

**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): October 15, 2024

CLIMB BIO, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40708
(Commission
File Number)

83-2273741
(IRS Employer
Identification No.)

**20 William Street, Suite 145
Wellesley Hills, Massachusetts**
(Address of Principal Executive Offices)

02481
(Zip Code)

Registrant's Telephone Number, Including Area Code: (866) 857-2596

**PMB #117
2801 Centerville Road 1st Floor
Wilmington, DE 19808-1609**
(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:

- 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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	CLYM	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

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

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.

Item 2.02 Results of Operations and Financial Condition.

On October 15, 2024, Climb Bio, Inc. (the “Company”) issued a press release in which it reported a preliminary estimate that, as of September 30, 2024, it had approximately \$218 million in cash, cash equivalents and marketable securities. This amount is preliminary and unaudited, represents a management estimate as of the date of this report, is subject to the completion of the Company’s quarter-end financial closing procedures that could result in changes to the amount and does not present all information necessary for an understanding of the Company’s financial condition as of September 30, 2024.

The information in this Item 2.02 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

On October 15, 2024, the Company will hold its previously announced virtual investor event beginning at 12:00 p.m. ET. During the investor event, members of the Company’s management will, among other things, provide an update on the Company’s development strategy for budoprutug, an anti-CD19 monoclonal antibody with potential to treat a broad range of B-cell mediated diseases. The event will also feature Dr. Frank Cortazar, Director of the New York Vasculitis and Glomerular Center and Chief of Clinical Research at St. Peter’s Health Partners, who was the primary investigator in the Phase 1b clinical trial of budoprutug for primary membranous nephropathy. A copy of the press release relating to the investor event is attached hereto as Exhibit 99.1 and incorporated herein by reference. A live webcast of the event, as well as a replay, will be available under “Events and Presentations” in the Investors section of the Company’s website: climbbio.com. The information contained in, or that can be accessed through the Company’s website, is not a part of this filing.

The information in this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated October 15, 2024
104	Cover Page Interactive Data File (formatted as Inline XBRL)



Climb Bio to Provide Budoprutug Development Strategy and Corporate Update at Virtual Investor Event

Completes Transition to Immune-Mediated Disease Focused Company

Highlights Additional Data from Phase 1b Primary Membranous Nephropathy (pMN) Study with plans to Advance to Late Phase Development in 2025

Outlines Plans for Clinical Trials in Systemic Lupus Erythematosus (SLE) and Immune Thrombocytopenia (ITP) with First Patients Dosed Targeted for 1H25

Cash runway through 2027 Expected to Enable Delivery of Key Value Inflection Points

Virtual Investor Event to be Held at 12:00 p.m. ET Today

WELLESLEY HILLS, MASS., —(GLOBE NEWSWIRE) – October 15, 2024 – Climb Bio, Inc. (Nasdaq: CLYM), will be hosting a virtual investor event, today, October 15, 2024, from 12:00 p.m. to 2:00 p.m. ET. The event will feature members of Climb Bio’s management team who will provide an update on the Company’s development strategy for budoprutug, an anti-CD19 monoclonal antibody with potential to treat a broad range of B-cell mediated diseases. The event will also feature Dr. Frank Cortazar, Director of the New York Vasculitis and Glomerular Center and Chief of Clinical Research at St. Peter’s Health Partners, who was the primary investigator in the Phase 1b trial of budoprutug in pMN. Dr. Cortazar will present additional data from the completed pMN trial and share clinical data from a single patient with Minimal Change Disease (MCD) treated with budoprutug.

“Our mission at Climb Bio is to develop better treatments for the approximately 50 million patients in the U.S. and many more globally living with immune-mediated diseases,” said Aoife Brennan, President and CEO of Climb Bio. “We are off to a great start with some world class talent and a cornerstone asset, budoprutug. We believe CD19 is the optimal target for B-cell mediated diseases and that an antibody is the modality with the broadest potential to help patients. We are thrilled today to share our development strategy and promising preclinical and clinical data that underscore our enthusiasm for budoprutug’s potential.”

Dr. Cortazar added, “I know firsthand the challenges of managing patients with pMN and the need for new treatment options. The patients in the pMN trial demonstrated high rates of complete clinical remission, as well as rapid reductions in B-cells and anti-PLA2R antibodies, two key biomarkers for pMN. These data potentially support a significant advancement in our fight against this challenging condition, and I am hopeful to continue to help advance this innovative therapy for those in need.”

Event Highlights

Rational and data driven clinical development strategy

- The Company's strategic approach to developing budoprutug will consider indications across three opportunity sets, including:
 - IgG4-mediated diseases, such as pMN;
 - Diseases caused by IgG1-3 that impact a single organ system, such as ITP; and
 - Complex systemic diseases, such as SLE.

Budoprutug is a differentiated anti-CD19 monoclonal antibody with potential for potent B-cell depletion

- The Company will share data supporting budoprutug's potential for deep and durable depletion of both peripheral and tissue-resident B-cells in patients with immune-mediated diseases
 - In a transgenic mouse model expressing human CD19, budoprutug achieved dose-dependent B-cell depletion in bone marrow, lymph nodes, and spleen.
 - Doses as low as 100 mg induced B-cell depletion to undetectable levels in pMN patients treated with budoprutug.

Continued advancement of subcutaneous formulation of budoprutug

- Budoprutug has been successfully formulated above 175 mg/ml while maintaining low viscosity, creating an opportunity to pursue a subcutaneous dosing form that potentially features a low volume injection.
- The Company plans to continue to advance the subcutaneous formulation clinical program, with non-clinical data expected in the first half of 2025.

