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 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 ☐

Positive Phase 3 Results from ABTECT 8-Week Induction Trials

On July 22, 2025, Abivax SA (the "Registrant") announced positive Phase 3 results from both ABTECT 8-week induction trials investigating obefazimod, the Registrant's potential first-in-class oral miR-124 enhancer, in moderate to severely active ulcerative colitis ("UC").

The ABTECT-1 and ABTECT-2 induction trials are global, multicenter, randomized, double-blind, placebo-controlled trials assessing once-daily oral administration of obefazimod at 25 mg or 50 mg doses in adult patients with moderately to severely active UC. Eligible participants had inadequate response, loss of response, or intolerance to conventional and/or advanced therapies. ABTECT-1 and ABTECT-2 were conducted simultaneously and have enrolled 1,275 patients from over 600 participating clinical trial sites in 36 countries with the intent to satisfy regulatory requirements globally. The ABTECT program is one of the largest Phase 3 UC trials ever conducted and includes the largest population of patients with inadequate response to JAK inhibitor therapy.

	FDA Primary Endpoint and Key Secondary Endpoints					
	ABTECT-1 (Study 105)			**ABTECT-2 (Study 106)**		
	Placebo (N=158)	**25 mg** (N=160)	**50 mg** (N=318)	**Placebo** (N=159)	**25 mg** (N=159)	**50 mg** (N=318)
Clinical Remission						
Week 8 - n (%)	4 (2.5%)	38 (23.8%)	69 (21.7%)	10 (6.3%)	18 (11.3%)	63 (19.8%)
P-value		<0.0001	<0.0001		0.1034	0.0001
Placebo-Adjusted Δ		Δ21.4%	Δ19.3%		Δ5.1%	Δ13.4%
Endoscopic Improvement						
Week 8 - n (%)	9 (5.7%)	60 (37.5%)	106 (33.3%)	16 (10.1%)	35 (22.0%)	113 (35.5%)
P-value		<0.0001	<0.0001		0.0029	<0.0001
Clinical Response						
Week 8 - n (%)	45 (28.5%)	105 (65.6%)	194 (61.0%)	53 (33.3%)	85 (53.5%)	201 (63.2%)
P-value		<0.0001	<0.0001		0.0002	<0.0001
HEMI[1]						
Week 8 - n (%)	5 (3.2%)	38 (23.8%)	73 (23.0%)	12 (7.5%)	21 (13.2%)	76 (23.9%)
P-value		<0.0001	<0.0001		0.0932	<0.0001

Results from the ABTECT-1 and ABTECT-2 trials demonstrated that obefazimod met its FDA primary endpoint of clinical remission at Week 8 in the 50 mg once-daily dose regimens for both trials. A 50 mg once-daily dose of obefazimod led to a compelling pooled 16.4% (p<0.0001) placebo-adjusted clinical remission rate at Week 8 in the ABTECT-1 (Study 105) and ABTECT-2 (Study 106) trials. Individually, the 50 mg dose demonstrated a placebo-adjusted remission rate of 19.3% (p<0.0001) in ABTECT-1 and a placebo-adjusted remission rate of 13.4% (p=0.0001) in ABTECT-2, each at the 50 mg once-daily dose, with all key secondary efficacy endpoints being met. 50 mg once-daily dose of obefazimod also met all key secondary endpoints demonstrating highly statistically significant and clinically meaningful benefits. ABTECT included a well-balanced distribution of advanced therapy naïve and advanced therapy experienced participants, with 47.3% of participants having had inadequate response to prior advanced therapy, including the largest population of patients with inadequate response to JAK inhibitor therapy in Phase 3 UC trials to date.

Obefazimod demonstrated favorable tolerability results, with no new safety signals observed. The treatment was generally well tolerated across both dose groups.

