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 June 2026

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 ☐

Positive Results from Phase 3 ABTECT 44-Week Maintenance Trial

On June 1, 2026, Abivax SA (the “Registrant” or the “Company”) announced positive results from its Phase 3 ABTECT 44-week maintenance trial evaluating obefazimod, the Registrant’s potential first-in-class oral miR-124 enhancer, in moderate to severely active ulcerative colitis (“UC”).

The Phase 3 ABTECT maintenance trial is a global 44-week multicenter, randomized, double-blind, placebo-controlled trial that evaluated the long-term efficacy and safety of obefazimod at 25 mg and 50 mg administered orally once-daily in adults with moderately to severely active UC. Participants who were clinical responders after the 8-week ABTECT-1 and ABTECT-2 induction trials (N=580) were re-randomized to receive 25 mg obefazimod, 50 mg obefazimod, or placebo.

Results from the trial demonstrated that obefazimod met the FDA primary endpoint of placebo-adjusted clinical remission at Week 44 in the 25 mg (Δ39.3%, $p<0.0001$) and 50 mg (Δ40.3%, $p<0.0001$) once-daily dose regimens in the Phase 3 maintenance trial. The trial also recorded a 10.4% placebo clinical remission rate, the lowest reported to date in a Phase 3 UC maintenance responder re-randomization trial.

Both doses of obefazimod met all key secondary endpoints (endoscopic improvement, endoscopic remission, Histologic-Endoscopic Mucosal Improvement (“HEMI”), corticosteroid-free clinical remission, and sustained clinical remission), demonstrating robust and clinically meaningful efficacy results across multiple measures of disease control.

Obefazimod demonstrated an overall favorable safety profile in the Phase 3 ABTECT maintenance trial with no new safety signals observed, and the treatment was generally well tolerated.

	FDA Primary Endpoint and Key Secondary Endpoints **ABTECT-Maintenance** (Study 107)		
	Placebo (N=192)	**25 mg** (N=193)	**50 mg** (N=195)
Clinical Remission			
Week 44 - n (%)	20 **(10.4%)**	98 **(50.8%)**	100 **(51.3%)**
Placebo-Adjusted Δ		Δ39.3%	Δ40.3%
P value		<0.0001	<0.0001
Endoscopic Improvement			
Week 44 - n (%)	24 **(12.5%)**	106 **(54.9%)**	125 **(64.1%)**
Placebo-Adjusted Δ		Δ42.5%	Δ51.0%
P value		<0.0001	<0.0001
Endoscopic Remission			
Week 44 - n (%)	19 **(9.9%)**	80 **(41.5%)**	93 **(47.7%)**
Placebo-Adjusted Δ		Δ31.4%	Δ37.8%
P value		<0.0001	<0.0001
HEMI			
Week 44 - n (%)	20 **(10.4%)**	97 **(50.3%)**	112 **(57.4%)**
Placebo-Adjusted Δ		Δ39.4%	Δ46.5%
P value		<0.0001	<0.0001
Corticosteroid-Free Clinical Remission			
Week 44 - n (%)	19 **(9.9%)**	87 **(45.1%)**	93 **(47.7%)**
Placebo-Adjusted Δ		Δ35.1%	Δ38.0%
P value		<0.0001	<0.0001
Sustained Clinical Remission			
Week 44 – n/N (%)	8/51 **(15.7%)**	49/73 **(67.1%)**	40/61 **(65.6%)**
Placebo-Adjusted Δ		Δ52.8%	Δ49.1%
P value		<0.0001	<0.0001

% Difference is for obefazimod minus placebo and is based on estimated common risk difference using the Mantel-Haenszel weights adjusting for the randomization stratification factors: clinical remission at maintenance baseline (yes/no), induction treatment (25 mg/50 mg), and maintenance baseline oral corticosteroids usage (yes/no); Clinical remission is defined as SFS = 0 or 1, and RBS = 0 and MES = 0 or 1; Endoscopic improvement is defined as MES = 0 or 1; Endoscopic remission is defined as MES = 0; HEMI is defined as MES = 0 or 1 and Geboes Index score <3.1; Corticosteroid-free clinical remission is defined as clinical remission (SFS = 0 or 1 and RBS = 0 and MES = 0 or 1) at Week 44 and corticosteroid-free for at least 12 weeks immediately prior to Week 44; Sustained clinical remission is defined as clinical remission at Week 44 in the sub-population of subjects in clinical remission at Week 8 of the induction trial

