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): October 18, 2022

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 8.01 Other Events.

On October 18, 2022, Instil Bio, Inc. (the "Company") issued a press release entitled "Instil Bio Announces First Patient Dosed with ITIL-306, our First Engineered TIL Therapy Using the CoStAR Platform Targeting Folate Receptor Alpha (FRα), in Non-Small Cell Lung 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 October 18, 2022.

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.

Date: October 18, 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 First Patient Dosed with ITIL-306, our First Engineered TIL Therapy Using the CoStAR Platform Targeting Folate Receptor Alpha (FRα), in Non-Small Cell Lung Cancer

– *ITIL-306 is a novel TIL therapy engineered with our CoStAR platform (CoStAR-TIL) targeting folate receptor alpha which is designed to boost TIL activity in the tumor microenvironment*

– *CoStAR-T cells demonstrate enhanced proliferation and other effector function, which may increase TIL efficacy and eliminate the need for high-dose interleukin-2*

– *Patient with non-small cell lung cancer that is refractory to standard therapies is first to receive ITIL-306*

– *Initial clinical data from dose escalation cohorts expected in 2023*

DALLAS, TX, October 18, 2022 (GLOBE NEWSWIRE) Instil Bio, Inc. ("Instil") (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 that the first patient has been dosed in a Phase 1 dose escalation study of ITIL-306 (NCT05397093 https://www.clinicaltrials.gov/ct2/show/NCT05397093?term=instil+bio&draw=2&rank=2) for the treatment of multiple solid tumors. ITIL-306 is Instil's first genetically-engineered Costimulatory Antigen Receptor-TIL (CoStAR-TIL) therapy.

"The successful initiation of the Phase 1 study of ITIL-306 underscores our commitment to evolving TIL therapy, using strategies to enhance product efficacy and safety, with the goal to achieve durable remissions in patients with treatment-refractory solid tumors," said Bronson Crouch, Chief Executive Officer of Instil Bio.

Instil's first-in-human Phase 1 study of ITIL-306 is an open-label, multicenter study in patients with non-small cell lung cancer, ovarian cancer, and renal cell carcinoma. Patients in the first dose cohort will receive a target dose of one billion CoStAR-transduced TILs after receiving a reduced intensity lymphodepletion regimen and no post-infusion interleukin-2. The study will evaluate safety of ITIL-306 in addition to efficacy and translational endpoints. The company anticipates reporting initial clinical data from the Phase 1 trial in 2023.

ITIL-306 is an autologous TIL cell therapy engineered with a novel and proprietary CoStAR molecule that is activated by folate receptor alpha (FRα) to provide robust costimulatory signals within the tumor microenvironment. CoStAR builds on the key advantages of native TILs to enhance the cytokine release, cytolytic activity, and proliferation of TILs in the tumor microenvironment. Previously published preclinical data (https://instilbio.com/wp-content/uploads/2022/06/ASCO-2022_Moon_CoStAR-In-Vivo-Poster_16May2022.pdf) demonstrates the ability of CoStAR-T cells to enhance tumor control *in vivo* in the absence of exogenous IL-2, supporting a treatment regimen free of IL-2 in the Phase 1 study of ITIL-306.

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. The Company has assembled an accomplished management team with a successful track record in the development, manufacture, and

commercialization of cell therapies. Using the Company's proprietary, optimized, and scalable manufacturing processes at its in-house manufacturing facilities, Instil is advancing its lead TIL product candidate, ITIL-168, for the treatment of advanced melanoma and other solid tumors as well as 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, our goal of achieving durable remissions in patients with challenging and treatment-refractory solid tumors, the design of our Phase 1 study of ITIL-306, our 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, 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 June 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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