UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 14, 2025

Instil Bio, Inc.

(Exact name of registrant as specified in its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-40215

(Commission File Number) 83-2072195

(IRS Employer Identification No.)

3963 Maple Avenue, Suite 350 Dallas, Texas

(Address of Principal Executive Offices)

75219

(Zip Code)

(972) 499-3350

(Registrant's Telephone Number, Including Area Code)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

	Trading	
Title of each class	Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.000001 par value	TIL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \boxtimes

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 8.01 Other Events.

On January 14, 2025, Instil Bio, Inc. issued a press release entitled "Instil Bio Announces Clinical Progress in China for IMM2510/SYN-2510, a Clinical-Stage PD-L1xVEGF Bispecific Antibody". A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	Description
99.1	Press release dated January 14, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Instil Bio, Inc.

Dated: January 14, 2025

By: /s/ Sandeep Laumas, M.D.

Sandeep Laumas, M.D. Chief Financial Officer and Chief Business Officer (Principal Financial Officer and Principal Accounting Officer)



Instil Bio Announces Clinical Progress in China for IMM2510/SYN-2510, a Clinical-Stage PD-L1xVEGF Bispecific Antibody

ImmuneOnco announced dosing of first patient in its recently initiated Phase 1b/2 clinical trial of IMM2510/SYN-2510 in combination with chemotherapy in patients with advanced NSCLC in China

ImmuneOnco announced initial clinical data from the 1L advanced NSCLC trial in China is expected as early as 2H 2025

Instil is targeting initiation of a potential first-line advanced NSCLC clinical trial of IMM2510/SYN-2510 combined with chemotherapy in 2H 2025, assuming necessary regulatory approvals

Dallas, Texas, Jan. 14, 2025 (GLOBE NEWSWIRE) –Instil Bio, Inc. (Nasdaq: TIL, "Instil"), today announced clinical progress of IMM2510/SYN-2510 in China by its collaborator, ImmuneOnco Biopharmaceuticals (Shanghai) Inc. (HKEX Code: 1541.HK, "ImmuneOnco").

ImmuneOnco announced that the first patient has been dosed in its phase 1b/2 clinical trial of IMM2510/SYN-2510 in combination with chemotherapy in patients with advanced non-small cell lung cancer (NSCLC) in China. ImmuneOnco announced it plans to enroll first-line patients in this trial and anticipates presenting initial clinical data, including data for first-line NSCLC patients, from this trial as soon as the second half of 2025.

Additionally, Instil announced that for its anticipated initial U.S. clinical trial of SYN-2510/IMM2510 in lung cancer, it plans to target enrollment of first-line patients with NSCLC in combination with chemotherapy with an expected initiation in the second half of 2025, assuming the necessary regulatory approvals are obtained.

"We anticipate that ImmuneOnco's initial clinical data of IMM2510/SYN-2510 in combination with chemotherapy in patients with frontline NSCLC could be extremely valuable in advancing our development of IMM2510/SYN-2510 in NSCLC," said Bronson Crouch, CEO of Instil. "The data generated, if positive, could position us to open a potential global registrational study in front-line NSCLC."

About SYN-2510/IMM2510

SYN-2510/IMM2510 is a PD-L1xVEGF bispecific antibody in development for the treatment of multiple solid tumor cancers. SYN-2510/IMM2510 is differentiated from other PD-(L)1xVEGF bispecific antibodies by its VEGF trap, which binds multiple VEGF receptor ligands beyond VEGF-A, a bispecific structure which leverages PD-L1 as an anchor in the tumor microenvironment (TME), and enhanced antibody-dependent cellular cytotoxicity (ADCC) to direct killing of PD-L1-positive tumor cells.

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 <u>www.instilbio.com</u>.



Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words (and variations of words) such as "anticipates," "believes," "could," "expects," "expected," "exploring," "future," "intends," "may," "plans," "potential," "projects," "will," "target," "targeting," and similar expressions are intended to identify forward-looking statements. Forward-looking statements include express or implied statements regarding Instil's expectations with respect to the therapeutic potential of SYN-2510/IMM2510, the clinical development of SYN-2510/IMM2510, including IND submissions and clearances, clinical trials and the timing, scope and design thereof, the availability and timing of data from clinical trials, regulatory approvals and interactions and other statements that are not historical fact. Forward-looking statements are based on Instil 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 in-licensing product candidates and clinical trial collaborations; the costly and time-consuming product development process and the uncertainty of clinical success; the risks inherent in relying on collaborators and other third parties, including for manufacturing and clinical trial operation; the risks and uncertainties related to successfully initiating, enrolling, completing and reporting data from 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; 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 Instil's business and operations; the risks and uncertainties associated with the time-consuming and uncertain regulatory approval process for product candidates across multiple indications and multiple regulatory authorities; the impact of product candidates that may compete with those developed by Instil: the sufficiency of Instil's cash resources; and other risks and uncertainties affecting Instil and its plans and development programs, including those discussed in the section titled "Risk Factors" in Instil's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 filed with the SEC, as well as Instil's other filings with the SEC. Additional information will be made available in other filings that Instil makes 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 Instil disclaims any obligation to update these statements except as may be required by law.

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