TEAEs[1], n (%)	Safety Results Summary ABTECT-Maintenance (Study 107) Placebo (N=192)	25 mg (N=193)	50 mg (N=195)
Any TEAE	96 **(50.0%)**	112 **(58.0%)**	140 **(71.8%)**
TEAE leading to study drug discontinuation	13 **(6.8%)**	5 **(2.6%)**	9 **(4.6%)**
Serious TEAE	8 **(4.2%)**	5 **(2.6%)**	11 **(5.6%)**
Death	0	0	0
Serious/severe (grade≥3) infections and opportunistic infections[2]	2 **(1.0%)**	2 **(1.0%)**	1 **(0.5%)**
Acute Pancreatitis	0	0	0
Cardiac abnormalities suggestive of cardiac fibrosis	0	0	0
Malignancies other than Non-Melanoma Skin Cancers (Non-NMSC)			
Prostate Cancer	**0**	**0**	**1 (0.5%)**
Breast Cancer	**0**	**0**	**1 (0.5%)**
Colonic Dysplasia	**0**	**0**	**1 (0.5%)**
Non-Melanoma Skin Cancers (NMSC)			
Basal Cell Carcinoma	1 **(0.5%)**	0	2 **(1.1%)**
Squamous Cell Carcinoma	0	1 **(0.5%)**	2 **(1.1%)**

- Non-NMSC: The prostate, breast, and colon cancer cases were considered unrelated to treatment by investigators, and no organ-specific clustering was observed
- NMSC:
  - Two of the four 50 mg patients were deemed not/unlikely related to drug by investigators; of the remaining two cases, one had a medical history of skin cancer
  - The mean age of observed NMSC cases was 62 years, compared with 42 years in the overall trial population, consistent with age-related NMSC risk

Based on current operating assumptions, the Registrant intends to submit a New Drug Application to the U.S. Food and Drug Administration in late fourth quarter of 2026.

Ongoing ENHANCE-CD Phase 2b Induction Trial

The ENHANCE-CD Phase 2b induction trial is ongoing with top-line results currently expected to be reported in mid-year 2027.

1 Treatment-Emergent Adverse Events

2 Serious/Severe Infections and Opportunistic Infections: Placebo = Anal abscess, bronchitis & gastroenteritis, 25 mg = 1 Lymph node tuberculosis, 1 tonsillitis, 50 mg = 1 Appendicitis, focal peritonitis

Press Release

A copy of the press release announcing the positive results from the Phase 3 ABTECT 44-week maintenance trial and the update on the ongoing ENHANCE-CD Phase 2b induction trial is furnished as Exhibit 99.1 to this Report on Form 6-K.

Incorporation by Reference

This Report on Form 6-K, excluding Exhibit 99.1, shall be deemed to be incorporated by reference into the Registrant's registration statements on Form F-3 (File Nos. 333-283336 and 333-288884) and Form S-8 (File Nos. 333-286069 and 333-294544) 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 June 1, 2026

Forward-Looking Statements

This Report on Form 6-K contains forward-looking statements, forecasts and estimates, including those relating to the Company's business and financial objectives. Words such as "expect," "intend," "potential" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning the potential therapeutic benefit of obefazimod, the expected timing for completion of the Phase 2b ENHANCE-CD induction trial of obefazimod and the availability and timing of results therefrom, the timing of regulatory filings including an NDA submission for obefazimod in UC, and other statements that are not historical fact. Although the Registrant'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 the Registrant, 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 March 23, 2026 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 Report. Readers are cautioned not to place undue reliance on these forward-looking statements. The Registrant 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 Report is not intended to constitute an advertisement. This Report 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.

