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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 13, 2021

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**Instil Bio, Inc.**  
(Exact name of registrant as specified in its Charter)

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**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)

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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:**

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 May 13, 2021, Instil Bio, Inc. (the “Company”) provided a corporate update and announced its financial results for the quarter ended March 31, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press release, dated May 13, 2021.</a>
104	The cover page of this report has been formatted in Inline XBRL.



## Instil Bio Reports First Quarter 2021 Financial Results and Provides Corporate Update

*IPO in March 2021 raising \$368M in gross proceeds*

*Received orphan drug designation from the U.S. FDA for lead product candidate ITIL-168*

**DALLAS, TX, May 13, 2021 (GLOBE NEWSWIRE)** Instil Bio, Inc. (“Instil”) (NASDAQ: TIL), a clinical-stage biopharmaceutical company developing tumor infiltrating lymphocytes, or TIL, therapies for the treatment of patients with cancer, today reported its first quarter 2021 financial results and provided a corporate update.

“In March of 2021, Instil completed an initial public offering to support the development of our TIL therapies. We believe that our continued investment in cell manufacturing and process science will enable the development of our current and future product candidates, with a goal of providing broad patient access,” said Bronson Crouch, Chief Executive Officer of Instil. “We recently presented clinical data from our compassionate use program at the AACR conference and received orphan drug designation from the U.S. Food and Drug Administration for ITIL-168 in melanoma. We continue to advance ITIL-168 towards a potentially registration-enabling Phase 2 clinical trial in advanced melanoma, which we expect to initiate in the second half of this year.”

### First Quarter 2021 Highlights and Upcoming Anticipated Milestones

#### Corporate:

- **Completed Initial Public Offering:** On March 23, 2021, Instil closed its initial public offering of 18,400,000 shares of common stock, including the full exercise of the underwriters’ option to purchase an additional 2,400,000 shares of common stock at the public offering price of \$20.00 per share. The gross proceeds of the offering were \$368 million, before underwriting discounts and commissions and other offering expenses payable by Instil. The Company’s common stock now trades on the Nasdaq Global Select Market under the symbol “TIL.”

#### Clinical and Regulatory:

- **Orphan Drug Designation for ITIL-168:** On April 27, 2021 Instil received orphan drug designation from the U.S. Food and Drug Administration for the treatment of melanoma stages IIB to IV for its ITIL-168 TIL product candidate.
- **American Association for Cancer Research (AACR) Virtual Annual Meeting:** Presented late-breaking e-Poster on clinical data from a compassionate use program for the treatment of metastatic melanoma at the AACR virtual meeting April 10 – 15, 2021.
- **Upcoming Phase 2 Clinical Trial:** Instil expects to initiate a Phase 2 clinical trial of ITIL-168 for the treatment of advanced melanoma and begin enrolling patients in the second half of 2021.

**Manufacturing:**

- **Facility Readiness for Clinical Trials:** Manufacturing facilities in the United Kingdom are functional and ready to support clinical manufacturing for the upcoming ITIL-168 clinical trial, with additional capacity expected to come online later this year. Instil also expects U.S. clinical manufacturing to be online in the first half of 2022.

**First Quarter 2021 Financial and Operating Results:**

As of March 31, 2021, cash and cash equivalents totaled \$609.6 million, compared to \$241.7 million as of December 31, 2020. The Company expects that its cash and cash equivalents as of March 31, 2021 will enable it to fund its operating plan into 2023.

Research and development expenses for the three months ended March 31, 2021 were \$14.4 million, compared to \$2.0 million for the same period in 2020.

General and administrative expenses for the three months ended March 31, 2021 were \$9.0 million, compared to \$1.9 million for the same period in 2020.

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

**Statements of Operations**

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
Revenue	\$ —	\$ 44
Operating expenses:		
Research and development	14,424	2,007
General and administrative	8,979	1,900
Total operating expenses	23,403	3,907
Loss from operations	(23,403)	(3,863)
Interest and other income (expense), net	71	(226)
Loss before income tax expense	\$ (23,332)	\$ (4,089)
Income tax benefit	204	—
Net loss	\$ (23,128)	\$ (4,089)
Net loss per share, basic and diluted	\$ (0.66)	\$ (0.31)
Weighted-average shares used in computing net loss per share, basic and diluted	34,976,652	12,997,353

### Selected Balance Sheet Data

	<b>March 31, 2021</b>	<b>December 31, 2020</b>
Cash and cash equivalents	\$ 609,639	\$ 241,714
Total assets	696,142	319,012
Total liabilities	30,989	26,645
Total stockholders' equity (deficit)	665,153	(39,599)

### 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](http://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 potential for these 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, and the potential benefits of orphan drug designation to ITIL-168. 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, which is available on the SEC's website at [www.sec.gov](http://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.

**Contacts:**

**Investor Relations Contact:**

**Brendan Payne**

**Stern Investor Relations**

**1-972-499-3350**

[investor.relations@instilbio.com](mailto:investor.relations@instilbio.com)

[www.instilbio.com](http://www.instilbio.com)

**Media Contact:**

**1-833-446-7845 Ext. 1009**

[mediarelations@instilbio.com](mailto:mediarelations@instilbio.com)

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