Instil Bio Reports Third Quarter 2024 Financial Results and Provides Corporate Update

November 13, 2024

Licensed SYN-2510, a potential best-in-class PD-L1xVEGF bispecific antibody, for global ex-China development and commercialization

Clinical data update for SYN-2510/IMM2510 in China from ImmuneOnco anticipated in 1H 2025

Initiation of Phase 1b/2 SYN-2510/IMM2510 + chemotherapy combination in first-line non-small cell lung cancer (NSCLC) and triple negative breast cancer (TNBC) anticipated in late 2024 and 1H 2025, respectively, by ImmuneOnco in China

U.S. clinical study of SYN-2510/IMM2510 in NSCLC initiation targeted for 2H 2025

DALLAS, Nov. 13, 2024 (GLOBE NEWSWIRE) -- Instil Bio, Inc. (“Instil”) (Nasdaq: TIL), a clinical-stage biopharmaceutical company focused on developing a pipeline of novel cancer therapies, today reported its third quarter 2024 financial results and provided a corporate update.

“Our recent license of SYN-2510 is a significant milestone for Instil, positioning us with a potentially best-in-class asset in one of the most significant areas of interest in oncology,” said Bronson Crouch, CEO of Instil. “As we continue to build our internal team to operationalize the clinical development of SYN-2510, we are excited for the progress ImmuneOnco continues to make in advancing the program in its China trials.”

Recent Highlights:

- **In-licensed SYN-2510/IMM2510 and SYN-27M/IMM27M:** In August 2024, SyntBioTx, Inc., a wholly owned subsidiary of Instil, entered into a license and collaboration agreement with ImmuneOnco Biopharmaceuticals (Shanghai) Inc. (HKEX Code: 1541.HK, “ImmuneOnco”) to in-license global development and commercialization rights outside of Greater China for SYN-2510/IMM2510, a potential best-in-class PD-L1xVEGF bispecific antibody, and SYN-27M/IMM27M, a next-generation ADCC-enhanced CTLA-4 antibody. For SYN-2510/IMM2510, ImmuneOnco has identified a recommended Phase 2 monotherapy dose of 20 mg/kg Q2W, and is continuing patient enrollment in China to support dose optimization and dose expansion in multiple solid tumor cancers.
- **Clinical data update for SYN-2510/IMM2510 in China anticipated in 1H 2025:** ImmuneOnco expects to provide a clinical data update for SYN-2510/IMM2510 monotherapy in multiple solid tumors in China in the first half of 2025. Approximately 65 additional patients have been dosed with SYN-2510/IMM2510 monotherapy in addition to the initial 33 patients reported in ImmuneOnco’s ASCO 2024 publication.
- **Initiation of Phase 1b/2 IMM2510/SYN-2510 studies expected in late 2024 and 1H 2025 in China by ImmuneOnco:** Instil and ImmuneOnco announced in September 2024 that ImmuneOnco is accelerating clinical development of IMM2510/SYN-2510 into phase 1b/2 studies in China. IMM2510/SYN2510 will be administered in combination with chemotherapy in first-line NSCLC and TNBC, with anticipated start dates in late 2024 and 1H 2025, respectively.
- **U.S. clinical study of SYN-2510 in NSCLC targeted initiation in 2H 2025:** Instil is targeting initiation of a U.S. study of SYN-2510 in NSCLC in 2H 2025.
- **Clinical update for SYN-27M/IMM27M in breast cancer from ImmuneOnco:** Today, ImmuneOnco announced initial clinical results for patients with estrogen receptor positive (ER+) advanced breast cancer treated in the Phase 1 dose escalation of SYN-27M/IMM27M and the initiation of a Phase 2 clinical trial of SYN-27M/IMM27M for patients with ER+ breast cancer that failed after endocrine therapy or have recurred. Additionally, patient enrollment continues in the dose escalation study of the combination of SYN-27M/IMM27M and SYN-2510/IMM2510.

Third Quarter 2024 Financial and Operating Results:

As of September 30, 2024, Instil had cash, cash equivalents, marketable securities and long-term investments of $122.9 million, which consisted of $6.7 million in cash and cash equivalents, $113.7 million in marketable securities, and $2.6 million in long-term investments, compared to $175.0 million in cash, cash equivalents, marketable securities and long-term investments as of December 31, 2023, consisting 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. Instil expects that its cash, cash equivalents, marketable securities and long-term investments as of September 30, 2024 will enable it to fund its operating plan beyond 2026.

In-process research and development expenses were $10.0 million for both the three and nine months ended September 30, 2024, compared to nil for both the three and nine months ended September 30, 2023.

Research and development expenses were $0.6 million and $10.7 million for the three and nine months ended September 30, 2024, respectively, compared to $8.5 million and $37.6 million for the three and nine months ended September 30, 2023, respectively.