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: June 1, 2026

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

Abivax Announces Landmark Phase 3 ABTECT Maintenance Trial Results Evaluating Obefazimod in Moderately to Severely Active Ulcerative Colitis

- *At Week 44, both the 25 mg and 50 mg once-daily obefazimod doses met the primary endpoint, demonstrating placebo-adjusted clinical remission rates of Δ39.3% and Δ40.3%, respectively (25 mg: 50.8%, 50 mg: 51.3% vs placebo 10.4%; p<0.0001)*
- *Both 25 mg and 50 mg obefazimod met all key secondary endpoints, demonstrating robust and clinically meaningful efficacy results across multiple measures of disease control*
- *Obefazimod demonstrated a favorable safety profile over the 44-week maintenance trial (N=580), with no new safety signals*
- *Recently reported Phase 2a/2b open-label extension data (Study 108) demonstrated durable clinical remission and a favorable safety profile with up to seven years of exposure*
- *The Company plans to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for obefazimod in ulcerative colitis in late Q4 2026*
- *Topline results of Phase 2b induction trial for Crohn's disease expected mid-year 2027*
- *Abivax to host a conference call and webcast today at 4:30 p.m. EDT (10:30 p.m. CEST) to discuss the results*

PARIS, France – June 1, 2026 – 10:05 pm CEST – Abivax SA (Euronext Paris: FR0012333284 – ABVX / Nasdaq: ABVX) ("Abivax" 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 announced positive topline results from the Phase 3 ABTECT maintenance trial evaluating obefazimod, its investigational oral, first-in-class miR-124 enhancer, in adults with moderately to severely active ulcerative colitis ("UC"). The results demonstrate that both the 25 mg and 50 mg doses of obefazimod met the primary endpoint of clinical remission and all key secondary endpoints at Week 44.

Marc de Garidel, MBA, Chief Executive Officer of Abivax, said: *"Today's landmark Phase 3 results highlight the exceptional potential of obefazimod to redefine the treatment landscape for ulcerative colitis. With its compelling durable efficacy and favorable safety profile, combined with the convenience of a once-daily oral treatment, obefazimod has the potential to transform UC patient care."*

David T. Rubin, M.D., Chief, Section of Gastroenterology, Hepatology and Nutrition, and Director of the Inflammatory Bowel Disease Center at the University of Chicago Medicine, commented: *"The 44-week maintenance data demonstrate obefazimod's potential to deliver meaningful efficacy and durable disease control in ulcerative colitis. The novel mechanism, sustained clinical remission, and favorable long-term safety profile highlight its potential to address a significant unmet need in UC."*

Topline Results

The Phase 3 ABTECT maintenance trial is a global 44-week multicenter, randomized, double-blind, placebo-controlled trial that evaluated the long-term efficacy and safety of obefazimod at 25 mg and 50 mg administered orally once-daily in adults with moderately to severely active UC. Participants who were clinical responders after the 8-week ABTECT-1 and ABTECT-2 induction trials (N=580) were re-randomized to receive 25 mg obefazimod, 50 mg obefazimod, or placebo.

Results from the trial demonstrated that obefazimod met the FDA primary endpoint of placebo-adjusted clinical remission at Week 44 in the 25 mg (Δ39.3%, $p<0.0001$) and 50 mg (Δ40.3%, $p<0.0001$) once-daily dose regimens in the Phase 3 maintenance trial. The trial also recorded a 10.4% placebo clinical remission rate, the lowest reported to date in a Phase 3 UC maintenance responder re-randomization trial.

Both doses of obefazimod met all key secondary endpoints (endoscopic improvement, endoscopic remission, HEMI[1], corticosteroid free clinical remission, and sustained clinical remission), demonstrating robust and clinically meaningful efficacy results across multiple measures of disease control.

Obefazimod demonstrated an overall favorable safety profile in the Phase 3 ABTECT maintenance trial with no new safety signals observed, and the treatment was generally well tolerated.

Abivax intends to submit an NDA to the FDA in late fourth quarter 2026.

