

**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 26, 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 October 26, 2022, Instil Bio, Inc. (the “Company”) notified the U.S. Food and Drug Administration (“FDA”) and other regulatory agencies that it has voluntarily paused enrollment in DELTA-1, the Company’s Phase 2 clinical trial of ITIL-168 in patients with advanced melanoma. No regulatory agencies, including the FDA, have notified the Company of a clinical hold in any of its clinical trials. The voluntary pause by the Company was instituted following a recent decrease in the rate of successful manufacturing of ITIL-168, resulting in the inability to dose some patients whose individual product of ITIL-168 was not successfully manufactured. A pre-specified safety analysis in the DELTA-1 trial has been conducted on patients who received ITIL-168 and did not identify any unexpected safety issues. The Company has commenced an end-to-end analysis of its manufacturing processes and upon completion of this analysis, plans to take corrective actions to improve the rate of manufacturing success and resume the study. In addition, the Company announced that it has voluntarily paused enrollment in DELTA-2, the Company’s Phase 1 study of ITIL-168 with pembrolizumab in patients with solid tumors. Although no manufacturing failures have been observed to date in the ongoing Phase 1 trial of ITIL-306, the Company has also voluntarily paused enrollment in this trial as part of its overall manufacturing analysis. The Company intends to provide an update on the manufacturing analysis by early Q1 2023.

Forward-Looking Statements

This Current Report on Form 8-K 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 Company’s pipeline of potential therapies, the Company’s investigation into manufacturing processes of ITIL-168 and the related corrective actions, future updates about the Company’s DELTA-1, DELTA-2 and ITIL-306 clinical trials 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 the Company’s product candidates may otherwise not be effective treatments in their planned indications; the ongoing COVID-19 pandemic, which could materially and adversely affect the Company’s business and operations, including the Company’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 the Company’s cash resources, and other risks and uncertainties affecting the Company and its development programs, including those discussed in the section titled “Risk Factors” in the Company’s 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 the Company makes 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 the Company disclaims any obligation to update these statements except as may be required by law.

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: October 31, 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)