
**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): August 14, 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 2.02 Results of Operations and Financial Condition.

On August 14, 2023, Instil Bio, Inc. (the “Company”) provided a corporate update and announced its financial results for the quarter ended June 30, 2023 in the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated August 14, 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: August 14, 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 Reports Second Quarter 2023 Financial Results and Provides Corporate Update

ITIL-306, first CoStAR-TIL in clinical development, anticipated to start clinical trial ITIL-306-202 in 2H 2023

Initial data from ITIL-306-202 clinical trial anticipated in 2024

ITIL-306 operational in Manchester, UK manufacturing facility with additional process improvements

DALLAS, TX, August 14, 2023 (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 reported its second quarter 2023 financial results and provided a corporate update.

“Successful manufacturing of ITIL-306 in our Manchester, UK facility is a major milestone on our path to clinical development of ITIL-306,” said Mark Dudley, Chief Scientific Officer of Instil Bio. “We have implemented improvements to the manufacturing process of ITIL-306 that were shown to result in a doubling of the number of CoStAR-TILs in the final product, which we believe could be meaningful for the therapeutic profile of ITIL-306 in patients with advanced cancer.”

Second Quarter 2023 Highlights and Anticipated Milestones:

- **ITIL-306, first CoStAR-TIL in clinical development, anticipated to start clinical trial ITIL-306-202 in 2H 2023:** Instil anticipates initiating phase 1 clinical trial ITIL-306-202 with an updated trial design versus ITIL-306-201; the ITIL-306-202 trial design has received positive initial feedback from the Medicines and Healthcare products Regulatory Agency, or MHRA in the United Kingdom. Instil expects Clinical Trial Application, or CTA, clearance from the MHRA in the second half of 2023 and initial clinical data from the ITIL-306-202 clinical trial in 2024.
- **ITIL-306 operational in Manchester, UK manufacturing facility:** Instil has successfully established ITIL-306, including multiple successful verification runs, in its Manchester, UK manufacturing facility. Instil has designed and implemented manufacturing process improvements that resulted in a doubling of the final yield of CoStAR-TILs from verification runs.
- **Cash runway beyond 2026:** Instil Bio confirms its previous guidance of cash runway beyond 2026.

Second Quarter 2023 Financial and Operating Results:

As of June 30, 2023, Instil had cash, cash equivalents, restricted cash and marketable securities of \$202.9 million, which consists of \$21.8 million in cash and cash equivalents, \$1.2 million in restricted cash and \$179.9 million in marketable securities, compared to \$260.9 million in total cash and cash equivalents and marketable securities, consisting of \$43.7 million in cash and cash equivalents and \$217.2 million in marketable securities as of December 31, 2022. Instil expects that its cash, cash equivalents and marketable securities as of June 30, 2023 will enable it to fund its operating plan beyond 2026.

Research and development expenses were \$8.5 million and \$29.1 million for the three and six months ended June 30, 2023, respectively, compared to \$41.5 million and \$80.7 million for the three and six months ended June 30, 2022, respectively.

General and administrative expenses were \$11.5 million and \$24.7 million for the three and six months ended June 30, 2023, respectively, compared to \$17.2 million and \$32.3 million for the three and six months ended June 30, 2022, respectively.

Restructuring and impairment charges were \$1.0 million and \$25.6 million for the three and six months ended June 30, 2023, respectively.

INSTIL BIO, INC.
SELECTED FINANCIAL DATA
(Unaudited; in thousands, except share and per share amounts)

Selected Balance Sheet Data

	June 30, 2023	December 31, 2022
Cash, cash equivalents, restricted cash and marketable securities	\$ 202,860	\$ 260,920
Total assets	\$ 408,310	\$ 482,128
Total liabilities	\$ 111,794	\$ 118,523
Stockholders' equity	\$ 296,516	\$ 363,605

Statements of Operations
(Unaudited; in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 8,459	\$ 41,500	\$ 29,129	\$ 80,674
General and administrative	11,518	17,224	24,740	32,336
Restructuring and impairment charges	1,010	—	25,564	—
Total operating expenses	20,987	58,724	79,433	113,010
Loss from operations	(20,987)	(58,724)	(79,433)	(113,010)
Interest income	2,287	486	4,358	583
Interest expense	(590)	(331)	(1,226)	(331)
Other income (expense), net	628	(1,032)	571	(1,448)
Loss before income tax benefit	(18,662)	(59,601)	(75,730)	(114,206)
Income tax benefit	—	609	—	1,097
Net loss	\$ (18,662)	\$ (58,992)	\$ (75,730)	\$ (113,109)
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.46)	\$ (0.58)	\$ (0.88)
Weighted-average shares used in computing net loss per share, basic and diluted	130,079,097	129,367,833	130,079,097	129,244,334

Note Regarding Use of Non-GAAP Financial Measures

In this press release, Instil Bio has presented certain financial information that has not been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). These non-GAAP financial measures include non-GAAP net loss and non-GAAP net loss per share, which are defined as net loss and net loss per share, respectively, excluding non-cash stock-based compensation expense. Instil Bio believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of Instil Bio’s financial performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of Instil Bio’s operating results. In addition, these non-GAAP financial measures are among the indicators Instil Bio’s management uses for planning purposes and to measure Instil Bio’s performance. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The non-GAAP financial measures used by Instil Bio may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies. Please refer to the below reconciliation of these non-GAAP financial measures to the comparable GAAP financial measures.

INSTIL BIO, INC.
Reconciliation of GAAP to Non-GAAP Net Loss
(Unaudited; in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	\$ (18,662)	\$ (58,992)	\$ (75,730)	\$ (113,109)
Adjustments:				
Non-cash stock-based compensation expense	4,413	8,323	8,943	15,816
Non-GAAP net loss	\$ (14,249)	\$ (50,669)	\$ (66,787)	\$ (97,293)
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.46)	\$ (0.58)	\$ (0.88)
Adjustments:				
Non-cash stock-based compensation expense per share	0.03	0.06	0.07	0.12
Non-GAAP net loss per share, basic and diluted*	\$ (0.11)	\$ (0.40)	\$ (0.51)	\$ (0.76)
Weighted-average shares outstanding, basic and diluted	130,079,097	129,367,833	130,079,097	129,244,334

* Non-GAAP net loss per share, basic and diluted may not total due to rounding.

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. Instil has assembled an accomplished management team with a successful track record in the research, development and manufacture of cell therapies. Using its proprietary and optimized manufacturing processes at its in-house manufacturing facilities, Instil is developing a novel class of genetically engineered TIL therapies using its Co-Stimulatory Antigen Receptor, or CoStAR™, platform, including 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,” “believes,” “expects,” “future,” “intends,” “plans,” “potential,” “projects,” 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, including our expectations of CTA clearance from the MHRA, the timing of our ongoing and potential future clinical trials and studies and the availability and presentation of data therefrom, including our expectations concerning the initiation of, and timing of updates on, our ITIL-306 clinical trial in the United Kingdom, the potential for us to make submissions concerning, and for our product candidates to receive, regulatory approval from the FDA, MHRA or equivalent foreign regulatory agencies and whether, if approved, these product candidates will be successfully distributed and marketed, 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; macroeconomic conditions, including as a result of the conflict between Russia and Ukraine, interest rates, inflation, bank failures and other factors, 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 and the risk that Instil's manufacturing process improvements do not ultimately result in enhancements to its product candidates; 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" Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 available on the SEC's website at www.sec.gov, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 to be filed with the SEC. Additional information will be made available in other filings that we make from time to time with the SEC. 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 the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

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