[1] HEMI = Histological Endoscopic Mucosal Improvement

	Summary of Adverse Events					
	ABTECT-1 (Study 105)			ABTECT-2 (Study 106)		
	Placebo (N=158)	**25 mg** (N=160)	**50 mg** (N=318)	**Placebo** (N=159)	**25 mg** (N=159)	**50 mg** (N=318)
TEAE[2], n (%)						
Any TEAE	84 (53.2%)	75 (46.9%)	189 (59.4%)	77 (48.4%)	81 (50.9%)	194 (61.0%)
TEAE leading to study drug discontinuation	6 (3.8%)	0 (0.0%)	17 (5.3%)	9 (5.7%)	8 (5.0%)	15 (4.7%)
Serious TEAE	3 (1.9%)	1 (0.6%)	14 (4.4%)	7 (4.4%)	6 (3.8%)	6 (1.9%)
Malignancy	0 (0.0%)	0 (0.0%)	1 (0.3%)*	0 (0.0%)	0 (0.0%)	0 (0.0%)
Serious/severe (grade ≥3) infections and opportunistic infections	1 (0.6%)¥	1 (0.6%)‡	2 (0.6%)†	0 (0.0%)	0 (0.0%)	2 (0.6%)d

Ongoing ABTECT Phase 3 Maintenance Trial

The ABTECT Maintenance Trial (ABX464-107) is ongoing with top-line results expected to report out in the second quarter of 2026. Among the 1,275 patients randomized in the induction trials, 678 achieved clinical response and enrolled into part 1 of the maintenance trial.

Preliminary Cash Balance as of June 30, 2025

The Registrant's preliminary cash and cash equivalents as of June 30, 2025 were approximately $71.4 million or €61.0 million (unaudited). The preliminary cash and cash equivalents as of June 30, 2025 are unaudited and subject to adjustment related to quarterly closing procedures and could differ from the Registrant's announcement of complete financial results for half-year 2025. Accordingly, you should not place undue reliance on these preliminary estimates.

Press Release

A copy of the press release announcing the positive Phase 3 results from both ABTECT 8-week induction trials, the update on the ongoing ABTECT maintenance trial and the Registrant's preliminary cash and cash equivalents as of June 30, 2025 is filed as Exhibit 99.1 to this Report on Form 6-K and is incorporated herein by reference.

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 No. 333-283336) and Form S-8 (File No. 333-286069) 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 July 22, 2025

[2] TEAE = Treatment Emergent Adverse Events; The final safety database lock will not occur until August 2025, but is more than 95% complete; n= number of subjects experiencing event; # = number of events; *prostate cancer, stage 1; †Covid-19, pneumonia
¥ Bronchopulmonary aspergillosis; ‡ Appendicitis; d Anal abscess, pneumonia

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 "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 anticipated timing for NDA and MAA submissions, the potential therapeutic benefit of obefazimod and the timing of release of its half-year 2025 financials. 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 24, 2025 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: July 22, 2025

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

Abivax Announces Positive Phase 3 Results from Both ABTECT 8-Week Induction Trials Investigating Obefazimod, its First-in-Class Oral miR-124 Enhancer, in Moderate to Severely Active Ulcerative Colitis

- *50 mg once-daily dose of obefazimod led to a compelling pooled 16.4% (p<0.0001) placebo-adjusted clinical remission rate at Week 8 in the ABTECT-1 (Study 105) and ABTECT-2 (Study 106) trials. Individually, the 50 mg dose demonstrated a placebo-adjusted remission rate of 19.3% (p<0.0001) in ABTECT-1 and a placebo-adjusted remission rate of 13.4% (p=0.0001) in ABTECT-2.*
- *50 mg once-daily dose of obefazimod met all key secondary endpoints demonstrating highly statistically significant and clinically meaningful benefits.*
- *ABTECT included a well-balanced distribution of advanced therapy naïve and advanced therapy experienced participants, with 47.3% of participants having had inadequate response to prior advanced therapy, including the largest population of patients with inadequate response to JAK inhibitor therapy in Phase 3 UC trials to date.*
- *Obefazimod demonstrated favorable tolerability results, with no new safety signals observed. The treatment was generally well tolerated across both dose groups.*
- *The ABTECT Maintenance Trial (ABX464-107) is ongoing with top-line results expected to report out in Q2 2026. Among the 1,275 patients randomized in the induction trials, 678 achieved clinical response and enrolled into part 1 of the maintenance trial. The ABTECT program is one of the largest Phase 3 ulcerative colitis trials ever conducted.*
- *Abivax to host a conference call and webcast today at 4:30 p.m. ET to discuss the results.*

