Instil Bio Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 11, 2023

ITIL-306 phase 1 study anticipated to receive CTA clearance from UK MHRA in 2H 2023

Anticipate initial clinical data from ITIL-306 phase 1 program in 2024

Cash runway beyond 2026

DALLAS, May 11, 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 first quarter 2023 financial results and provided a corporate update.

First Quarter 2023 Highlights and Anticipated Milestones:

- **ITIL-306 phase 1 study in UK anticipated to initiate in 2H’2023** : Instil has recently received positive initial feedback from the Medicines and Healthcare products Regulatory Agency, or MHRA, on the proposed study design for the phase 1 dose escalation study of ITIL-306 in the United Kingdom, and anticipates initiating such study in the second half of 2023 following anticipated Clinical Trial Application, or CTA, clearance from the MHRA. Instil expects to report initial clinical data from the ITIL-306 program in 2024.
- **Instil confirms cash runway beyond 2026 with consolidation of R&D operations to the UK**: In January 2023, the Company announced the consolidation of the Phase 1 clinical trial and related manufacturing of CoStAR-TIL™ to its active operations in Manchester, UK leading to an extension of the expected cash runway to beyond 2026. Instil’s Manchester, UK operations have extensive experience in the manufacture and development of TIL and other cell therapies since 2011. Instil continues to pursue a potential lease or sale of its manufacturing facility in Tarzana, California. Under the current operating plan, starting in the second half of 2023, Instil expects quarterly cash burn of less than $10 million through the end of 2024.

First Quarter 2023 Financial and Operating Results:

As of March 31, 2023, Instil had cash, cash equivalents, restricted cash and marketable securities of $223.9 million, which consists of $27.4 million in cash and cash equivalents, $0.7 million in restricted cash and $195.8 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 March 31, 2023 will enable it to fund its operating plan beyond 2026.

Research and development expenses were $20.7 million for the three months ended March 31, 2023, compared to $39.2 million for the three months ended March 31, 2022.

General and administrative expenses were $13.2 million for the three months ended March 31, 2023, compared to $15.1 million for the three months ended March 31, 2022.

Restructuring and impairment charges were $24.6 million for the three months ended March 31, 2023.

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

Selected Balance Sheet Data

	March 31, 2023	December 31, 2022
Cash, cash equivalents, restricted cash and marketable securities	$ 223,870	$ 260,920
Total assets	$ 427,172	$ 482,128
Total liabilities	$ 116,018	$ 118,523
Stockholders’ equity	$ 311,154	$ 363,605

Statements of Operations

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 20,670	$ 39,174
General and administrative	13,222	15,112
Restructuring and impairment charges	24,554	—
Total operating expenses	58,446	54,286
Loss from operations	(58,446)	(54,286)
Interest income	2,071	97
Interest expense	(636)	—
Other expense, net	(57)	(416)
Loss before income tax expense	(57,068)	(54,605)
Income tax benefit	—	488
Net loss	$ (57,068)	$ (54,117)
Net loss per share, basic and diluted	$ (0.44)	$ (0.42)
Weighted-average shares used in computing net loss per share, basic and diluted	130,079,097	129,119,462

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 March 31,	
	2023	2022
Net loss	$ (57,068)	$ (54,117)
Adjustments:		
Non-cash stock-based compensation expense	4,530	7,493
Non-GAAP Net loss	$ (52,538)	$ (46,624)
Net loss per share, basic and diluted	$ (0.44)	$ (0.42)
Adjustments:		
Non-cash stock-based compensation expense per share	0.03	0.06
Non-GAAP net loss per share, basic and diluted*	$ (0.41)	$ (0.36)
Weighted-average shares outstanding, basic and diluted	130,079,097	129,119,462

* 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, the anticipated sale or lease of our Tarzana, California manufacturing facility, our

cash runway and quarterly cash burn, 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 ongoing COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, 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; 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, 2022 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, 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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