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 30, 2023

Instil Bio, Inc.
(Exact name of registrant as specified in its Charter)

Delaware	**001-40215**	**83-2072195**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3963 Maple Avenue, Suite 350 **Dallas, Texas**		**75219**
(Address of Principal Executive Offices)		(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:

Title of each class	**Trading 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 ☒

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 January 30, 2023, the Board of Directors (the "Board") of Instil Bio, Inc. (the "Company") approved an expansion of its previously announced realignment plan implementing a strategic prioritization of the Company's preclinical and clinical development programs. In connection with the expanded realignment plan (the "Plan"), the Company will extend its previously announced U.S. reduction in force, resulting in a team of approximately 15 in the United States to lead global business operations. The reduction is expected to be substantially completed in April 2023. The Plan is designed to reduce operating expenses, which is expected to preserve financial resources and extend the Company's cash runway beyond 2026 based on the Plan as currently contemplated. In connection with the Plan, the Company expects to transition clinical manufacturing and trial operations of ITIL-306 to its operations in the United Kingdom. In addition, the Company is evaluating opportunities for a potential sale/sublease of its Tarzana, California manufacturing site, as well as other facilities currently under lease.

In connection with the Plan, the Company estimates that it will incur aggregate restructuring costs of up to $3.0 million, excluding any charges or costs associated with any potential sale of its facilities. At the time of the filing of this Current Report on Form 8-K, the Company is unable in good faith to make a determination of an estimate of the total amount or range of amounts expected to be incurred by the Company in connection with each major type of cost associated with the Plan or the amount or range of amounts of the charge that will result in future cash expenditures. 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.

The Company issued a press release announcing the Plan on January 31, 2023, which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

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, 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, estimates regarding the Company's cash runway and expectations regarding, and the impact of, the transition of the Company's ITIL-306 clinical manufacturing and trial operations to the United Kingdom, and plans concerning the Company's facilities. 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 and uncertainties associated with the costly and time-consuming cell therapy product development process and the uncertainty of clinical success, including risks related to failures or delays in successfully initiating, enrolling, reporting data from or completing clinical studies, including as a result of our transition of our ITIL-306 clinical trial to the United Kingdom, 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 for their planned indications; the risk that the implementation of additional quality safeguards to our manufacturing processes may not be effective; the ongoing COVID-19 pandemic, which could materially and adversely affect our business and operations, including our ability to timely initiate, enroll and complete our ongoing and 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; our ability to achieve the expected benefits of our corporate reorganization; the risk that we may be unable to successfully transition our manufacturing and clinical trial operations to our UK facility and execute on any additional facility restructuring in a timely manner; and other risks and uncertainties affecting Instil and its development programs, including those discussed in the section titled "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 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. Such risks may be amplified by the impacts of the COVID-19 pandemic. 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 of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated January 31, 2023.
104	The cover page of this report has been formatted in Inline XBRL.

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 31, 2023

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 Extension of Cash Runway Beyond 2026 with the Consolidation of R&D Operations to its Manchester, U.K. Site

Company anticipates cash resources to provide runway beyond 2026

Initial clinical data from the ITIL-306 program expected in 2023

Instil is consolidating manufacturing and Phase 1 clinical trial of CoStAR-TIL™ to its operations in Manchester, U.K.

Instil to extend previously announced reduction-in-force to reduce US headcount

DALLAS, TX, January 31, 2023 (GLOBE NEWSWIRE) Instil Bio, Inc. ("Instil" or the "Company") (NASDAQ: TIL), a clinical-stage biopharmaceutical company focused on developing next-generation tumor infiltrating lymphocyte, or TIL, therapies for the treatment of patients with cancer, today announced an extension of its previously announced reduction-in-force to a team of approximately 15 employees in the U.S. to lead global business operations, including the consolidation of clinical manufacturing and trial operations of its CoStAR-TIL™ to its active Manchester, U.K. operations. Instil's Manchester, U.K. operations have extensive experience and success in the manufacture and development of TIL and other cell therapy products since 2011. With these changes, Instil expects cash resources to provide runway beyond 2026 and continues to expect initial clinical data from the ITIL-306 program in 2023. Instil is also evaluating opportunities for a potential sale of the Tarzana manufacturing site which would further extend the cash runway.

"I am confident in the ability of our Manchester team to progress ITIL-306 in the clinic, building on more than a decade of proven experience in manufacturing TIL, including our historical compassionate use program in metastatic melanoma," said Bronson Crouch, CEO of Instil Bio. "The consolidation we announce today, while difficult, is consistent with our responsibilities as an early clinical phase company. We look forward to presenting initial clinical data in 2023 and continuing to progress the CoStAR-TIL platform."

About Instil Bio
Instil Bio, Inc. (Nasdaq: TIL) is a clinical-stage biopharmaceutical company focused on developing next-generation TIL therapies for the treatment of patients with cancer. The Company has assembled an accomplished management team with a successful track record in the research, development, manufacture, and commercialization of cell therapies. Instil is advancing its lead CoStAR-TIL product candidate, ITIL-306, a next-generation, genetically-engineered TIL therapy for multiple solid tumors. For more information visit www.instilbio.com and LinkedIn.

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," "potential," "projects," and "will" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying our pipeline of potential therapies and the development thereof, our plans regarding transition of our manufacturing and enrollment in our ITIL-306 clinical trial to our U.K. operations, expectations concerning the availability of initial clinical data from our ITIL-306 study and the timing thereof, our cash runway, our potential plans with respect to our facilities, 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 and uncertainties associated with the costly and time-consuming cell therapy product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating, enrolling, reporting data from or completing clinical studies, including as a result of our transition of our ITIL-306 clinical trial to the United Kingdom, 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; the risk that the implementation of additional quality safeguards to our manufacturing processes may not be effective; the ongoing COVID-19 pandemic, which could materially and adversely affect our business and operations, including our ability to timely initiate, enroll and complete our ongoing and 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; our ability to achieve the expected benefits of our corporate reorganization; the risk that we may be unable to successfully transition our manufacturing and clinical trial operations to our U.K. facility and execute on any additional facility restructuring in a timely manner; and other risks and uncertainties affecting Instil and its development programs, including those discussed in the section titled "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 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. Such risks may be amplified by the impacts of the COVID-19 pandemic. 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 of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

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