UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 25, 2025

IO BIOTECH, INC.
(Exact name of Registrant as Specified in its Charter)

Delaware	001-41008	87-0909276
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Ole Maaløes Vej 3
DK-2200 Copenhagen N
Denmark
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: +45 7070 2980

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	IOBT	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.05. Costs Associated with Exit or Disposal Activities.

On September 25, 2025, the Board of Directors of IO Biotech, Inc. (the "Company") approved a restructuring and workforce reduction plan (the "Plan") to conserve capital to align the Company's operations with its primary focus of advancing development of Cylembio® (imsapepimut and etimupepimut, adjuvanted). The Plan is expected to result in a reduction of approximately 50% of the Company's workforce globally.

In connection with the implementation of the Plan, the Company expects to incur one-time charges and cash expenditures in a range of approximately $1.0 million to $1.5 million, primarily related to employee wages and severance payments, healthcare continuation, earned vacation time and related termination costs.. The Company expects to incur these charges primarily during the third quarter of 2025 and payment of these charges is expected to be completed by the fourth quarter of 2025.

The actual timing and amount of these charges may differ from the Company's current estimates due to a variety of factors, including the finalization of severance terms, jurisdiction-specific legal requirements, and the pace of transition activities. The Company may also incur additional non-material charges in future periods related to the Plan.

Item 7.01. Regulation FD Disclosure.

On September 29, 2025, the Company issued a press release (the "Press Release") announcing the Plan and providing an update following the Company's meeting with the U.S. Food and Drug Administration (the "FDA").

A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in this Item 7.01 Current Report on Form 8-K, including Exhibit 99.1 hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events

On September 29, 2025, the Company announced that the FDA has recommended that the Company not submit a BLA based on the data from the IOB-013 clinical trial. As previously announced, in the IOB-013 trial treatment with Cylembio plus pembrolizumab improved progression free survival, but the results narrowly missed statistical significance. The Company plans to continue the dialogue with FDA to align on an efficient path to market for Cylembio, including the design of a potential additional registrational study for Cylembio. The Company also plans to discuss the data from the IOB-13 clinical trial with the European regulators and determine a path to approval in the EU.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	IO Biotech, Inc. Press Release, dated as of September 29, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

IO BIOTECH, INC.

Date: September 29, 2025

By: /s/ Mai-Britt Zocca, Ph.D.
Name: Mai-Britt Zocca, Ph.D.
Title: Chief Executive Officer

IO Biotech Provides Update Following Pre-BLA Meeting with FDA

- *FDA recommends that IO Biotech not submit a Biologics License Application (BLA) based on the data from the IOB-013 clinical trial*
- *Company plans to design new registrational study for Cylembio for the treatment of first-line patients with advanced melanoma*
- *Company implementing a restructuring, reducing its workforce by approximately 50 percent*

New York, NY – September 29, 2025: IO Biotech (Nasdaq: IOBT), a clinical-stage biopharmaceutical company developing novel, immune-modulatory, off-the-shelf therapeutic cancer vaccines, today provided an update on the regulatory pathway for Cylembio® (imsapepimut and etimupepimut, adjuvanted) following a pre-BLA meeting with the U.S. Food and Drug Administration (FDA). The FDA has recommended that IO Biotech not submit a BLA based on the data from the IOB-013 clinical trial. As previously announced, in the IOB-013 trial, treatment with Cylembio plus pembrolizumab improved progression free survival (PFS), however the results narrowly missed statistical significance. The company plans to continue the dialogue with FDA to align on the design of a potential new registrational study for Cylembio.

"We had a productive meeting with the FDA; while this is not the outcome we had hoped for, we respect the FDA's feedback and remain confident in the therapeutic potential of Cylembio," said Mai-Britt Zocca, PhD, president and chief executive officer of IO Biotech. "We look forward to continuing the dialogue with the FDA to align on the design for a potential new registrational study. Additionally, we plan to discuss the data from our IOB-013 study with European regulators and determine a path to submission in the EU."

The company is implementing a plan to conserve capital while it pursues a pathway to regulatory approval for Cylembio and works to complete ongoing studies. The company currently has capital to run its operations into the first quarter of 2026 and is restructuring to reduce the company's ongoing expense structure. The company expects to incur a non-recurring charge of between $1.0 - $1.5 million in the third quarter of 2025 related to the restructuring, which includes an approximate 50 percent reduction in full-time employees.

