Instil Bio Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

March 21, 2024

DALLAS, March 21, 2024 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (“Instil”) (Nasdaq: TIL), a clinical-stage biopharmaceutical company focused on developing a pipeline of novel therapies, today reported its fourth quarter and full year 2023 financial results and provided a corporate update.

Recent Highlights:

- Announced entering into a strategic collaboration to develop an autologous folate receptor α (FRα)-CoStAR enhanced TIL for a potential investigator-initiated trial (IIT) in non-small cell lung cancer in China
- Announced a strategic update to the ITIL-306 program, including closure of Instil’s UK manufacturing and cessation of ITIL-306 clinical trial activities
- Exploring opportunities to in-license/acquire and develop novel therapeutic candidates in diseases with significant unmet medical need
- Cash runway expected beyond 2026

Fourth Quarter and Full Year 2023 Financial and Operating Results:

As of December 31, 2023, Instil had $175.0 million in total cash, cash equivalents, restricted cash, marketable securities and long-term investments, which consisted of $9.2 million in cash and cash equivalents, $1.5 million in restricted cash, $141.2 million in marketable securities and $23.2 million in long-term investments, compared to $260.9 million in total cash, cash equivalents and marketable securities, which consisted 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, marketable securities and long-term investments as of December 31, 2023 will enable it to fund its operating plan beyond 2026.

Research and development expenses were $2.0 million and $39.6 million for the fourth quarter and full year ended December 31, 2023, respectively, compared to $20.7 million and $141.1 million for the fourth quarter and full year ended December 31, 2022, respectively.

General and administrative expenses were $10.9 million and $47.6 million for the fourth quarter and full year ended December 31, 2023, respectively, compared to $12.9 million and $62.2 million for the fourth quarter and full year ended December 31, 2022, respectively.

Restructuring and impairment charges were $0.2 million and $72.0 million for the fourth quarter and full year ended December 31, 2023, respectively, compared to $23.2 million for the fourth quarter and full year ended December 31, 2022.

Net loss per share, basic and diluted were $1.99 and $24.00 for the fourth quarter and full year ended December 31, 2023, respectively, compared to $8.29 and $34.46 for the fourth quarter and full year ended December 31, 2022. Non-GAAP net loss per share, basic and diluted were $1.26 and $10.14 for the fourth quarter and full year ended December 31, 2023, respectively, compared to $3.70 and $26.18 for the fourth quarter and full year ended December 31, 2022.

Note Regarding Use of Non-GAAP Financial Measures

In this press release, Instil 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 restructuring and impairment charges and non-cash stock-based compensation expense. Instil believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of Instil’s financial performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of Instil’s operating results. In addition, these non-GAAP financial measures are among the indicators Instil’s management uses for planning purposes and to measure Instil’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 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.

About Instil Bio

Instil Bio Inc. (Nasdaq: TIL) is a clinical-stage biopharmaceutical company focused on developing a pipeline of novel therapies. Instil seeks to in-license/acquire and develop novel therapeutic candidates in diseases with significant unmet medical need. 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," "may," "plans," "potential," "projects," "exploring" and "will" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying our ability to acquire and develop new product candidates with compelling data, the therapeutic potential of our product candidates, our research, development and regulatory plans for our product candidates, including the timing of our ongoing and potential future preclinical studies and future clinical trials and the availability of data therefrom, our expectations concerning the closure of our UK manufacturing and clinical operations and the related reduction in force and the benefits thereof, expectations concerning our collaboration and the generation of preclinical and clinical data therefrom, our expectations regarding our capital position, resources, and balance sheet, and the potential impact thereof on development of any product candidates, 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 acquiring product candidates, the costly and time-consuming product development process and the uncertainty of clinical success; the risks inherent in successfully manufacturing cell therapy products and relying on collaborators and other third parties for manufacturing; the risks and uncertainties related to successfully initiating, enrolling, completing and reporting data from clinical studies, including a collaborator-led IIT in China, 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 our product candidates may otherwise not be effective treatments in their planned indications; risks associated with reliance on third-party collaborators, and our ability to achieve the expected benefits of the closure of our UK manufacturing and clinical operations; risks related to macroeconomic conditions, including as a result of international conflicts, U.S.-China trade and political tensions, interest rates, inflation, and other factors, which could materially and adversely affect our business and operations; the risks and uncertainties associated with the time-consuming and uncertain regulatory approval process and the sufficiency of our cash resources; and other risks and uncertainties affecting Instil and our plans and 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, 2023 to be filed with the SEC, as well as our other filings 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.

Contacts:

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

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

Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 1,983	$ 20,722	$ 39,604	$ 141,056
General and administrative	10,872	12,910	47,553	62,235
Restructuring and impairment charges	165	23,167	72,012	23,167
Total operating expenses	13,020	56,799	159,169	226,458
Loss from operations	(13,020)	(56,799)	(159,169)	(226,458)
Interest income	2,195	1,796	8,866	3,655
Interest expense	(1,980)	(745)	(5,209)	(1,883)
Other (expense) income, net	(120)	1,299	(575)	(564)
Loss before income tax benefit	(12,925)	(54,449)	(156,087)	(225,250)
Income tax benefit	—	605	—	2,073
Net loss	$ (12,925)	$ (53,844)	$ (156,087)	$ (223,177)
Net loss per share, basic and diluted	$ (1.99)	$ (8.29)	$ (24.00)	$ (34.46)
Weighted-average shares used in computing net loss per share, basic and diluted	6,503,913	6,493,641	6,503,913	6,475,631

Selected Consolidated Balance Sheet Data

	December 31, 2023	December 31, 2022
Cash, cash equivalents, restricted cash, marketable securities and long-term investments	$ 175,018	$ 260,920
Total assets	$ 325,630	$ 482,128
Total liabilities	$ 99,801	$ 118,523

Convertible preferred stock and stockholders' equity	$ 225,829	$ 363,605

Reconciliation of GAAP to Non-GAAP Financial Measures
(Unaudited; in thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Net loss	$ (12,925)	$ (53,844)	$ (156,087)	$ (223,177)
Adjustments:				
Non-cash stock-based compensation expense	4,553	6,643	18,166	30,441
Restructuring and impairment charges	165	23,167	72,012	23,167
Non-GAAP net loss	$ (8,207)	$ (24,034)	$ (65,909)	$ (169,569)
Net loss per share, basic and diluted	$ (1.99)	$ (8.29)	$ (24.00)	$ (34.46)
Adjustments:				
Non-cash stock-based compensation expense per share	0.70	1.02	2.79	4.70
Restructuring and impairment charges	0.03	3.57	11.07	3.58
Non-GAAP net loss per share, basic and diluted*	$ (1.26)	$ (3.70)	$ (10.14)	$ (26.18)
Weighted-average shares outstanding, basic and diluted	6,503,913	6,493,641	6,503,913	6,475,631

* Non-GAAP net loss per share, basic and diluted may not total due to rounding.