PARIS, France – July 22, 2025 – 10:05 PM CET – 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 its Phase 3 ABTECT-1 (Study 105) and ABTECT-2 (Study 106) 8-week induction trials evaluating its oral, first-in-class miR-124 enhancer, obefazimod (ABX464), in adult patients with moderately to severely active ulcerative colitis ("UC").

Marc de Garidel, Chief Executive Officer of Abivax, commented: *"Today marks a significant milestone for Abivax, and more importantly, for the ulcerative colitis community. The strength of these results reinforces our belief in obefazimod, our first-in-class miR-124 enhancer, and its potential to become a transformative new treatment modality for patients with UC. Pending successful results from the 44-week maintenance trial, we are preparing to submit a New Drug Application to the FDA in the second half of 2026. We would like to thank the patients who participated in the trials as well as the investigators and staff at over 600 sites in 36 countries who contributed to the landmark trials."*

David 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 results of the two induction studies for this first-in-class therapy for ulcerative colitis are both statistically significant and clinically meaningful. Based on the impressive safety and tolerability profile demonstrated to date, and pending similar results in the maintenance study, obefazimod will offer a welcome new option for those who suffer from ulcerative colitis, both as an attractive early option as well as for those who have had inadequate response or loss of response to prior advanced therapies."*

Topline Results

The ABTECT-1 and ABTECT-2 induction trials are global, multicenter, randomized, double-blind, placebo-controlled trials assessing once-daily oral administration of obefazimod at 25 mg or 50 mg doses in adult patients with moderately to severely active UC. Eligible participants had inadequate response, loss of response, or intolerance to conventional and/or advanced therapies. ABTECT-1 and ABTECT-2 were conducted simultaneously and have enrolled 1,275 patients from over 600 participating clinical trial sites in 36 countries with the intent to satisfy regulatory requirements globally. The ABTECT Program is one of the largest Phase 3 ulcerative colitis trials ever conducted and includes the largest population of patients with inadequate response to JAK inhibitor therapy.

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Clinical Response						
Week 8 - n (%)	45 **(28.5%)**	105 **(65.6%)**	194 **(61.0%)**	53 **(33.3%)**	85 **(53.5%)**	201 **(63.2%)**
P value		<0.0001	<0.0001		0.0002	<0.0001
HEMI[1]						
Week 8 - n (%)	5 **(3.2%)**	38 **(23.8%)**	73 **(23.0%)**	12 **(7.5%)**	21 **(13.2%)**	76 **(23.9%)**
P value		<0.0001	<0.0001		0.0932	<0.0001

Results from the ABTECT-1 and ABTECT-2 trials demonstrated that obefazimod met its FDA primary endpoint of clinical remission at Week 8 in the 50 mg once-daily dose regimens for both trials. Individually, ABTECT-1 showed a placebo-adjusted clinical remission rate of 19.3% (p<0.0001) and ABTECT-2 demonstrated 13.4% (p=0.0001), each at the 50 mg once-daily dose, with all key secondary efficacy endpoints being met.