About Cylembio®

Cylembio® (imsapepimut and etimupepimut, adjuvanted) is an investigational, immune-modulatory, off-the-shelf therapeutic cancer vaccine candidate designed to kill both tumor cells and immune-suppressive cells in the tumor microenvironment (TME) by stimulating activation and expansion of T cells against indoleamine 2,3-dioxygenase 1 (IDO1) positive and/or programmed death-ligand 1 (PD-L1) positive cells. The company is currently conducting a pivotal Phase 3 trial (IOB-013/KN-D18; NCT05155254) investigating Cylembio in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) versus pembrolizumab alone in patients with advanced melanoma, a Phase 2 basket trial (IOB-022/KN-D38; NCT05077709) investigating Cylembio in combination with pembrolizumab as first line treatment in patients with advanced solid tumors, and a Phase 2 basket trial (IOB-032/PN-E40; NCT05280314) investigating Cylembio in combination with pembrolizumab as neo-adjuvant/adjuvant treatment of patients with solid tumors. Enrollment in the Phase 3 trial was completed rapidly by December 2023 with topline results from this trial reported in the third quarter of 2025. Enrollment in the two ongoing company-sponsored Phase 2 clinical trials is complete.

The clinical trials are sponsored by IO Biotech and conducted in collaboration with Merck, which is supplying pembrolizumab. IO Biotech maintains global commercial rights to Cylembio.

Cylembio® is a registered trademark of IO Biotech ApS, a subsidiary of IO Biotech.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA (known as MSD outside of the US and Canada).

About the IOB-013/KN-D18 Phase 3 Clinical Trial

IOB-013/KN-D18 (ClinicalTrials.gov: NCT05155254) is an open label, randomized Phase 3 pivotal clinical trial evaluating Cylembio® in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) versus pembrolizumab alone in patients with previously untreated, unresectable or metastatic (advanced) melanoma. Enrollment in the trial was completed by December 2023 with a total of 407 patients enrolled from more than 100 centers across the United States, Europe, Australia, Turkey, Israel and South Africa. The primary endpoint of the study was progression free survival. Secondary endpoints include overall response rate, overall survival, durable objective response rate, complete response rate, duration of response, time to complete response, disease control rate, and incidence of adverse events and serious adverse events (safety and tolerability). Biomarkers in the blood and tumor tissue will also be assessed as exploratory endpoints. The company reported topline results from this trial in the third quarter of 2025. IO Biotech is sponsoring the Phase 3 trial and Merck is supplying pembrolizumab.

About IO Biotech

IO Biotech is a clinical-stage biopharmaceutical company developing novel, immune-modulatory, off-the-shelf therapeutic cancer vaccines based on its T-win® platform. The T-win platform is based on a novel approach to cancer vaccines designed to activate T cells to target both tumor cells and the immune-suppressive cells in the tumor microenvironment. IO Biotech is advancing its lead cancer vaccine candidate, Cylembio®, in clinical trials, and additional pipeline candidates through preclinical development. IO Biotech is headquartered in Copenhagen, Denmark and has US headquarters in New York, New York.

For further information, please visit www.iobiotech.com. Follow us on our social media channels on LinkedIn and X (@IOBiotech).

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including statements regarding the regulatory pathway for Cylembio/IO102-IO103, the timing or outcome of communications with regulatory authorities including the FDA and EMA, the timing or outcome of the submission of marketing applications, including a BLA, for Cylembio, the timing or outcome of the launch of Cylembio, and statements regarding other current or future clinical trials, their timing, progress, enrollment or results, or the company's financial position or cash runway, are based on IO Biotech's current assumptions and expectations of future events and trends, which affect or may affect its business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be

predicted or quantified. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of the date hereof and should not be unduly relied upon. Except to the extent required by law, IO Biotech undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise.

Contact:

Investors

Maryann Cimino, Director of Investor Relations
IO Biotech, Inc.
617-710-7305
mci@iobiotech.com

Media

Julie Funesti
Edelman
917-498-1967
julie.funesti@edelman.com