
**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): December 2, 2022

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:

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 December 2, 2022, the Board of Directors (the “Board”) of Instil Bio, Inc. (the “Company”) approved a realignment plan (the “Plan”) to implement a strategic prioritization of the Company’s preclinical and clinical development programs. The Plan is designed to reduce costs and reallocate resources to focus on advancing the Company’s CoStimulatory Antigen Receptor (CoStAR) platform and other next-generation tumor infiltrating lymphocyte (TIL) technologies. As part of the Plan, the Company’s ITIL-168 development program will be discontinued.

In addition, as part of the Plan, the Company will reduce its US workforce by approximately 60%. This workforce reduction is expected to be substantially completed in February 2023.

In connection with the Plan, the Company estimates that it will incur aggregate restructuring costs of up to \$20 million. 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 December 8, 2022, which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

In connection with the Plan, Timothy Moore, the Company’s Chief Operating Officer, will separate from the Company, effective December 8, 2022. Mr. Moore has agreed to remain as a consultant for the Company for a three-month term.

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. For a discussion of these risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, see the discussions of potential risks, uncertainties and other important factors in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated December 8, 2022.
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: December 8, 2022

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 Prioritization of Genetically Engineered CoStAR-TIL Program with ITIL-306 in Advanced Solid Tumors and Reduction in Workforce

- *Discontinuing unmodified TIL programs, including DELTA-1 and DELTA-2 trials of ITIL-168*
- *Prioritizing CoStAR-TIL programs for clinical development, including ITIL-306 in Phase 1 trial for NSCLC, ovarian, and renal cell carcinoma*
- *Reducing U.S. headcount by approximately 60%*

DALLAS, TX, December 7, 2022 (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 a reprioritization of its clinical programs to focus on development of its CoStAR-TIL product candidates.

“From the beginning of Instil, we have been committed to advancing TIL therapy by enhancing the native activity of TILs with innovative strategies designed to improve product efficacy and safety,” said Bronson Crouch, CEO of Instil Bio. “Although it was a difficult decision to discontinue the development of ITIL-168, this decision provides us the opportunity to accelerate the development of CoStAR and other novel technologies to enhance TIL therapies for patients. We are excited to resume dosing patients in the Phase 1 ITIL-306 study and anticipate providing initial data readouts next year.”

Strategic Update

Instil has prioritized development of its proprietary, genetically-engineered CoStAR-TIL programs, which are designed to boost the efficacy of T cells by providing potent synthetic costimulatory signals within the tumor microenvironment (TME). Instil’s lead CoStAR-TIL program, ITIL-306, is in a Phase 1 dose escalation trial in non-small cell lung cancer (“NSCLC”), ovarian cancer, and renal cell carcinoma, with the first patient dosed earlier this year (<https://ir.instilbio.com/news-releases/news-release-details/instil-bio-announces-first-patient-dosed-itil-306-our-first>). The Company expects to report data from the dose escalation cohorts of the Phase 1 ITIL-306 study in 2023.

Instil is undertaking a reduction in its U.S. workforce of approximately 60% to re-align its operating model from a registration-focused company to a development-stage company.

ITIL-168 Program Update

Instil is discontinuing its ITIL-168 clinical programs, the DELTA-1 trial in advanced melanoma and the DELTA-2 trial in NSCLC, cervical cancer, and head and neck squamous cell carcinoma. After an analysis of the potential scenarios to restart and complete a registration-enabling cohort in advanced melanoma in the DELTA-1 trial, the Company has decided to prioritize 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 enrollment in our ITIL-306 clinical trial and expectations concerning the availability of initial clinical data from such study and the timing thereof, 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, 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 Instil’s product candidates may otherwise not be effective treatments in their planned indications; the ongoing COVID-19 pandemic, which could materially and adversely affect Instil’s business and operations, including Instil’s ability to timely initiate, enroll and complete its 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 Instil’s cash resources; our ability to achieve the expected benefits of our corporate reorganization; 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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