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

August 12, 2022

Cash runway expected to extend from 2024 into 2025 upon completion of anticipated sale-leaseback of Tarzana, CA manufacturing site

DELTA-1 trial of ITIL-168 in advanced melanoma with registrational intent anticipated to complete enrollment in 1H 2023 with top-line clinical data expected in early 2024

Phase 1 study initiated for ITIL-306, Instil's first CoStAR-TIL product candidate

Phase 1 study initiated for ITIL-168 in combination with pembrolizumab (DELTA-2) for NSCLC, cervical cancer, and squamous cell carcinoma of the head and neck

DALLAS, Aug. 12, 2022 (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 2022 financial results and provided a corporate update.

Second 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 in 1H 2023 for the registrational cohort and expects top-line safety and efficacy data in early 2024, which could potentially support a biologics license application (BLA) submission and a European Medicines Agency marketing authorization application (MAA) filing.

- **Cash runway expected to extend from 2024 into 2025 with anticipated sale-leaseback of Tarzana, CA manufacturing site:** Instil expects its current cash reserves along with expected proceeds from a potential sale-leaseback of its Tarzana, CA, manufacturing site to fund Company operations into 2025.

- **Enrolling Phase 1 study of ITIL-306, Instil's first CoStAR-TIL:** Instil has initiated a Phase 1 study of ITIL-306, its first CoStAR-TIL product candidate. CoStAR is a genetic modification designed to enhance the activity of TILs within the tumor microenvironment. The Phase 1 study of ITIL-306 features a TIL treatment regimen free of IL-2 and will enroll patients with non-small cell lung cancer (NSCLC), ovarian cancer (OC), and renal cell carcinoma (RCC).

- **Initiated DELTA-2, a Phase 1 study of ITIL-168 in combination with pembrolizumab:** Instil has initiated DELTA-2, a Phase 1 study of ITIL-168 in combination with pembrolizumab, which will enroll patients with NSCLC, cervical cancer, and squamous cell carcinoma of the head and neck.

- **Tarzana, CA manufacturing facility operational:** Instil was cleared by the US Food and Drug Administration (FDA) for manufacturing of both ITIL-168 and ITIL-306 at its Tarzana, CA manufacturing facility, which will support DELTA-1, DELTA-2, and ITIL-306 clinical trials.

- **Presented Preclinical Data on CoStAR T cells at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting:** Instil presented findings from preclinical studies evaluating anti-FOLR1 CoStAR T cells *in vitro* as well as a murine solid tumor model *in vivo* demonstrating enhanced T cell function and tumor control by CoStAR-modified T cells.

  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.*

- **Presented Product Characterization Data from Unmodified TILs in Cutaneous Melanoma at the American Society of Gene and Cell Therapy (ASGCT):** Instil presented advanced correlative analyses from a cohort of melanoma patients enrolled in a compassionate use program that were treated with TIL products made by Instil at the 25th Annual ASGCT meeting.

  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.*

Second Quarter 2022 Financial and Operating Results:

As of June 30, 2022, we had $354.6 million in total cash and cash equivalents and marketable securities, comprised of $42.5 million in cash and cash equivalents and $312.1 million in marketable securities compared to $454.1 million in total cash and cash equivalents and marketable securities, comprised of $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 June 30, 2022 will enable it to fund its operating plan into 2025 upon completion of the anticipated sale-leaseback of its Tarzana, CA manufacturing site.

Research and development expenses were $41.5 million and $80.7 million for the three and six months ended June 30, 2022, respectively, compared to $21.2 million and $35.6 million for the three and six months ended June 30, 2021, respectively.

General and administrative expenses were $17.2 million and $32.3 million for the three and six months ended June 30, 2022, respectively, compared to $14.2 million and $23.2 million for the three and six months ended June 30, 2021, respectively.

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

Selected Balance Sheet Data

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 354,607	$ 454,099
Total assets	$ 568,536	$ 609,983
Total liabilities	$ 110,204	$ 54,784
Stockholders' equity	$ 458,332	$ 555,199

Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 41,500	$ 21,186	$ 80,674	$ 35,610
General and administrative	17,224	14,195	32,336	23,174
Total operating expenses	58,724	35,381	113,010	58,784
Loss from operations	(58,724)	(35,381)	(113,010)	(58,784)
Interest income	486	15	583	23
Interest expense	(331)	—	(331)	—
Other expense, net	(1,032)	(104)	(1,448)	(41)
Loss before income tax benefit	(59,601)	(35,470)	(114,206)	(58,802)
Income tax benefit	609	159	1,097	363
Net loss	$ (58,992)	$ (35,311)	$ (113,109)	$ (58,439)
Net loss per share, basic and diluted	$ (0.46)	$ (0.27)	$ (0.88)	$ (0.71)
Weighted-average shares used in computing net loss per share, basic and diluted	129,367,833	128,743,123	129,244,334	82,478,284

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 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss—GAAP	$ (58,992)	$ (35,311)	$ (113,109)	$ (58,439)
Adjustments:				
Non-cash stock-based compensation expense	8,323	5,745	15,816	8,557
Net loss—Non-GAAP	$ (50,669)	$ (29,566)	$ (97,293)	$ (49,882)
Net loss per share, basic and diluted—GAAP	$ (0.46)	$ (0.27)	$ (0.88)	$ (0.71)
Adjustments:				
Non-cash stock-based compensation expense per share	0.06	0.04	0.12	0.10
Net loss per share, basic and diluted—Non-GAAP	$ (0.40)	$ (0.23)	$ (0.76)	$ (0.61)
Weighted-average shares outstanding, basic and diluted	129,367,833	128,743,123	129,244,334	82,478,284

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," "believes," "expects," "future," "intends," "potential," "projects," and "will" 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 studies and the availability of data therefrom, including our expectations concerning the completion of enrollment in our DELTA-1 clinical trial, the availability of top-line data from our DELTA-1 clinical trial, 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, our expanded clinical manufacturing capabilities, the anticipated sale-leaseback of our Tarzana, CA manufacturing facility, our 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 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; 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 Quarterly Report on Form 10-Q for the quarter ended March 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 June 30, 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.

Contacts:

Janhavi Mohite
Stern Investor Relations
1-212-362-1200
janhavi.mohite@sternir.com

Investor Relations
1-972-499-3350
investorrelations@instilbio.com
www.instilbio.com