Additional promising Phase 1b Study Results in pMN

- Dr. Frank Cortazar, Director of the New York Nephrology Vasculitis and Glomerular Center, will present additional data from the Phase 1b study of budoprutug in patients with pMN.
- The study demonstrated the following for the 5 patients who received all 4 doses of budoprutug:
 - Complete remission of proteinuria achieved by 3/5 (60%) of patients.
 - Rapid and significant reductions in anti-PLA2R autoantibodies, a key driver of pMN, with serological remission occurring in the 3 patients that were PLA2R positive at baseline.
 - Complete and sustained B-cell depletion was observed in all patients, with undetectable levels of B-cells occurring after just two doses of study drug as low as 100 mg.
 - Budoprutug was generally well-tolerated, with no reported drug-related serious adverse events.
- Full data from this study will be presented in a poster presentation on October 24th at the American Society of Nephrology's Kidney Week 2024 being held in San Diego, CA.
- Dr. Cortazar will also share data from a single patient trial for MCD showing the MCD patient was able to fully taper steroid and remains in complete remission 18 months following final administration of budoprutug, given as 4 doses over 6 months, 600mg cumulative dose.

Initiation of Phase 1b clinical trial in SLE planned for the first half of 2025, subject to regulatory clearance

- SLE is a complex, chronic systemic disease opportunity affecting multiple organ systems, leading to significant morbidity and mortality that affects approximately 200,000 to 300,000 people in the U.S.
- Design of Phase 1b trial in SLE:
 - An open-label trial in patients with active lupus is planned.
 - Endpoints will include clinical response, decline in pathogenic autoantibodies, and assessment of B-cell subsets upon recovery.
 - The trial will utilize informative serum biomarkers to accelerate proof-of-concept, optimize dosing, and benchmark against other B-cell depleting therapies.

Initiation of Phase 2 clinical trial in ITP planned for the first half of 2025, subject to regulatory clearance

- ITP is an IgG 1-3 immune-mediated disorder affecting an estimated 60,000 adults in the U.S. and where there is compelling proof-of-concept validating the clinical rationale for using B-cell depletion therapies.
- Design of Phase 2 trial in ITP:
 - Single-arm, open-label study in adult patients with chronic ITP is planned.
 - Primary endpoint will measure platelet improvement along with other disease parameters.
 - A unique “treat-to-target” approach is included in the study protocol to allow for personalized redosing based on individual patient needs.

Corporate Update and Upcoming Milestones

- As of September 30, 2024, the Company had cash, cash equivalents and marketable securities of approximately \$218 million, which is expected to fund operations through 2027.
- Initiation of clinical trials in SLE and ITP with first patients dosed targeted for the first half of 2025, subject to regulatory clearance.
- Advancement of subcutaneous formulation clinical program, with non-clinical data expected in the first half of 2025.
- Advancement of pMN clinical program to late phase development expected in 2025.

Event Details

Climb Bio, Inc. will host its virtual investor event, today, October 15, 2024, from 12:00 p.m. to 2:00 p.m. ET. To attend the virtual event, please register [here](#). The live webcast of the event, as well as a replay, will be available under “Events and Presentations” in the Investors section of the Company’s website: climbbio.com.

About Climb Bio, Inc.

Climb Bio, Inc. is a clinical-stage biotechnology company developing therapeutics for patients with immune-mediated diseases. The Company’s lead product candidate, budoprutug, is an anti-CD19 monoclonal antibody that has demonstrated B-cell depletion and has potential to treat a broad range of B-cell mediated diseases. For more information, please visit climbbio.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation statements regarding: future expectations, plans and prospects for Climb Bio; the anticipated benefits of the acquisition of Tenet Medicines, Inc.; expectations regarding budoprutug’s therapeutic benefits, clinical potential and clinical development; the trial design for the planned clinical trials of budoprutug; plans to optimize the administration of budoprutug; the anticipated timelines for initiating clinical trials of budoprutug; the sufficiency of Climb Bio’s cash resources for the period anticipated and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” “will,” “working” and similar expressions. Forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. Climb Bio may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. These risks and uncertainties include, but are not limited to, important risks and uncertainties associated with: the ability of Climb Bio to timely and successfully achieve or recognize the anticipated benefits of its acquisition of Tenet Medicines, Inc.; changes in applicable laws or regulation; the possibility that Climb Bio may be adversely affected by other economic, business and/or competitive factors; Climb Bio’s ability to advance budoprutug on the timelines expected or at all and to obtain and maintain necessary approvals from the U.S. Food and Drug Administration and other regulatory authorities; obtaining and maintaining the necessary approvals from investigational review boards at clinical trial sites and independent data safety monitoring boards; replicating in clinical trials positive results found in early-stage clinical trials of budoprutug; competing successfully with other companies that are seeking to develop treatments for systemic lupus erythematosus, immune thrombocytopenia and membranous nephropathy and other immune-mediated diseases; maintaining or protecting intellectual property rights related to budoprutug and/or its other product candidates; managing expenses; and raising the substantial additional capital needed, on the timeline necessary, to continue development of budoprutug and any other product candidates Climb Bio may develop. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Climb Bio’s actual results to differ materially from those contained in the forward-looking statements, see the “Risk Factors” section, as well as discussions of potential risks, uncertainties and other important factors, in Climb Bio’s most recent filings with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Climb Bio’s views as of the date hereof and should not be relied upon as representing Climb Bio’s views as of any date subsequent to the date hereof. Climb Bio anticipates that subsequent events and developments will cause Climb Bio’s views to change. However, while Climb Bio may elect to update these forward-looking statements at some point in the future, Climb Bio specifically disclaims any obligation to do so, except as required by law.

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