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 July 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 July 15, 2024, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Exhibit Index

Exhibit 99.1. Press release dated July 15, 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: July 15, 2024

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

Abivax Provides Operational and Key Program Update

Abivax Provides Operational and Key Program Update

- Phase 3 ABTECT Trial evaluating obefazimod in moderately to severely active ulcerative colitis (UC) on track to complete enrollment in early Q1 2025
- Top-line results from the ABTECT 8-week induction trial expected early Q2 2025, with 44-week maintenance data on pace to read out in Q1 2026; timing assumptions for New Drug Application (NDA) submission remain unchanged
- Continued progress on pre-clinical combination therapy program
- Sylvie Grégoire named Chair of Abivax's Board of Directors; Dr. Fabio Cataldi named Chief Medical Officer and Dr. David Zhang named Chief Strategy Officer
- Cash position allows for runway into Q4 2025 through ABTECT 8-week induction top-line results

PARIS, France, July 15, 2024, 10:00 p.m. CEST – Abivax SA (Euronext Paris & Nasdaq: ABVX) ("Abivax", "we" or the "Company"), 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, today provided an update on the progress of key clinical and preclinical programs and its leadership and operational updates.

Marc de Garidel, Chief Executive Officer (CEO) of Abivax: "During the first half of 2024, the Abivax team made significant progress with our Phase 3 ABTECT program, and we are on pace to complete enrollment for the Phase 3 ABTECT program in early Q1 2025, followed by the read-out of the top-line results of the 8-week induction trial in early Q2 2025, and the top-line results from the long-term maintenance trial evaluating patients treated at 52 weeks in Q1 2026."

Mr. de Garidel continued, "As previously announced, based on its early clinical profile, the formal process evaluating combination therapy of oral and injectable candidates with obefazimod in UC began in January. Over the past six months, the company has initiated the preclinical evaluation of combination therapies in mouse models. We have generated exciting preliminary data that we plan to communicate at an upcoming scientific congress."

Abivax also announces the election of Sylvie Grégoire as the new Chair of the Abivax Board of Directors, taking over for current CEO and Interim Chair, Marc de Garidel. With Ms. Grégoire joining the Board of Directors, Carol Brosgart, MD will be resigning from the Abivax Board.

Mr. de Garidel said "On behalf of the Abivax Board of Directors, I would like to warmly welcome Sylvie to the team. With more than three decades of successful operational and leadership experience, Sylvie will serve Abivax well as we enter a critical time in our company's evolution." Mr. de Garidel went on to say "We thank Carol Brosgart for the significant contributions that she brought to Abivax over the past several years."

Ms. Grégoire said "I am enthusiastic to join Abivax as the new Chair of the Board of Directors at such an exciting time, and I look forward to working with the team to realize the potential of obefazimod."

Didier Blondel, Chief Financial Officer (CFO): "We continue into the second half of 2024 with a cash runway to take the Company through critical milestones that will advance our pivotal Phase 3 ABTECT program for obefazimod in moderate-to-severe ulcerative colitis." Mr. Blondel continued, "We will continue to focus on careful expense management and thoughtful capital allocation to support execution of the ABTECT Program".

Operating highlights and ongoing clinical trials

ABTECT Obefazimod Phase 3 Program in UC

ABTECT is a randomized, double-blinded placebo-controlled trial evaluating the efficacy and safety of 50mg and 25mg doses of obefazimod administered once daily (QD) compared to placebo. In patients with moderately to severely active UC, the trial is enrolling 1,200 subjects across 36 countries at 600 trial sites and consists of an 8-week induction trial followed by a 44-week maintenance trial (for a total of 52 weeks of treatment).

Anticipated milestones:

- Early Q1 2025: Anticipated enrollment completion of ABTECT program
- Early Q2 2025: Expected top-line induction data read-out after eight weeks of treatment
- Q1 2026: Planned top-line maintenance results after one year of treatment

With the milestone of 600 active trial sites in 36 countries achieved recently, and with close to 50% of patients currently enrolled, the obefazimod Phase 3 ABTECT program investigating efficacy and safety in adults with moderately to severely active UC is actively recruiting in all regions with an accelerated pace and is expected to reach full enrollment in early Q1 2025, with top-line results anticipated in early Q2 2025.

Based on these timelines, assuming favorable results from the ABTECT trial program, the Company anticipates being in position to submit an NDA to the FDA in late H1 2026, seeking approval of obefazimod for the treatment of moderately to severely active

UC.

Obefazimod 25 mg long-term extension trial in UC

The obefazimod 25mg long-term extension trial is an open-label trial evaluating the long-term safety and efficacy of 25mg of obefazimod given once a day (QD) in subjects who have been previously enrolled in the Phase 2a and Phase 2b trials who were previously treated with 50mg of obefazimod (OLE and maintenance trials) and who are willing to continue their treatment.

Anticipated milestone:

- Q3 2024: Anticipated trial data read-out after one and two years of continued treatment with a reduced dose of obefazimod at 25 mg

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

Planned clinical trials

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

ENHANCE-CD is a Phase 2b, multicenter, double-blind, placebo-controlled trial that will evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of obefazimod in subjects with moderately to severely active CD. The trial design consists of a 12-week induction period and a subsequent 40-week maintenance period.

Anticipated milestones:

- September 2024: ENHANCE-CD planned start of patient enrollment
- 2H 2026: ENHANCE-CD planned 12-week induction data read-out

In alignment with FDA feedback on the Company's initial Phase 2a IND application submission early 2024, the CD trial design was adapted to be a dose-ranging Phase 2b clinical trial. These adjustments to the obefazimod CD clinical program are not expected to have an impact on the overall program budget and projected supplemental New Drug Application (sNDA) submission timeline.