1 HEMI = Histological Endoscopic Mucosal Improvement

The 25 mg once-daily dose of obefazimod achieved the FDA primary endpoint of clinical remission at Week 8 in ABTECT-1 demonstrating a placebo-adjusted remission rate of 21.4%. While the 25 mg dose did not achieve statistical significance for this endpoint in ABTECT-2, it achieved a pooled placebo-adjusted clinical response rate of 28.6%, indicating a strong signal for these patients to achieve clinical remission with extended treatment in the maintenance trial.

The safety profile of obefazimod remained consistent with prior clinical experience. No new safety signals were observed in either trial and the treatment was generally well tolerated across both dose groups.

Summary of Adverse Events

	ABTECT-1 (Study 105)			**ABTECT-2** (Study 106)		
	Placebo (N=158)	**25 mg** (N=160)	**50 mg** (N=318)	**Placebo** (N=159)	**25 mg** (N=159)	**50 mg** (N=318)
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TEAE leading to study drug discontinuation	6 **(3.8%)**	0 **(0.0%)**	17 **(5.3%)**	9 **(5.7%)**	8 **(5.0%)**	15 **(4.7%)**
Serious TEAE	3 **(1.9%)**	1 **(0.6%)**	14 **(4.4%)**	7 **(4.4%)**	6 **(3.8%)**	6 **(1.9%)**
Malignancy	0 **(0.0%)**	0 **(0.0%)**	1 **(0.3%)***	0 **(0.0%)**	0 **(0.0%)**	0 **(0.0%)**
Serious/severe (grade ≥3) infections and opportunistic infections	1 **(0.6%)**¥	1 **(0.6%)**‡	2 **(0.6%)**†	0 **(0.0%)**	0 **(0.0%)**	2 **(0.6%)**d

2 TEAE = Treatment Emergent Adverse Events; The final safety database lock will not occur until August 2025, but is more than 95% complete; n= number of subjects experiencing event; # = number of events; *prostate cancer, stage 1; †Covid-19, pneumonia
¥ Bronchopulmonary aspergillosis; ‡ Appendicitis; d Anal abscess, pneumonia

Ongoing ABTECT Phase 3 Maintenance Trial:

- **Maintenance Trial:** 678 of 1,275 participants entered Part 1, the responder cohort.
- **Topline maintenance results** are expected in Q2 2026, which are intended to support regulatory filings globally.
- **Regulatory Strategy:** Contingent on positive 44-week maintenance results, Abivax intends to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application ("MAA") to the European Medicines Agency (EMA) in the second half of 2026.

Fabio Cataldi, M.D. Chief Medical Officer, stated: *"The exemplary results from the ABTECT induction trials reflect our dedication to scientific rigor and disciplined execution. We are thrilled to report outcomes that not only met but exceeded the bar set by our Phase 2b trial, a remarkable achievement that speaks volumes about the quality of our development program. We look forward to presenting more detailed analysis, including patients with inadequate response to prior JAK therapy at an upcoming medical conference."*

Please note that the Company will be postponing reporting H1 2025 financial results that were originally scheduled for August 11, 2025 to September 8, 2025. Preliminary cash and cash equivalents as of June 30, 2025, were approximately $71.4M or EUR 61.0M (unaudited)[3].

Investor Conference Call and Webcast

Abivax management will host an investor and analyst conference call today at **4:30 p.m. ET / 10:30 p.m. CET** to discuss the topline results. To participate, please use the following dial-in or webcast link:
https://register-conf.media-server.com/register/BI48058afba0d840b4b027a59daa065dd8

About the ABTECT Ulcerative Colitis Program

The global obefazimod ulcerative colitis program evaluates 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).

[3] The preliminary cash and cash equivalents as of June 30, 2025 is unaudited and subject to adjustment related to quarterly closing procedures and could differ from the Company's announcement of complete financial results for H1 2025. Accordingly, you should not place undue reliance on these preliminary estimates.

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.

Contact:

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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 anticipated timing for NDA and MAA submissions, the potential therapeutic benefit of obefazimod and the timing of release of its half-year 2025 financials. 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 March 24, 2025 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.