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 15, 2021

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 2.02 Results of Operations and Financial Condition.

On November 15, 2021, Instil Bio, Inc. (the "Company") provided a corporate update and announced its financial results for the quarter ended September 30, 2021 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

Exhibit No.	Description
99.1	Press release, dated November 15, 2021
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: November 15, 2021

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 Third Quarter 2021 Financial Results and Provides Corporate Update

– *Patients enrolled and recruitment ongoing in Phase 2 trial of ITIL-168 in melanoma (DELTA-1)*
– *Fast Track Designation granted by FDA for ITIL-168 in metastatic melanoma*
– *CoStAR mechanism of action data presented at SITC 2021*
– *Successful pre-IND meeting for ITIL-306*

DALLAS, TX, November 15, 2021 (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 third quarter 2021 financial results and provided a corporate update.

"We have achieved key milestones in our continued development of ITIL-168 with clearance of our IND for the DELTA-1 study, Fast Track Designation approval and initiation of enrollment in DELTA-1," said Bronson Crouch, Chief Executive Officer of Instil. "Our progress in establishing a platform for cell therapy continues with the expansion of our UK clinical manufacturing capabilities which are on track to reach an annual capacity of over 200 lots by year end 2021 as well as with US clinical manufacturing coming online next year. With this added capacity, we expect to initiate additional trials in the months ahead as we progress both ITIL-168 and ITIL-306, our first genetically-engineered CoStAR-TIL."

Third Quarter 2021 Highlights and Recent Corporate Updates:

Clinical Development:

- **Received IND Clearance from the FDA to Initiate DELTA-1, a Phase 2 Clinical Trial for Patients with Advanced Melanoma:** On September 13, 2021, Instil reported clearance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) to initiate DELTA-1, a global Phase 2 clinical trial of ITIL-168 with registrational intent in patients with advanced melanoma. The DELTA-1 trial was expanded during the IND review process in consultation with FDA to include additional populations of patients with advanced melanoma, including patients who discontinued PD-1 inhibitor therapy due to intolerable toxicity and patients who had an unsatisfactory response to prior PD-1 inhibitor.

- **Initiated enrollment in DELTA-1:** Instil reported that patients have been enrolled and recruitment is ongoing into the pivotal study. Enrollment for Cohort 1 is expected to be completed within 12 months, with Cohorts 2 and 3 finishing enrollment thereafter. Instil expects top-line data and BLA filing submission in 2023 and a European Medicines Agency (EMA) marketing authorization application (MAA) filing in 2024.

- **ITIL-168 in Advanced Melanoma Granted FDA Fast Track Designation:** Instil was recently granted Fast Track Designation from the U.S. FDA for ITIL-168 in advanced melanoma. Fast Track designation confers certain benefits on the development process, including more frequent communications with the FDA and potential eligibility for accelerated approval and priority review.

- **Readiness to Initiate DELTA-2 in H1 2022:** Preparations are on track to initiate enrollment in DELTA-2, a Phase 1 study of ITIL-168 in non-small cell lung cancer (NSCLC), head and neck squamous cell carcinoma (HNSCC), cervical cancer, and cutaneous squamous cell carcinoma (CSCC). Enrollment in DELTA-2 is planned to initiate in H1 2022.

- **Presented Clinical Data in Advanced Cutaneous Melanoma at ESMO:** Instil presented a subset analysis of treatment outcomes with TILs in 12 patients with checkpoint inhibitor-refractory advanced cutaneous melanoma, demonstrating a 58% objective response rates and median overall survival of 21.3 months; all patients in the subset analysis had experienced disease progression following treatment with a PD-1 inhibitor and CTLA-4 inhibition with ipilimumab.

Manufacturing and Technical Operations:

- **Clinical Manufacturing Readiness:** U.K. manufacturing capacity remains on track for regulatory approval of the additional IMPACT manufacturing suite in Q4 2021, which will approximately triple the current U.K. manufacturing capacity. U.S. clinical manufacturing in Tarzana, CA remains on track for launch of clinical manufacturing in H1 2022, with qualification ongoing.