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1 HEMI: Histologic-Endoscopic Mucosal Improvement

	FDA Primary Endpoint and Key Secondary Endpoints ABTECT-Maintenance (Study 107)		
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Week 44 - n (%)	19 **(9.9%)**	87 **(45.1%)**	93 **(47.7%)**
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TEAEs[2], n (%)	Safety Results Summary ABTECT-Maintenance (Study 107) Placebo (N=192)	25 mg (N=193)	50 mg (N=195)
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TEAE leading to study drug discontinuation	13 **(6.8%)**	5 **(2.6%)**	9 **(4.6%)**
Serious TEAE	8 **(4.2%)**	5 **(2.6%)**	11 **(5.6%)**
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Serious/severe (grade≥3) infections and opportunistic infections[3]	2 **(1.0%)**	2 **(1.0%)**	1 **(0.5%)**
Acute Pancreatitis	0	0	0
Cardiac abnormalities suggestive of cardiac fibrosis	0	0	0
Malignancies other than Non-Melanoma Skin Cancers (Non-NMSC)			
Prostate Cancer	0	0	1 **(0.5%)**
Breast Cancer	0	0	1 **(0.5%)**
Colonic Dysplasia	0	0	1 **(0.5%)**
Non-Melanoma Skin Cancers (NMSC)			
Basal Cell Carcinoma	1 **(0.5%)**	0	2 **(1.1%)**
Squamous Cell Carcinoma	0	1 **(0.5%)**	2 **(1.1%)**

- Non-NMSC: The prostate, breast, and colon cancer cases were considered unrelated to treatment by investigators, and no organ-specific clustering was observed
- NMSC:
  - Two of the four 50 mg patients were deemed not/unlikely related to drug by investigators; of the remaining two cases, one had a medical history of skin cancer
  - The mean age of observed NMSC cases was 62 years, compared with 42 years in the overall trial population, consistent with age-related NMSC risk

2 Treatment-Emergent Adverse Events

3 Serious/Severe Infections and Opportunistic Infections: Placebo = Anal abscess, bronchitis & gastroenteritis, 25 mg = 1 Lymph node tuberculosis, 1 tonsillitis, 50 mg = 1 Appendicitis, focal peritonitis

Fabio Cataldi, MD, Chief Medical Officer of Abivax, added, *"Today's ABTECT maintenance results represent an important milestone for the obefazimod program and we thank the patients, investigators, and site staff who made this trial possible. The totality of the data reinforces obefazimod's potential to meaningfully change the treatment landscape for ulcerative colitis. We look forward to sharing additional results from this trial at upcoming medical congresses and remain on track for NDA filing for obefazimod in ulcerative colitis by year end."*

Anticipated Upcoming Key Milestones

- Half-year financial results on September 21, 2026
- NDA submission for obefazimod in UC in Q4 2026
- Topline results of Phase 2b induction trial for Crohn's disease in mid-year 2027

Investor Conference Call and Webcast

Abivax management will host an investor and analyst conference call today at **4:30 p.m. EDT / 10:30 p.m. CEST** to discuss the topline results. To participate, please use the following dial-in or webcast link: https://edge.media-server.com/mmc/p/j7jbwm5g/

About the ABTECT Ulcerative Colitis Program

The global obefazimod ulcerative colitis program is evaluating more than 1,200 patients with moderately to severely active ulcerative colitis across three pivotal trials. These studies include assessments of efficacy and safety of obefazimod. More information on these trials can be found at www.clinicaltrials.gov (NCT05507203, NCT05507216, NCT05535946).

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. Words such as "anticipate," "expect," "on track," "potential," "will" and variations of such words and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements concerning the potential therapeutic benefit of obefazimod and obefazimod's potential to transform UC patient care, the timing for sharing additional results from the Phase 3 ABTECT maintenance trial, the expected timing for completion of the Phase 2b ENHANCE-CD induction trial of obefazimod and the availability and timing of results therefrom, the timing of regulatory filings including an NDA submission for obefazimod in UC, the timing for reporting Abivax's half year 2026 financial results, 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 its Annual Report on Form 20-F for the fiscal year ended December 31, 2025 filed with the U.S. Securities and Exchange Commission on March 23, 2026 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.