
**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 9, 2023

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 8.01 Other Events.

On January 9, 2023, Instil Bio, Inc. (the “Company”) issued a press release entitled “Instil Bio Announces Resumption of Clinical Trial of CoStAR-TIL Candidate ITIL-306 in Lung, Ovarian, and Renal Cancer.” The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated January 9, 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 9, 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 Resumption of Clinical Trial of CoStAR-TIL Candidate ITIL-306 in Lung, Ovarian, and Renal Cancer

- Phase 1 trial of ITIL-306 in NSCLC, ovarian, and RCC re-opened to enrollment after voluntary pause
- Initial data readout for ITIL-306 expected in 2023
- With recent reprioritization of clinical programs and corporate restructuring, company expects cash runway into 2025, excluding potential financing or other monetization of Tarzana manufacturing site

DALLAS, TX, January 9, 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 the resumption of its Phase 1 clinical trial of ITIL-306 for the treatment of non-small cell lung cancer (NSCLC), ovarian cancer, and renal cell carcinoma (RCC).

With the resumption of the ITIL-306 Phase 1 study, the Company expects to release initial safety, translational, and efficacy data from dose escalation cohorts at a medical conference in 2023. The trial was resumed after the implementation of additional quality safeguards designed to further protect the manufacturing process from potential contaminants in reagents from external suppliers.

Following its recent reprioritization of clinical programs and corporate restructuring, Instil expects its cash runway to extend into 2025, excluding the potential financing or other monetization of its Tarzana manufacturing site. Instil intends to provide further updates on its pre-clinical pipeline in 2023, including the potential to nominate additional CoStAR candidates and novel TIL technologies for clinical development.

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, including potential nomination of additional CoStAR candidates and novel TIL technologies for clinical development and the timing 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, our cash runway, the anticipated financing or other monetization of our Tarzana, CA manufacturing facility 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 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; 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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