Research:

- **Appointed Mark Dudley, Ph.D. as Head of Research:** Instil has appointed Mark Dudley, Ph.D. as Head of Research. Prior to Instil, Dr. Dudley led early development of T cell therapies at Adaptimmune Therapeutics plc, and before that was on the technical R&D leadership team at Novartis. Before Novartis, Dr. Dudley spent nearly two decades at the Surgery Branch of the National Cancer Institute, where he contributed to a diverse portfolio of experimental T cell therapies, including TIL, TCR-T, and CAR-T products. Dr. Dudley is a recognized pioneer in adoptive cell therapy, having published seminal studies in TIL therapy for refractory melanoma patients, and the first studies of CD19 CAR-T in humans, IL-2 and IL-12 genetically engineered T cells in clinical trials, and TCR-T cells in clinical trials.

- **Successful Pre-IND Meeting with FDA on First-in-Human Study of ITIL-306:** Instil Bio recently completed a pre-IND meeting with the FDA for the proposed first-in-human Phase 1 study of ITIL-306, a TIL product genetically engineered to express a Costimulatory Antigen Receptor (CoStAR) molecule, to gain alignment on nonclinical, manufacturing, and clinical aspects of the program. The company expects initiate a Phase 1 study of ITIL-306 in multiple cancer indications in H1 2022.

- **Presented Pre-clinical Data on the CoStAR Platform at SITC:** Instil presented posters highlighting pre-clinical data from the CoStAR platform which demonstrated that CoStAR expression by T cells led to marked enhancement of effector function and proliferation of T cells and TILs. The novel design of CoStAR, which includes two intracellular costimulatory domains derived from CD28 and CD40, showed significantly improved activity compared to a CoStAR that contained only a CD28 domain, demonstrating the superiority of CD40-containing CoStAR molecules and important synergies of CD40 and CD28 signaling. Further details can be found in the poster publications available here https://instilbio.com/publications/ .

Third Quarter 2021 Financial and Operating Results:

As of September 30, 2021, we had $20.4 million in cash and cash equivalents and $495.0 million in marketable securities, compared to $241.7 million in cash and cash equivalents and no investments in marketable securities as of December 31, 2020. The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2021 will enable it to fund its operating plan into 2023.

Research and development expenses were $29.1 million and $64.7 million for the three and nine months ended September 30, 2021, compared to $4.9 million and $9.2 million for the three and nine months ended September 30, 2020.

General and administrative expenses were $14.0 million and $37.1 million for the three and nine months ended September 30, 2021, compared to $2.9 million and $7.2 million for the three and nine months ended September 30, 2020.

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

Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ —	$ 52	$ —	$ 138
Operating expenses:				
Research and development	29,064	4,908	64,674	9,152
General and administrative	13,960	2,855	37,134	7,153
Total operating expenses	43,024	7,763	101,808	16,305
Loss from operations	(43,024)	(7,711)	(101,808)	(16,167)
Interest and other (expense) income, net	(639)	449	(657)	(4,386)
Loss before income tax benefit	$ (43,663)	$ (7,262)	$ (102,465)	$ (20,553)
Income tax benefit	658	—	1,021	—
Net loss	$ (43,005)	$ (7,262)	$ (101,444)	$ (20,553)
Net loss per share, basic and diluted	$ (0.33)	$ (0.43)	$ (1.03)	$ (1.32)
Weighted-average shares used in computing net loss per share, basic and diluted	128,794,142	16,928,831	98,256,027	15,616,389

Selected Balance Sheet Data

	September 30, 2021	**December 31, 2020**
Cash, cash equivalents and marketable securities	$ 515,358	$ 241,714
Total assets	647,397	319,012
Total liabilities	45,977	26,645
Convertible preferred stock and stockholders' equity (deficit)	601,420	292,367

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. 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,” “intends,” “projects,” and “future” 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 the availability of data therefrom, the potential for our product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, whether, if approved, these product candidates will be successfully distributed and marketed, our plans to expand clinical manufacturing capabilities, and the potential benefits of orphan drug designation to ITIL-168, the adequacy of our cash resources, 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. 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. Risks regarding our business are described in detail in our Securities and Exchange Commission (“SEC”) filings, including in our prospectus dated March 18, 2021, as filed with the SEC on March 22, 2021, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, and the section titled “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 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. 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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