R&D progress

Anticipated milestones:

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

Obefazimod in combination therapy: As previously announced, based on its early clinical profile, the formal process evaluating combination therapy of oral and injectable candidates with obefazimod in UC began in January 2024. Over the past six months, the Company has initiated the preclinical evaluation of combination therapies in mouse models. The Company has generated exciting preliminary data that will be submitted for presentation at an upcoming scientific congress. Additional preclinical combination studies are ongoing.

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 before the end of 2024 to further strengthen the Abivax pipeline.

Financial update

Based upon the strong dynamics of its current R&D portfolio with obefazimod in UC in Phase 3 trials, in CD in Phase 2b trial and in UC for potential combination therapy, as well as with the final research work to bring a follow-on compound of obefazimod into development before 2024 year-end, the Company has decided to further focus its planned resources toward R&D, while gating commercial spends until after the UC Phase 3 induction readout, and carrying on streamlining G&A expenses.

From a financial standpoint, on June 21, 2024, the Company drew down the €25m remaining tranche (Tranche C) under the Kreos and Claret debt agreements signed in August 2023.

With €222m cash and cash equivalent in hand as of June 30, 2024, cash position allows for runway into Q4 2025 through ABTECT 8-week induction top-line results milestone in early Q2 2025, with a potential opportunity to extend into Q1 2026, should the Company decide to draw the remaining tranche (Tranche B) pursuant to the Heights Capital convertible bonds agreement signed in August 2023.

Leadership and organizational updates

Abivax announces the appointment of Dr. Sylvie Grégoire as Chair of the Board of Directors effective immediately. Dr. Grégoire is a distinguished pharmaceutical and biotech executive with over 30 years in international leadership roles. Her expertise encompasses late-stage development, financial raises and commercial expansion. Dr. Grégoire is the Co-Founder and was Executive Chair of the Board at EIP Pharma Inc., based in Boston, MA. Under her leadership, EIP Pharma transitioned into CervoMed, a publicly listed company on NASDAQ (CRVO), developing the first disease-modifying treatment for Dementia with Lewy Bodies. Dr. Grégoire has previously served on the board of Cubist, Glycofi, Vifor Pharma, Revvity and chaired the board of IDM Pharma, Corvidia and CervoMed. Dr. Grégoire is currently a member of the board of Novo Nordisk, CervoMed and F2G Ltd.

Dr. Carol Brosgart has announced her resignation from the board. Dr. Brosgart joined the Abivax board in 2018 and we thank her for her significant contributions to the evolution and progress of the Company.

As Abivax enters into the final stages of the ABTECT program and prepares to commence the Phase 2b ENHANCE-CD trial, we are pleased to announce the appointment of Dr. Fabio Cataldi as Chief Medical Officer. Dr. Cataldi joins Abivax with more than 20 years of successful experience in the development and commercialization of innovative therapies. He brings deep clinical, medical and scientific knowledge and expertise in immunology and gastroenterology, having served in senior research and development roles at Arena Pharmaceuticals, AbbVie, Shire, Pfizer, Biogen and Novartis. Most recently he held the role of CMO at Landos BioPharma until the successful sale to AbbVie. Dr. Cataldi will have internal responsibility for Clinical Operations, Clinical Development, Pharmacovigilance and Medical Affairs.

Additionally, David Zhang, Ph.D will join Abivax as Chief Strategy Officer. Dr. Zhang joins Abivax from Alumis, where he held the role of Chief Information Officer responsible for building up capabilities in Biometrics, IT, Facilities and Investor Relations during the early days of the company. Before Alumis, Dr. Zhang held the role of Vice President of Biometrics and Digital Health at Myokardia where he played a pivotal role in the study design, data read-out, and New Drug Application submission for Camyzos. Dr. Zhang will have internal responsibility for Biometrics, Quality, HEOR and Regulatory.

The Company also announces Dr. Sheldon Sloan, MD, M Bioethics will be leaving his role as Chief Medical Officer. After 37 years of clinical medicine and various roles in the Pharmaceutical Industry, Dr. Sloan has decided to retire. We deeply appreciate all his contributions to Abivax and to the ABTECT program which include recruiting and building the medical team functions of Pharmacovigilance, Clinical Development, Clinical Pharmacology, Biometrics and Medical Affairs. The Company also announces that Chief Commercial Officer Michael Ferguson has left the organization to pursue other opportunities.

About Obefazimod
Obefazimod, Abivax's lead investigational drug candidate, is an orally administered small molecule that was demonstrated to potentially enhance the expression of a single microRNA, miR-124. Phase 2 clinical trials in patients with UC have generated positive data, resulting in the initiation of a pivotal global Phase 3 clinical trial program (ABTECT Program), with first patients enrolled in the United States in October 2022. Initiation of a Phase 2b clinical trial in Crohn's disease is expected in Q3 2024, and exploration of potential combination therapy opportunities in UC is ongoing.

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. More information on the Company is available at www.abivax.com. Follow us on LinkedIn and X (former Twitter).

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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 "design," "expect," "forward," "future," "potential," "plan," "project" 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 candidates, Abivax's expectations regarding the availability of data as well as timing of enrollment and reporting results from its clinical trials, including its Phase 3 ABTECT induction trial, obefazimod extension trials in UC, and obefazimod Phase 2b 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, the timing of NDA and sNDA submissions, obefazimod's potential to provide meaningful benefit to patients suffering from UC, CD, IBD or other indications, and enrollment of patients in clinical trials, 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) and in our 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. 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) 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 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.