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 2025

Commission File Number: 001-41842

Abivax SA
(Translation of registrant's name into English)

7-11 boulevard Haussmann
75009 Paris, France
+33 (0) 1 53 83 08 41
(Address, including zip code, and telephone number, including area code, of registrant's 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 ☐

On January 9, 2025, Abivax SA (the "Company") issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Incorporation by Reference

This Report on Form 6-K, including Exhibit 99.1, except for the quotes contained therein, shall be deemed to be incorporated by reference into the Company's registration statement on Form F-3 (File No. 333-283336) and to be part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently filed.

Exhibit Index

Exhibit 99.1 Press Release, dated January 9, 2025

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.

Abivax SA
(Registrant)

Date: January 10, 2025

/s/ Marc de Garidel
Marc de Garidel
Chief Executive Officer

Abivax Achieves Key Milestone in Phase 3 ABTECT Trial Enrollment

- *Phase 3 ABTECT Trial evaluating obefazimod for moderately to severely active ulcerative colitis ("UC") reaches 1,003 of 1,224 participants, representing 82% of target enrollment. Enrollment completion expected in Q2 2025.*
- *Top-line results for the 8-week induction trial anticipated in Q3 2025, with 44-week maintenance data on track for Q2 2026 and, if successful, NDA submission planned for H2 2026.*
- *Blinded baseline characteristics align with pre-specified target population and consistent with Phase 2b UC trial*
- *Cash runway through ABTECT induction trial readout and into Q4 2025*

PARIS, France – January 9, 2025 – 5:35 PM CET – Abivax SA (Euronext Paris: FR0012333284 – ABVX / Nasdaq: ABVX) ("Abivax" or the "Company"), a clinical-stage biotechnology company developing innovative therapies to address chronic inflammatory diseases, today announced a significant milestone in the Phase 3 ABTECT clinical trial evaluating obefazimod for the treatment of moderately to severely active UC.

Marc de Garidel, Chief Executive Officer of Abivax, commented:

"We are thrilled to announce that the ABTECT Phase 3 trial has reached a significant milestone, with over 1,000 participants enrolled, representing 82% of our targeted enrollment. This progress underscores the enthusiasm of investigators and patients for this important trial, which remains among the fastest-enrolling Phase 3 UC trials to date."

Mr. de Garidel went on to say, "In order to ensure a balanced representation of bio-naïve and bio-experienced participants amid heightened competition in UC trial recruitment, we now anticipate completing enrollment in Q2 2025 and delivering top-line results for the 8-week induction trial in Q3 2025. With the ABTECT trial, we aim to validate the value of obefazimod as a potentially first-in-class safe and effective oral treatment option, which remains a significant unmet need for patients with UC."

Looking Ahead to 2025:

With Phase 3 enrollment nearing completion and key data readouts on the horizon, the Company believes 2025 is shaping up to be a pivotal year. Beyond the ABTECT trial, the Company is advancing its broader portfolio to address chronic inflammatory conditions that affect millions worldwide.

Didier Blondel, Chief Financial Officer of Abivax, added:

"Without the need for additional financing, our cash runway extends beyond the expected top-line results from the ABTECT induction trial and into Q4 2025, ensuring we remain well-positioned to execute our strategy."

ABTECT Phase 3 Update:

- **Enrollment Progress:** 1,003 of the targeted 1,224 participants enrolled to date.
- **Top-Line Results:** Induction trial results expected in Q3 2025, with 44-week maintenance data to follow in Q2 2026.
- **Regulatory Pathway:** NDA submission planned for H2 2026, assuming positive clinical data.
- **Participant Characteristics:** Blinded baseline data aligns with the target population defined during Phase 2b.
- **Safety Profile:** No new safety signals observed to date with the oversight of the independent Data Monitoring Committee.

About Abivax

Abivax is a clinical-stage biotechnology company focused on developing therapeutics that harness the body's natural regulatory mechanisms to stabilize the immune response in patients with chronic inflammatory diseases. Based in France and the United States, Abivax's lead drug candidate, obefazimod (ABX464), is in Phase 3 clinical trials for the treatment of moderately to severely active ulcerative colitis.

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FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, forecasts and estimates, including those relating to the Company's business and financial objectives. Words such as "anticipate," "expect," "potential" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning the Company's expectations for 2025 and 2026, including anticipated timing for top-line data readout of its ABTECT clinical trials and NDA submission, potential therapeutic benefit of obefazimod, and the Company's expected cash runway. Although Abivax's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks, contingencies and uncertainties, many of which are difficult to predict and generally beyond the control of Abivax, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. A description of these risks, contingencies and uncertainties can be found in the documents filed by the Company with the French Autorité des Marchés Financiers pursuant to its legal obligations including its universal registration document (Document d'Enregistrement Universel) and in its Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on April 5, 2024 under the caption "Risk Factors." These risks, contingencies and uncertainties include, among other things, the uncertainties

inherent in research and development, future clinical data and analysis, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug candidate, as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, and the availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements. Special consideration should be given to the potential hurdles of clinical and pharmaceutical development, including further assessment by the Company and regulatory agencies and IRBs/ethics committees following the assessment of preclinical, pharmacokinetic, carcinogenicity, toxicity, CMC and clinical data. Furthermore, these forward-looking statements, forecasts and estimates are made only as of the date of this press release. Readers are cautioned not to place undue reliance on these forward-looking statements. Abivax disclaims any obligation to update these forward-looking statements, forecasts or estimates to reflect any subsequent changes that the Company becomes aware of, except as required by law. Information about pharmaceutical products (including products currently in development) that is included in this press release is not intended to constitute an advertisement. This press release is for information purposes only, and the information contained herein does not constitute either an offer to sell or the solicitation of an offer to purchase or subscribe for securities of the Company in any jurisdiction. Similarly, it does not give and should not be treated as giving investment advice. It has no connection with the investment objectives, financial situation or specific needs of any recipient. It should not be regarded by recipients as a substitute for exercise of their own judgment. All opinions expressed herein are subject to change without notice. The distribution of this document may be restricted by law in certain jurisdictions. Persons into whose possession this document comes are required to inform themselves about and to observe any such restrictions.