# 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): January 14, 2024

# Instil Bio, Inc.

(Exact name of registrant as specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-40215

(Commission File Number) 83-2072195

(IRS Employer Identification No.)

3963 Maple Avenue, Suite 350 Dallas, Texas

(Address of Principal Executive Offices)

75219

(Zip Code)

(972) 499-3350

(Registrant's Telephone Number, Including Area Code)

Not Applicable

(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 Instructions 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:

	Trading	
Title of each class	Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.000001 par value	TIL	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 $\boxtimes$

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.  $\Box$ 

# Item 2.05 Costs Associated with Exit or Disposal Activities.

On January 14, 2024, the Board of Directors of Instil Bio, Inc. (the "Company") approved a restructuring plan (the "Plan") to effect the closure of its Manchester, UK manufacturing and clinical trial operations, thereby reducing its UK workforce by approximately 61%. This workforce reduction is expected to be substantially completed by the first half of 2024. As a result of the foregoing, the Company no longer expects to report clinical data from the ITIL-306-202 clinical trial in 2024.

In connection with the Plan, the Company estimates that it will incur aggregate restructuring costs of up to \$6.1 million, including employee termination costs, including severance and other benefits, and contract termination costs. The charges that the Company expects to incur in connection with the Plan are subject to a number of assumptions, and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Plan.

#### Item 8.01 Other Events.

On January 16, 2024, the Company issued a press release entitled "Instil Bio Announces Strategic Update." A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

#### Item 9.01 Financial Statements and Exhibits.

#### (d) Exhibits

Exhibit No.	Description
99.1	Press release, dated January 16, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### **Cautionary Note Regarding Forward-Looking Statements**

This Current Report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the scope and the timing of the restructuring and the expected costs related to the restructuring and expectations regarding, and plans concerning, the Company's facilities, which are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements, including the sufficiency of the Company's cash resources; the Company's ability to achieve the expected benefits of its corporate restructuring; and other risks and uncertainties affecting the Company and its development programs, including those discussed in the section titled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 and in subsequent filings with the SEC. Forward-looking statements in this Current Report are made as of the date of this Current Report and the Company undertakes no duty to update any such statements unless required by law.

# SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# Instil Bio, Inc.

Dated: January 16, 2024

By: /s/ Sandeep Laumas, M.D.

Sandeep Laumas, M.D. Chief Financial Officer and Chief Business Officer (Principal Financial Officer and Principal Accounting Officer)



# Instil Bio Announces Strategic Update

**DALLAS, TX, January 16, 2024 (GLOBE NEWSWIRE)** Instil Bio, Inc. ("Instil" or the "Company") (NASDAQ: TIL), a clinical-stage biopharmaceutical company focused on developing tumor infiltrating lymphocyte, or TIL, therapies for the treatment of patients with cancer, today announced a strategic update.

Instil has entered into an agreement with a collaborator that has a successful track record of manufacturing and dosing patients with cell therapies to conduct preclinical manufacturing feasibility studies in the ITIL-306 program. The feasibility studies have been initiated, and if the feasibility studies are successful, Instil's collaborator may open an investigator-initiated clinical trial (IIT) to enroll patients with non-small cell lung cancer (NSCLC) in China. In the event the IIT generates compelling proof-of-concept clinical data in 2024, Instil may explore options for a potential transition of ITIL-306 to a US-based CDMO for manufacturing and clinical development primarily at US clinical trial sites.

With the objective of saving costs and improving time efficiency, the Company is announcing the closure of its UK manufacturing and clinical operations, thereby reducing its UK workforce which is expected to be substantially completed by the first half of 2024. Instil plans to retain key process development, research, and related personnel to advance early-stage pipeline development of CoStAR<sup>™</sup> and other novel TIL technologies, and to support the company's collaboration.

## **About Instil Bio**

Instil Bio, Inc. (Nasdaq: TIL) is a clinical-stage biopharmaceutical company focused on developing TIL therapies for the treatment of patients with cancer. Instil has assembled an accomplished management team with a successful track record in the research, development and manufacture of cell therapies. Instil is developing a novel class of genetically engineered TIL therapies using its Co-Stimulatory Antigen Receptor, or CoStAR<sup>™</sup>, platform, including ITIL-306, a next-generation, genetically engineered TIL therapy, for multiple solid tumors. For more information visit <u>www.instilbio.com</u>.

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "expects," "future," "intends," "may," "plans," "potential," "projects," and "will" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying the therapeutic potential of our product candidates, our research, development and regulatory plans for our product candidates, including the timing of our ongoing and potential future preclinical studies and clinical trials and the availability of data therefrom, including our expectations concerning our ITIL-306 program, our expectations concerning the closure of our UK manufacturing and clinical operations and the related reduction in force and the benefits thereof, expectations concerning our collaboration and the generation of preclinical and clinical data therefrom, plans for potential impact thereof on our development of ITIL-306, and other statements that are not historical fact. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements, including risks related to failure or delays in completing feasibility studies and successfully initiating, enrolling, reporting data from or completing clinical studies, as well as the risks that results obtained in clinical trials to date may not be indicative of results obtained in ongoing or future trials and that our



product candidates may otherwise not be effective treatments in their planned indications; risks associated with reliance on third-party collaborators; risks associated with conducting clinical trials outside the United States; our ability to achieve the expected benefits of the closure of our UK manufacturing and clinical operations; macroeconomic conditions, including as a result of the conflicts in Ukraine and in the Middle East, interest rates, inflation, bank failures and other factors, which could materially and adversely affect our business and operations, including our ability to timely initiate, enroll and complete future clinical trials; the time-consuming and uncertain regulatory approval process; risks inherent in manufacturing and testing of cell therapy products; the sufficiency of our cash resources, and other risks and uncertainties affecting Instil and its development programs, including those discussed in the section titled "Risk Factors" Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that we make from time to time with the SEC. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements speak only as the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

#### Contacts:

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