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 2024

Commission File Number: **001-41842**

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

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75009 Paris, France
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(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 [X] Form 40-F [ ]

On January 22, 2024, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

(c) Exhibit 99.1. Press release dated January 22, 2024

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 22, 2024

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

Abivax provides 2024 strategic outlook and lays out key milestones over next 12 months

Abivax provides 2024 strategic outlook and lays out key milestones over next 12 months

- *Induction data read-out expected Q1 2025 from the pivotal Phase 3 ABTECT program evaluating obefazimod in moderately to severely active ulcerative colitis (UC)*
- *Formal process evaluating oral and injectable combination therapy candidates with obefazimod in UC has commenced; preclinical data to support decision-making on combination agent expected in 2H 2024*
- *Top-line data from long-term extension trial with 25mg obefazimod once-daily oral after one and two years of treatment expected to read-out in Q3 2024*
- *IND for Phase 2 trial of obefazimod in Crohn's disease (CD) cleared; Abivax to consider protocol modifications based on FDA recommendations*
- *Obefazimod follow-on candidate selection expected in Q3 2024*

PARIS, France, January 22, 2024, 8:30 a.m. CET – Abivax SA (Euronext Paris & Nasdaq: ABVX) ("Abivax" or the "Company"), a clinical-stage biotechnology company focused on developing therapeutics that harness the body's natural regulatory mechanisms to modulate the immune response in patients with chronic inflammatory diseases, today provides an outlook on its 2024 strategic priorities and milestones.

Marc de Garidel, Chief Executive Officer of Abivax, says*: "We are on track to deliver our strategic roadmap as laid out in September last year to prepare obefazimod for commercialization if approved, starting with ulcerative colitis in the US. Our US office has recently been opened and we have completed the recruitment of a very experienced team with a particular focus in the US. For 2024, our priority stays on the completion of patient recruitment into the ABTECT Phase 3 induction trials."*

Didier Blondel, Chief Financial Officer of Abivax, adds: "*With the successful Nasdaq IPO in October 2023, the largest ever Nasdaq IPO of a French-listed biotech company, we expect to be fully financed through the planned data read-outs of the UC and CD induction trials. In parallel, we continue to implement our multi-pronged financing strategy to fund our ambitious projects in 2024 and beyond, with the objective to increase shareholder value."*

Clinical trial priorities and milestones

Obefazimod Phase 3 program in UC (ABTECT)

The obefazimod Phase 3 ABTECT program investigating efficacy and safety in adults with moderately to severely active UC is progressing. Recruitment into both induction trials, ABTECT-1 and ABTECT-2, is ongoing in all designated regions.

The ABTECT program is designed for 1,200 UC patients across 36 countries in over 600 trial sites to take part in the pivotal Phase 3 program that covers North America, Europe, Latin America and Asia Pacific. Clinical remission is the primary endpoint for the eight-week induction trials as well as for the maintenance trial at week 52 (which is week 44 of the maintenance trial).

Anticipated milestones:

- Q4 2024: ABTECT planned enrollment of last patient into induction trials
- Q1 2025: ABTECT planned top-line induction data read-out after eight weeks of treatment
- Q1 2026: ABTECT planned top-line maintenance results after one year of treatment

Objectives:

- Obtain robust Phase 3 data for obefazimod in moderately to severely active UC as a potentially differentiated oral treatment option
- Establish obefazimod as a potential first-line advanced therapy for the treatment of UC

Obefazimod 25 mg long-term extension trial in UC

UC patients initially treated with 50 mg of oral, once-daily obefazimod and who completed the Phase 2a or Phase 2b maintenance trials could roll over into a follow-on, open-label maintenance trial with a reduced dose of 25 mg.

In an interim analysis as of July 31, 2023, of the 71 eligible patients, 63 completed their 48-week visit, with a demonstrated disease control rate (stable or improved Modified Mayo Score) of 84% (53 of 63 patients) with the 25 mg once-daily dose of obefazimod. No new safety signals were detected in UC patients treated up to five years with oral, once-daily obefazimod.

Anticipated milestones:

- Q3 2024: New obefazimod UC extension trial read-out after one and two years of continued treatment with reduced dose of 25 mg

Objectives:

- Confirm safety and efficacy data of Phase 2 maintenance trials and long-term extension trial interim analysis
- Confirm safety and efficacy results for reduced dose of 25 mg obefazimod for chronic long-term use
- Conduct further clinical laboratory parameter analysis to validate obefazimod's novel mechanism of action and its capacity to relieve UC symptoms

Obefazimod Phase 2 trial in Crohn's disease (ENHANCE-CD)

Based on existing supportive preclinical and clinical Inflammatory Bowel Disease (IBD) data, Abivax is advancing obefazimod in a Phase 2 trial in moderately to severely active Crohn's disease (CD).

