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

November 14, 2022

Manufacturing update on voluntary pause of DELTA-1 trial of ITIL-168 in advanced melanoma expected in Q1'23

Reprioritization of resources with enrollment deferred in DELTA-2 trial of ITIL-168

First patient with non-small cell lung cancer dosed with ITIL-306, the first engineered TIL therapy using CoStAR Platform, with plans to share clinical data in 2023

Appointment of cell therapy pioneer Dr. Robert Hawkins as Head of Research and Development, and resignation of Chief Medical Officer, Dr. Zachary Roberts

Company confirms cash runway into 2025 with anticipated sale-leaseback transaction of its Tarzana manufacturing facility

DALLAS, Nov. 14, 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 third quarter 2022 financial results and provided a corporate update.

Third Quarter 2022 Highlights and Anticipated Milestones:

- **DELTA-1 manufacturing and regulatory update:** As previously announced, enrollment in DELTA-1 was voluntarily paused following the observation of decreased rates of successful manufacturing of ITIL-168. Our ongoing investigation of the manufacturing failures identified a central source of contamination in the cell media. In conjunction with this pause, we are also evaluating opportunities to increase the robustness of our manufacturing process. In addition, in October 2022, we notified the FDA and other regulatory agencies that an unplanned review of the data for the initial patients that had been dosed with ITIL-168 in the DELTA-1 trial was conducted in order to review risk-benefit. This review was inconclusive because the response data were not mature. Subsequently, the Data Safety Monitoring Board's prespecified review found no safety concerns. We plan to discuss next steps for the DELTA-1 trial with the FDA and other regulatory agencies, and after such discussions, or as a result of our ongoing investigation of our manufacturing process, we may be required to modify, delay or restart our ITIL-168 clinical development program. We plan to provide an update on our ITIL-168 clinical development program in the first quarter of 2023.

- **DELTA-2 clinical update:** The Company is deferring enrollment in the DELTA-2 study to focus resources toward higher-priority clinical programs.

- **First patient dosed in Phase 1 dose escalation study of ITIL-306, Instil's first CoStAR-TIL:** Instil recently announced dosing of the first patient with non-small cell lung cancer in the Phase 1 dose escalation study of ITIL-306 for the treatment of multiple solid tumors. The ITIL-306 product contained the target dose of approximately 1 billion CoStAR-TILs in addition to unmodified TILs. The CoStAR platform introduces a genetic modification which is designed to enhance the activity of TILs within the tumor microenvironment. The Phase 1 trial of ITIL-306 excludes the high-dose interleukin-2 regimen after ITIL-306 infusion. The Company remains committed to the CoStAR platform and expects to report initial clinical data from the trial in 2023.

- **Appointment of Head of Research and Development:** Instil announced the appointment of Robert Hawkins, M.B.B.S., Ph.D., as Head of Research and Development. Dr. Hawkins is a world-renowned oncologist and biotechnology innovator, with a focus on development of novel cell and gene therapies. Dr. Hawkins was the founder and CEO of Immetacyte Ltd., a cell therapy company spun out of the University of Manchester where Dr. Hawkins served as Professor of Medical Oncology. Immetacyte Ltd. generated the foundational TIL technology and clinical data on which Instil was founded.

- **Resignation of Chief Medical Officer:** Instil announced that, pursuant to a separation agreement, Zachary Roberts, M.D., Ph.D., Chief Medical Officer of the Company, has resigned effective November 11, 2022 to pursue other opportunities. The company appreciates Dr. Roberts' contributions and wishes him the best in his future endeavors.

- **Company confirms cash-runway into 2025 with anticipated sale-leaseback transaction of its Tarzana manufacturing facility**

Third Quarter 2022 Financial and Operating Results:

As of September 30, 2022, we had $303.3 million in total cash and cash equivalents and marketable securities, comprised of $41.1 million in cash and cash equivalents and $262.2 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 September 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 $39.7 million and $120.3 million for the three and nine months ended September 30, 2022, respectively, compared to $29.1 million and $64.7 million for the three and nine months ended September 30, 2021, respectively.

General and administrative expenses were $17.0 million and $49.3 million for the three and nine months ended September 30, 2022, respectively, compared to $14.0 million and $37.1 million for the three and nine months ended September 30, 2021, respectively.

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

Selected Balance Sheet Data

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 303,287	$ 454,099
Total assets	$ 532,741	$ 609,983
Total liabilities	$ 122,153	$ 54,784
Stockholders' equity	$ 410,588	$ 555,199

Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 39,660	$ 29,064	$ 120,334	$ 64,674
General and administrative	16,989	13,960	49,325	37,134
Total operating expenses	56,649	43,024	169,659	101,808
Loss from operations	(56,649)	(43,024)	(169,659)	(101,808)
Interest income	1,276	22	1,859	45
Interest expense	(807)	—	(1,138)	—
Other expense, net	(415)	(661)	(1,863)	(702)
Loss before income tax benefit	(56,595)	(43,663)	(170,801)	(102,465)
Income tax benefit	371	658	1,468	1,021
Net loss	$ (56,224)	$ (43,005)	$ (169,333)	$ (101,444)
Net loss per share, basic and diluted	$ (0.43)	$ (0.33)	$ (1.31)	$ (1.03)
Weighted-average shares used in computing net loss per share, basic and diluted	129,680,217	128,794,142	129,391,225	98,256,027

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss—GAAP	$ (56,224)	$ (43,005)	$ (169,333)	$ (101,444)
Adjustments:				
Non-cash stock-based compensation expense	7,982	8,734	23,798	17,293
Net loss—Non-GAAP	$ (48,242)	$ (34,271)	$ (145,535)	$ (84,151)
Net loss per share, basic and diluted—GAAP	$ (0.43)	$ (0.33)	$ (1.31)	$ (1.03)
Adjustments:				
Non-cash stock-based compensation expense per share	0.06	0.07	0.18	0.18
Net loss per share, basic and diluted—Non-GAAP	$ (0.37)	$ (0.26)	$ (1.13)	$ (0.85)
Weighted-average shares outstanding, basic and diluted	129,680,217	128,794,142	129,391,225	98,256,027

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," "plans," "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 timing of updates on our ITIL-306 clinical trial and the deferral of enrollment in our DELTA-2 clinical trial, our plans to discuss the DELTA-1 trial with the FDA and other regulatory agencies, the investigation into our manufacturing process and expectations concerning the outcome thereof and updates related thereto, 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 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, including the risk that our investigation into our manufacturing process will not yield conclusive or actionable results; 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 June 30, 2022 available on the SEC's website at www.sec.gov, and in our Quarterly Report on Form 10-Q for the quarter ended September 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.

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