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): November 8, 2022

Instil Bio, Inc.

(Exact name of registrant as specified in its Charter)

Delaware001-4021583-2072195(State or Other Jurisdiction
of Incorporation)(Commission
File Number)(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 F	'orm 8-K filing is inte	ended to simultar	neously satisfy	the filing obligati	ion of the registran	t under any of the
following provisions (see General Instru	ctions A.2. below):					

IUII	owing provisions (see General Institutions 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)

 $\ \square$ 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).

F			
Emerging	growin	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. \Box

Item 8.01 Other Events.

On November 8, 2022, Instil Bio, Inc. (the "Company") issued a press release entitled "Instil Bio Announces Poster Presentations of CoStAR Platform at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting. "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 November 8, 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: November 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 Poster Presentations of CoStAR Platform at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting

DALLAS, TX, November 8, 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 poster presentations of pre-clinical data and trial-in-progress for the ongoing ITIL-306 Phase 1 clinical trial using the CoStimulatory Antigen Receptor (CoStAR) platform at the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), to be held from November 8-12, 2022.

Pre-clinical data demonstrating the activity of CoStAR across physiologically-relevant ranges of FR α expression and TCR affinity are featured in **Poster 282**. These data demonstrated that CoStAR amplified T-cell responses at all FR α expression levels as long as FR α was expressed, supporting the clinical exploration of ITIL-306 in multiple solid tumor types with a variety of FR α expression levels. Furthermore, CoStAR-expressing cells do not respond to FR α in the absence of TCR stimulation, underscoring the expected safety profile of the CoStAR platform. Currently, ITIL-306 is being evaluated in a first-in-human Phase 1 dose escalation clinical study for treatment of refractory solid tumors with the first patient dosed in October 2022.

The company also is presenting a trial-in-progress poster summarizing the design of the ongoing Phase 1 study of ITIL-306 (Poster 776). ITIL-306-201 is a Phase 1 multicenter, single-arm, dose escalation and expansion study evaluating the safety and feasibility of ITIL-306 in adult patients with advanced epithelial ovarian cancer (EOC), non-small cell lung cancer (NSCLC), and renal cell carcinoma (RCC) who relapsed from or are refractory to ≥1 prior line of systemic therapy. Importantly, the Phase 1 study of ITIL-306 features a treatment regimen free of high-dose interleukin-2.

Details of the poster presentations are as follows:

Title: Anti-folate receptor alpha (FR α) CoStimulatory Antigen Receptor (CoStAR) improves T-cell function across physiologically relevant ranges of FR α expression and T-cell receptor (TCR) affinities

Authors: Martina Sykorova, Michelle Mojadidi, Leyuan Bao, Eric Gschweng, Milena Kalaitsidou, Gray Kueberuwa, Xingliang (Tim) Zhou, Rubén Alvarez-Rodríguez, John S. Bridgeman

Poster/Abstract Number: 282

Title: ITIL-306-201: A multicenter, first-in-human phase 1a/1b study of ITIL-306, an engineered autologous tumor-infiltrating lymphocyte (TIL) cell therapy product, in adults with advanced solid tumors

Authors: Jeffrey Ward, Armin Ghobadi, John B. Liao, Adam Schoenfeld, Scott S. Tykodi, Yizhou Jiang, John Le Gall, Ruben Alvarez-Rodriguez, Marika Sherman, Tiffany Singson, Jeff McLeroy

Poster/Abstract Number: 776

The posters are available on the publications section of the Instil Bio website: www.instilbio.com/publications.

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 inhouse 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 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 the potential of our product candidates to positively impact quality of life and alter the course of disease in the patients we seek to treat, our research, development and regulatory plans for our product candidates, the timing of our ongoing and potential future clinical trials and studies and the availability of data therefrom, including our expectations concerning the clinical exploration of ITIL-306 in multiple solid tumor types with a variety of FRα expression levels, the expected safety profile of the CoStAR platform, 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, and 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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