General and administrative expenses were $10.7 million and $33.8 million for the three and nine months ended September 30, 2024, respectively, compared to $11.9 million and $36.7 million for the three and nine months ended September 30, 2023, respectively.

Restructuring and impairment charges were $2.4 million and $7.1 million for the three and nine months ended September 30, 2024, respectively, compared to $46.3 million and $71.8 million for three and nine months ended September 30, 2023, respectively.

Net loss per share, basic and diluted were $3.54 and $9.57 for the three and nine months ended September 30, 2024, respectively, compared to $10.37 and $22.01 for the three and nine months ended September 30, 2023, respectively. Non-GAAP net loss per share, basic and diluted, were $2.55 and $6.51 for the three and nine months ended September 30, 2024, respectively, compared to $2.53 and $8.87 for the three and nine months ended September 30, 2023, respectively.

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 non-cash stock-based compensation expense and restructuring and impairment charges. 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 is a clinical-stage biopharmaceutical company focused on developing a pipeline of novel therapies. Instil's lead asset, SYN-2510, is a novel and differentiated PD-L1xVEGF bispecific antibody in development for the treatment of multiple solid tumor cancers. 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," "expected," "exploring," "future," "intends," "may," "plans," "potential," "projects," "targets" and "will" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include express or implied statements regarding our expectations with respect to the license and collaboration agreement with ImmuneOnco, the therapeutic potential of SYN-2510 and SYN-27M, clinical development of SYN-2510 and SYN-27M, including the initiation of clinical trials for SYN-2510 and SYN-27M and the generation of clinical data for SYN-2510 and SYN-27M; concerning or implying our ability to in-license or acquire and develop additional product candidates; our research, development and regulatory plans for our product candidates; our expectations regarding our capital position, resources, and balance sheet and the expected impact of the lease of our U.S. manufacturing facility with respect thereto, and the potential impact thereof on the 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 additional product candidates, the costly and time-consuming drug product development process and the uncertainty of clinical success; the risks inherent in relying on collaborators and other third parties, including for manufacturing and generating clinical data, and the ability to rely on any such data from clinical trials in China in regulatory filings submitted to regulatory authorities outside of China; the risks and uncertainties related to successfully making regulatory submissions and initiating, enrolling, completing and reporting data from clinical studies, particularly collaborator-led clinical trials, as well as the risks that results obtained in any 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 related to macroeconomic conditions, including as a result of international conflicts and U.S.-China trade and political tensions, as well as 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 us and our plans and development programs, including those discussed in the section titled "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 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.

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

Selected Condensed Consolidated Balance Sheet Data

	September 30, 2024	December 31, 2023
Cash, cash equivalents, restricted cash, marketable securities and long-term investments	$ 122,910	$ 175,018
Total assets	$ 272,562	$ 325,630
Total liabilities	$ 96,230	$ 99,801

Total stockholders' equity	$ 176,332	$ 225,829

Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
In-process research and development	$ 10,000	$ —	$ 10,000	$ —
Research and development	562	8,492	10,739	37,621
General and administrative	10,707	11,941	33,837	36,681
Restructuring and impairment charges	2,362	46,283	7,146	71,847
Total operating expenses	23,631	66,716	61,722	146,149
Loss from operations	(23,631)	(66,716)	(61,722)	(146,149)
Interest income	1,654	2,313	5,635	6,671
Interest expense	(2,007)	(2,003)	(5,988)	(3,229)
Other rental income	1,493	—	1,493	—
Other expense, net	(530)	(1,026)	(1,658)	(455)
Net loss	$ (23,021)	$ (67,432)	$ (62,240)	$ (143,162)
Net loss per share, basic and diluted	$ (3.54)	$ (10.37)	$ (9.57)	$ (22.01)
Weighted-average shares used in computing net loss per share, basic and diluted	6,506,681	6,503,913	6,504,842	6,503,913

INSTIL BIO, INC.
Reconciliation of GAAP to Non-GAAP Net Loss and Net Loss per Share
(Unaudited; in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net loss	$ (23,021)	$ (67,432)	$ (62,240)	$ (143,162)
Adjustments:				
Non-cash stock-based compensation expense	4,068	4,670	12,756	13,613
Restructuring and impairment charges	2,362	46,283	7,146	71,847
Non-GAAP net loss	$ (16,591)	$ (16,479)	$ (42,338)	$ (57,702)
Net loss per share, basic and diluted	$ (3.54)	$ (10.37)	$ (9.57)	$ (22.01)
Adjustments:				
Non-cash stock-based compensation expense per share	0.63	0.72	1.96	2.09
Restructuring and impairment charges per share	0.36	7.12	1.10	11.05
Non-GAAP net loss per share, basic and diluted*	$ (2.55)	$ (2.53)	$ (6.51)	$ (8.87)
Weighted-average shares outstanding, basic and diluted	6,506,681	6,503,913	6,504,842	6,503,913

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