Instil Bio Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 16, 2022

- *Targeting completion of enrollment in registrational cohort of DELTA-1 in 2022*
- *Presenting preclinical efficacy and safety data of CoStAR platform at ASCO 2022*
- *Cash runway into 2024 through key clinical data expected in 2023*

DALLAS, May 16, 2022 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (“Instil” or the “Company”) (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 2022 financial results and provided a corporate update.

First Quarter 2022 Highlights and Anticipated Milestones:

- **Enrollment Ongoing in DELTA-1, a Phase 2 trial of ITIL-168 in advanced melanoma with registrational intent:** Instil is targeting completion of enrollment by 2022 for the registrational cohort and expects top-line safety and efficacy data in 2023, which could potentially support a biologics license application (BLA) submission and a European Medicines Agency marketing authorization application (MAA) filing.

- **On track with DELTA-2, a Phase 1 trial of ITIL-168 with pembrolizumab in additional cancers with unmet need:** Study is expected to initiate in non-small cell lung cancer (NSCLC), cervical cancer and squamous cell carcinoma of head and neck (HNSCC) in the second quarter of 2022. The study will evaluate ITIL-168 with pembrolizumab in patients who have failed standard therapies.

- **Readiness to Initiate Phase 1 Study of ITIL-306, the first product candidate from the CoStAR platform, in the second quarter:** Instil is on track to initiate a Phase 1 study of ITIL-306, its first genetically engineered TIL using the CoStAR platform in the second quarter of 2022.

- **Presenting Preclinical Data on the CoStAR Platform at ASCO 2022**: Instil plans to present in vivo and supporting in vitro data at the 2022 ASCO Annual Meeting. Abstract details are below:

  Title: *Antitumor activity of T cells expressing a novel anti-folate receptor alpha (FOLR1) costimulatory antigen receptor (CoStAR) in a human xenograft murine solid tumor model and implications for in-human studies.*

- **Presenting Product Characterization Data From Unmodified TILs in Cutaneous Melanoma:** Instil plans to present advanced correlative analyses on TIL products administered to patients in a compassionate use program at the 25th Annual ASGCT meeting. Abstract details are below:

  Title: Characterization of the Transcriptomic and TCR Clonal Heterogeneity of TIL Therapy Infusion Products by Single-Cell Sequencing and Correlative Analyses With Clinical Efficacy in Patients with Advanced Cutaneous Melanoma. ASGCT link.

- **Cash Runway Into 2024 through key clinical data expected in 2023:** Instil expects its current cash reserves to fund Company operations into 2024.

First Quarter 2022 Financial and Operating Results:

As of March 31, 2022, we had $61.5 million in cash and cash equivalents and $318.0 million in marketable securities, compared to $37.6 million in cash and cash equivalents and $416.5 million in marketable securities as of December 31, 2021. The Company expects that its cash, cash equivalents and marketable securities as of March 31, 2022, will enable it to fund its operating plan into 2024.

Research and development expenses were $39.2 million for the three months ended March 31, 2022, compared to $14.4 million for the three months ended March 31, 2021.

General and administrative expenses were $15.1 million for the three months ended March 31, 2022, compared to $9.0 million for the three months ended March 31, 2021.

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

Selected Balance Sheet Data

	March 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 379,520	$ 454,099
Total assets	$ 564,936	$ 609,983
Total liabilities	$ 56,377	$ 54,784
Stockholders' equity	$ 508,559	$ 555,199

Statements of Operations

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 39,174	$ 14,424
General and administrative	15,112	8,979
Total operating expenses	54,286	23,403
Loss from operations	(54,286)	(23,403)
Other (expense) income, net	(319)	71
Loss before income tax benefit	(54,605)	(23,332)
Income tax benefit	488	204
Net loss	$ (54,117)	$ (23,128)
Net loss per share, basic and diluted	$ (0.42)	$ (0.66)
Weighted-average shares used in computing net loss per share, basic and diluted	129,119,462	34,976,652

Note Regarding Use of Non-GAAP Financial Measures

Instil Bio provides non-GAAP net loss and non-GAAP net loss per share that include adjustments to U.S. Generally Accepted Accounting Principles (GAAP) figures. These adjustments to GAAP net loss exclude 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 measuring 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 below for a 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,	
	2022	2021
Net loss—GAAP	$ (54,117)	$ (23,128)
Adjustments:		
Non-cash stock-based compensation expense	7,493	2,812
Net loss—Non-GAAP	$ (46,624)	$ (20,316)
Net loss per share, basic and diluted—GAAP	$ (0.42)	$ (0.66)
Adjustments:		
Non-cash stock-based compensation expense per share	0.06	0.08
Net loss per share, basic and diluted—Non-GAAP	$ (0.36)	$ (0.58)
Weighted-average shares outstanding, basic and diluted	129,119,462	34,976,652

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. Instil has assembled an accomplished management team with a successful track record in the development,

manufacture, and commercialization of cell therapies. Using Instil'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 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," "expects," "future," "intends," "target," 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; the timing of our ongoing and potential future clinical trials and studies and the availability of data therefrom, including our expectations concerning the completion of enrollment of, and availability of top-line data from, our DELTA-1 clinical trial, the initiation of our DELTA-2 clinical trial in certain indications, the initiation of a Phase 1 study of ITIL-306;, the potential for us to make submissions concerning, and for our product candidates to receive, regulatory approval from the FDA or equivalent foreign regulatory agencies and whether, if approved, these product candidates will be successfully distributed and marketed; the adequacy of our cash resources and our expected cash runway; 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 pre-clinical studies or 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; the ongoing COVID-19 pandemic, 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; additional regulatory risks associated with developing our product candidates for use in combination with other therapies or third-party product candidates; risks inherent in the 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, 2021 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, 2022 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. 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 we disclaim any obligation to update these statements except as may be required by law.

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