarify that obefazimod may be positioned as an early-line, or first-line after failure of conventional therapies, treatment choice for both prescribers and patients, if approved.

## 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.

In response to the Staff's comment, the Company has amended the disclosure to remove references to obefazimod as "derisked" and "first-in-class".

# 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.

In response to the Staff's comment, the Company has amended the disclosure on page 126 to clarify that "The most frequently reported adverse events reported in the 25 mg group were GI disorders, experienced by 19% of subjects in the obefazimod group and 16% of subjects in the placebo group and headaches (21% for 25 mg and 8% for placebo), which occurred early and were transient (lasting only a few days), mainly mild or moderate (grade 1 or 2) and manageable with or without over-the-counter medications. No serious adverse events related to treatment were observed."

The Company has also included disclosure on pages 2, 113, 122 and 130, which clarifies that no new adverse safety signals were observed to date in its Phase 2b trial.



July 28, 2023 Page Six

## 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.

The Company respectfully acknowledges the Staff's comment and has amended the disclosure on page 154 to clarify the identity or identities of any coowners.

#### 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.

In response to the Staff's comment, the Company has amended the disclosure on page 158.

# 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 Prosynergia.



July 28, 2023 Page Seven

The Company respectfully acknowledges the Staff's comment. Due to the passage of time, the unaudited interim condensed consolidated financial statements as of June 30, 2022 are no longer included in the Amended Draft Registration Statement. Therefore, the Company no longer states that it prepares consolidated financial statements.

The Company has amended the disclosure in the Amended Draft Registration Statement to clarify that the control was obtained on April 1, 2022. While the Company prepared unaudited interim condensed consolidated financial statements as of June 30, 2022, consolidated financial statements were no longer necessary as of December 31, 2022, following the merger of Prosynergia (under French legal procedure for a merger *"Transmission Universelle de Patrimoine"*) when all the assets and liabilities of Prosynergia were merged into the Company, and Prosynergia was dissolved on December 12, 2022.

Therefore, the Company has included in the Management's Discussion and Analysis section of the Amended Draft Registration Statement to include the following statements: "On April 1, 2022, we acquired 100% of the share capital of Prosynergia with the aim of strengthening our research and development portfolio, for an amount of €3.25 million. On December 12, 2022, we completed the merger with Prosynergia through a TUP and all of Prosynergia's assets and liabilities were transferred to us. Following the merger, Prosynergia was dissolved. Accordingly, as Prosynergia was dissolved, we did not prepare consolidated financial statements as of December 31, 2022." (Please see pages 92-93 of the Amended Draft Registration Statement).

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.

The Company respectfully acknowledges the Staff's comment and refers to its response above.

• 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.

The Company respectfully acknowledges the Staff's comment and refers to its response above. On December 12, 2022, the assets and liabilities of Prosynergia were merged into the Company under the French legal procedure for a merger "Transmission Universelle de Patrimoine" and Prosynergia was dissolved.

• Please clarify in Management's Discussion and Analysis on page 134 the effect the acquisition of Prosynergia had on your results of operations.



#### July 28, 2023 Page Eight

The Company respectfully acknowledges the Staff's comment. The Company notes that Prosynergia's contribution to the Company's consolidated net loss for the period ended June 30, 2022 amounted to €55,000. Accordingly, as of June 30, 2022, the effect of the acquisition of Prosynergia on its results of operations was not significant.

# <u>General</u>

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.

The Company respectfully acknowledges the Staff's comment and will supplementally provide to the Staff, under separate cover, copies of all written communications, as defined in Rule 405 under the Securities Act that the Company, or anyone the Company authorized to on its behalf, presented to potential investors in reliance of Section 5(d) of the Securities Act.

\* \* \* \*

Please direct any questions or further comments concerning the Amended Draft Registration Statement or this response letter to either the undersigned at (212) 479-6474, Marc Recht of Cooley LLP at (617) 937-2316, Ryan Sansom of Cooley LLP at (617) 937-2335 or Denny Won of Cooley LLP at (415) 693-2032.

Sincerely,

/s/ Divakar Gupta

Divakar Gupta

cc: Marc de Garidel, Abivax SA Didier Blondel, Abivax SA Marc Recht, Cooley LLP Ryan Sansom, Cooley LLP Denny Won, Cooley LLP Nathan Ajiashvili, Latham & Watkins LLP Alison A. Haggerty, Latham & Watkins LLP