
**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): May 18, 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 8.01 Other Events.

On May 18, 2022, Instil Bio, Inc. (the “Company”) issued a press release entitled “Instil Bio to Present Novel TIL Analytics at American Society of Gene and Cell Therapy (ASGCT)” 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated May 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: May 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 to Present Novel TIL Analytics at American Society of Gene and Cell Therapy (ASGCT)

Presentation to highlight correlates of response to TIL product attributes and elements of Instil Bio's cell therapy data analytics and computational platform

DALLAS, TX, May 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 results of genomic and correlative analyses in a cohort of patients with metastatic melanoma treated with TILs manufactured by Instil (ORR of 67% in 14/21 patients). All TIL products were analyzed using T-cell receptor (TCR) sequencing, RNA and protein expression, and correlated with patient demographic and historical treatment data. Results will be presented at an oral presentation at the American Society of Gene and Cell Therapy (ASGCT) 25th Annual Meeting.

"We believe that TILs represent more than a potential therapy for patients, as they are also a platform to understand fundamental T cell biology," said Bronson Crouch, Chief Executive Officer of Instil Bio. "We are applying the recent advances in analytical technologies to deeply probe the function of TILs, and expect to generate insights that could be foundational for the development of anti-cancer therapies."

In the presentation, a correlation between tumor response and clonal expansion of TILs is shown, as well as an inverse correlation between tumor response and specific T cell populations in the product. Expression profiling and transcriptional network analysis points to "master regulator" genes which can be manipulated during TIL manufacturing to enhance TIL activity.

"This correlative analysis is one of the most informative looks to date at T-cell product attributes that impact patient outcomes and underscores the power of single cell analytic approaches to inform our product and process development strategies," said Mark Dudley, Ph.D., Chief Scientific Officer of Instil Bio.

"We believe this is one of the first published single-cell analyses of TIL products provided to patients, and the identification of potential manipulations to enhance the efficacy of TILs exemplifies the sort of insights we hope to achieve using our cell therapy data analytics and computational platform."

Details of the oral presentation are as follows:

Title: Characterization of the Transcriptomic and T-Cell Receptor (TCR) Clonal Heterogeneity of Tumor-Infiltrating Lymphocyte (TIL) Therapy Infusion Products by Single-Cell Sequencing and Correlative Analyses with Clinical Efficacy in Patients with Advanced Cutaneous Melanoma

Session Type: Oral Abstract

Session Title: Cell-based Cancer Immunotherapies II

Location: Salon G

Date & Time: Wednesday May 18, 2022, 3:45 – 4:00 pm EDT

Abstract Number: 847

Full abstracts are available on the ASGCT conference website <https://annualmeeting.asgct.org/>

About Instil Bio

Instil Bio, Inc. (Nasdaq: TIL) is a clinical-stage biopharmaceutical company focused on developing tumor infiltrating lymphocyte, or (TIL), therapies for the treatment of patients with cancer. Instil has assembled an accomplished management team with a successful track record in the development, manufacture, and commercialization of cell therapies. Using Instil'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 using the CoStAR platform for multiple solid tumors. For more information visit www.instilbio.com.

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,” “expects,” “future,” “intends,” “target,” and “will,” or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying the therapeutic potential of our product candidates; 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 completion of enrollment of, and availability of top-line data from, our DELTA-1 clinical trial, the initiation of our DELTA-2 clinical trial in certain indications, the initiation of a Phase 1 study of ITIL-306; the potential for us to make submissions concerning, and for our product candidates to receive, regulatory approval from the FDA or equivalent foreign regulatory agencies and whether, if approved, these product candidates will be successfully distributed and marketed; the adequacy of our cash resources and our expected cash runway; 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 pre-clinical studies or 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; additional regulatory risks associated with developing our product candidates for use in combination with other therapies or third-party product candidates; risks inherent in the 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 Annual Report on Form 10-K for the year ended December 31, 2021 available on the SEC’s website at www.sec.gov, and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the SEC. 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.

Contacts:

Investor Relations

1-972-499-3350

investorrelations@instilbio.com

www.instilbio.com

Janhavi Mohite

Stern Investor Relations

1-212-362-1200

janhavi.mohite@sternir.com