Anticipated milestones:

- Q4 2023: IND for ENHANCE-CD trial was submitted and cleared. Abivax is currently evaluating FDA comments and will consider any recommended adjustments to trial design
- H2 2025: ENHANCE-CD planned top-line induction data read-out pending decision to modify the trial design after evaluation of FDA comments

Objectives:

- Reproduce obefazimod UC Phase 2 safety and efficacy data for the treatment of CD

R&D progress

- **Obefazimod in combination therapy:** Based on its early clinical profile, the formal process evaluating combination therapy of oral and injectable candidates with obefazimod in UC is ongoing and preclinical data to support decision-making on a combination agent is expected in 2H 2024.
- **Obefazimod follow-on candidate selection from miR-124 library:** R&D work on potential follow-on drug candidates to be selected from Abivax's compound library is ongoing. Selection of the first follow-on drug candidate is expected in Q3 2024 to further strengthen the Abivax pipeline.

Anticipated Milestones:

- 2H 2024: Disclosure of preclinical data of obefazimod combination therapy for the treatment of moderately to severely active UC
- Q3 2024: Selection of first obefazimod follow-on drug candidate from Abivax's miR-124 library

Objectives:

- Strengthen Abivax product pipeline with 1) additional opportunities to use obefazimod in a combination therapy and 2) additional compounds in the field of chronic inflammatory diseases

Abivax scientific congress participation in 1H 2024

Crohn's and Colitis Congress (Jan. 25-27, 2024, Bellagio, Las Vegas, US)

- Visit the Abivax booth at the CCC exhibitor hall (booth #1127)

19th Congress of European Crohn's and Colitis Organisation (Feb. 21-24, 2024, Stockholm, Sweden)

- All four submitted Abivax abstracts were accepted for presentation at the ECCO Congress 2024
- Abivax to organize an Industry Symposium on "Expanding the Armamentarium: Emerging MOAs for Treating Ulcerative Colitis" under the participation of KOLs Prof. Bruce Sands, MD, MS (United States), and Prof. Raja Atreya, MD, (Germany) on Feb. 23, 2024 at 07:15-08:15am CET in room A12

- Visit the Abivax booth at the ECCO exhibitor hall (booth #15)

Digestive Disease Week (May 18-21, 2024, Washington, D.C., US)

- Visit the Abivax booth at the DDW exhibitor hall (booth #529)

Financial update

Abivax successfully completed its initial public offering on the Nasdaq Global Market in October 2023, raising USD 235.8 million in gross proceeds (app. USD 212.2 million in net proceeds) under challenging market conditions:

- Abivax's offering is the largest ever US IPO of a French-listed biotech company
  - Abivax is in the Top 5 biotechs by total capital raised in 2023

Objectives:

- Fund the clinical development programs of obefazimod for UC and CD
- Under the current assumptions, these funds are expected to finance Abivax operations through the planned announcement of its top-line data from the ABTECT UC induction trials in Q1 2025 and the planned announcement of its top-line data from ENHANCE-CD induction trial in 2H 2025
- To ensure long-term financing and extend its current cash runway, Abivax is implementing a multi-pronged strategy to finance its additional projects as well as the expansion of its clinical, medical and commercial capabilities

Financial Agenda:

- Tuesday, April 2, 2024: 2023 Annual Business and Financial Report (as of December 31, 2023)
  A webcast will be organized following the publication of the annual financial results

- Thursday, May 30, 2024 – 10:00 a.m. CEST | 4:00 a.m. EST: Shareholders' Meeting

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About Abivax

Abivax is a clinical-stage biotechnology company focused on developing therapeutics that harness the body's natural regulatory mechanisms to modulate the immune response in patients with chronic inflammatory diseases. Based in France and the US, Abivax's lead drug candidate, obefazimod (ABX464), is in Phase 3 clinical trials for the treatment of moderately to severely active ulcerative colitis. More information on the Company is available at www.abivax.com. Follow us on LinkedIn and on X, formerly Twitter, @ABIVAX.

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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 "continue," "could," "design," "expect," "goal," "intend," "objective," "plan," "potential," "project," "will" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning or implying the therapeutic potential of Abivax's drug candidate, Abivax's expectations regarding the availability of data and timing of reporting results from its clinical trials, including its Phase 3 ABTECT-1 and ABTECT-2 induction trials, obefazimod extension trials in UC, and obefazimod Phase 2 trial in CD, the availability and timing of preclinical data to support decision-making on therapy candidates for use in combination with obefazimod in UC, as well as the availability and timing of disclosure of preclinical data of any such combination therapy, the selection of an obefazimod follow-on drug candidate from Abivax's miR-124 library, and enrollment of patients in clinical trials, Abivax's plans to strengthen its product pipeline with additional opportunities to use obefazimod in a combination therapy and additional compounds in the field of chronic inflammatory diseases, Abivax's cash runway and strategy to extend its cash runway, and other statements that are not historical fact. 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). 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. 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 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) which 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.