Instil Bio Reports Second Quarter 2021 Financial Results and Provides Corporate Update

August 12, 2021

- Presented compassionate use study in advanced melanoma demonstrating 67% of subjects achieved an objective response with 19% achieving a complete response

- Received orphan drug designation from the U.S. FDA for lead asset ITIL-168

- Developed 21-day manufacturing process for ITIL-306 with robust transduction efficiency

DALLAS, Aug. 12, 2021 (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 2021 financial results and provided a corporate update.

“We confirm our commitment to initiating a Phase 2 trial of ITIL-168 in advanced melanoma in the second half of 2021,” said Bronson Crouch, Chief Executive Officer of Instil. “With the installation and ongoing qualification of modular clean room pods at our Tarzana, California facility and our progress toward activating additional manufacturing capabilities in Manchester, U.K., we expect increased clinical manufacturing capacity in late 2021 and early 2022 to support our clinical development plans for ITIL-168 and ITIL-306. Our commitment to innovation in manufacturing continues with the development of a shortened 21-day manufacturing process with robust levels of TIL transduction efficiency for ITIL-306, our first genetically engineered CoStAR-TIL. We expect to pursue further enhancements to both ITIL-168 and ITIL-306 manufacturing processes in the future.”

Second Quarter 2021 Highlights and Anticipated Milestones:

Clinical Development:

a. **Presented Clinical Data in Advanced Melanoma at AACR:** Instil presented clinical data demonstrating a 67% objective response rate and 19% complete response rate from a compassionate use program of TILs for the treatment of metastatic melanoma as a late-breaking e-Poster at the AACR virtual meeting in April 2021.

b. **Orphan Drug Designation**: On April 27, 2021, ITIL-168 received orphan drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of melanoma stages IIB to IV.

c. **Phase 2 Clinical Trial Initiation of ITIL-168:** Instil expects to start a Phase 2 clinical trial of ITIL-168 for the treatment of advanced melanoma in the second half of 2021. Topline safety and efficacy data would be expected in 2023, followed by submission of a BLA to the FDA and a Marketing Authorization Application to the European Medicines Agency expected in 2023 and 2024, respectively.

d. **Phase 1 Clinical Trial Initiation of ITIL-306:** Instil expects to start a Phase 1 clinical trial of ITIL-306 for the treatment of FOLR1-expressing cancer in the first half of 2022.

Manufacturing and Technical Operations:

a. **Facility Readiness for Clinical Trials:** Current manufacturing capacity in the U.K. is sufficient to support capacity needs at the start of the expected upcoming Phase 2 clinical trial of ITIL-168. Further expansion of our U.K. manufacturing capacity is expected later this year. Instil has also installed and begun qualification of its modular clean room pods at its Tarzana, California facility. These pods will support U.S. regional manufacturing and are expected to begin producing clinical batches in the first half of 2022.

b. **ITIL-306 Manufacturing Process:** Instil’s focus on continued improvements in manufacturing is highlighted by the development of a 21-day manufacturing process for ITIL-306. This process is capable of achieving high TIL transduction efficiencies that are well in excess of published literature.

Second Quarter 2021 Financial and Operating Results:

As of June 30, 2021, cash and cash equivalents totaled $566.7 million, compared to $241.7 million as of December 31, 2020. The Company expects that its cash and cash equivalents as of June 30, 2021 will enable it to fund its operating plan into 2023.

Research and development expenses were $21.2 million and $35.6 million for the three and six months ended June 30, 2021, compared to $2.2 million and $4.2 million for the three and six months ended June 30, 2020.

General and administrative expenses were $14.2 million and $23.2 million for the three and six months ended June 30, 2021, compared to $2.4 million and $4.3 million for the three and six months ended June 30, 2020.

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

Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ —	$ 42	$ —	$ 87
Operating expenses:				
Research and development	21,186	2,237	35,610	4,245
General and administrative	14,195	2,398	23,174	4,298
Total operating expenses	35,381	4,635	58,784	8,543
Loss from operations	(35,381)	(4,593)	(58,784)	(8,456)
Interest and other expense, net	(89)	(4,609)	(18)	(4,835)
Loss before income tax benefit	$ (35,470)	$ (9,202)	$ (58,802)	(13,291)
Income tax benefit	159	—	363	—
Net loss	$ (35,311)	$ (9,202)	$ (58,439)	$ (13,291)
Net loss per share, basic and diluted	$ (0.27)	$ (0.55)	$ (0.71)	$ (0.89)
Weighted-average shares used in computing net loss per share, basic and diluted	128,743,123	16,846,552	82,478,284	14,942,479

Selected Balance Sheet Data

	June 30, 2021	**December 31, 2020**
Cash and cash equivalents	$ 566,725	$ 241,714
Total assets	672,670	319,012
Total liabilities	37,198	26,645
Total stockholders' equity (deficit)	635,472	(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 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, our plans to expand clinical manufacturing capabilities, 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. 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.

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