

**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): May 14, 2025

CLIMB BIO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40708

83-2273741
(IRS Employer
Identification No.)

(Commission File Number)

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

02481
(Zip Code)

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

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:

- 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 May 14, 2025, Climb Bio, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2025. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the 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 into any filing under the Exchange Act or the Securities Act of 1933, as amended, whether filed before or after the date hereof and regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release of Climb Bio, Inc., dated May 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.

Climb Bio, Inc.

Date: May 14, 2025

By: _____ /s/ Aoife Brennan
Aoife Brennan, M.B., Ch.B.
President and Chief Executive Officer



Climb Bio Reports First Quarter 2025 Financial Results and Provides Business Updates

Clinical Trials of Budoprutug in Primary Membranous Nephropathy (pMN), Immune Thrombocytopenia (ITP), and Systemic Lupus Erythematosus (SLE) on Track to Initiate in 2025

CLYM116 Progressing Towards Anticipated IND or CTA Submission in Second Half 2025

Appointed Kim Cobleigh Drapkin, CPA, and Bo Cumbo as Independent Directors and Perrin Wilson, Ph.D., as Chief Business Officer

Strong Financial Position, with Cash Runway Expected Through 2027

WELLESLEY HILLS, MASS., (GLOBE NEWSWIRE) – May 14, 2025 – Climb Bio, Inc. (Nasdaq: CLYM), a clinical stage biotechnology company developing therapeutics for patients with immune-mediated diseases, today reported financial results for the first quarter ended March 31, 2025, and provided business updates.

“2025 is a critical year of execution for Climb Bio and we continue to make excellent progress developing a differentiated pipeline targeting immune-mediated diseases with expansive therapeutic and commercial potential,” said Aoife Brennan, President and CEO of Climb Bio. “Our most advanced program, budoprutug, a potential best-in-class anti-CD19 monoclonal antibody designed to treat B-cell mediated diseases, remains on track to initiate clinical studies in ITP and SLE in the coming weeks and in pMN in the second half of 2025. We plan to provide clarity on the anticipated timing of clinical readouts later this year when enrollment dynamics are clearer. In parallel, we are advancing the subcutaneous formulation of budoprutug and subject to regulatory clearance, anticipate initiating a Phase 1 clinical trial in healthy volunteers in the second half of the year.”

Dr. Brennan continued, “We have also made progress with our CLYM116 program, a potential best-in-class anti-APRIL monoclonal antibody with potential to provide therapeutic benefit to patients living with IgA nephropathy and other B-cell mediated diseases. We look forward to sharing detailed preclinical data from the program, including pharmacokinetic and pharmacodynamic markers of biological activity, in the second half of 2025 and we anticipate submitting an investigational new drug (IND) or clinical trial application (CTA) for CLYM116 by year end.”

First Quarter 2025 and Recent Highlights

- **FDA clearance for budoprutug Phase 2 pMN clinical trial.** In March 2025, the Company announced that it had received clearance from the FDA to initiate a Phase 2 clinical trial of budoprutug in patients with pMN. This open-label, dose-ranging trial is designed to further evaluate the efficacy and safety of budoprutug in pMN.
- **FDA clearance of budoprutug IND in ITP.** In March 2025, the Company announced that it had received clearance from the FDA of its IND to initiate a Phase 1b/2a clinical trial of budoprutug in patients with ITP. In parallel, the Company is also pursuing ex-U.S. regulatory clearance for this clinical trial. This open-label, dose escalation and expansion trial is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary clinical efficacy of budoprutug in ITP.
- **Pursuing ex-U.S. regulatory clearance for budoprutug clinical trial in SLE.** Following the Company’s receipt of clearance from the FDA of its IND for SLE, the Company is also pursuing regulatory clearance to initiate the Phase 1b clinical trial of budoprutug in SLE at sites outside the United States. The open-label, single ascending dose study is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary signs of clinical efficacy of budoprutug in SLE.

- **Completed studies supporting a cell line switch for budoprutug.** In March 2025, the Company announced that it was advancing the productivity and scalability of the manufacturing process for budoprutug to support later-stage clinical development.
- **Expanded pipeline to include CLYM116, an antibody targeting the APRIL pathway for IgAN.** In January 2025, Climb Bio entered into a technology transfer and exclusive license agreement with Beijing Mabworks Biotech Co., Ltd. (Mabworks) for the rights to develop and commercialize CLYM116 in the territory outside of Greater China. CLYM116 is a highly potent, Fc-engineered antibody that has the potential to enable more rapid, deep, and durable inhibition of APRIL signaling through its novel, pH-dependent mechanism of action. CLYM116 is currently in IND-enabling studies and the Company anticipates submitting an IND or CTA by year end.
- **Appointed Kim Cobleigh Drapkin, CPA, and Bo Cumbo as Independent Directors in April 2025.** Kim Cobleigh Drapkin, CPA, is a seasoned financial leader with over 30 years of experience guiding private and publicly traded biotechnology and pharmaceutical companies through strategic growth, financial planning, capital raises, and transformative transactions. Ms. Drapkin most recently served as Chief Executive Officer of Graphite Bio. Bo Cumbo brings over 30 years of experience in the pharmaceutical and biotechnology industries, with a proven track record of leading successful commercial launches for 11 specialty and rare disease therapies. Mr. Cumbo currently serves as President, Chief Executive Officer, and Director of Solid Biosciences.
- **Appointed Perrin Wilson, Ph.D., as Chief Business Officer in February 2025.** Dr. Wilson has over 17 years of experience in the pharmaceutical and biotech industry and has deep expertise in business development and commercial strategy. During her career, she has led brand strategy and launch preparations and has overseen multiple successful acquisitions and integrations.

Anticipated Milestones

- Budoprutug (anti-CD19 monoclonal antibody):
 - ITP Phase 1b/2a study - first patient in (H1 2025)
 - SLE Phase 1b study - first patient in (H1 2025)
 - pMN Phase 2 study - first patient in (H2 2025)
 - Subcutaneous formulation - obtain additional non-clinical data (H1 2025) and initiation of a Phase 1 clinical trial in healthy volunteers (H2 2025)
- CLYM116 (anti-APRIL monoclonal antibody):
 - Reporting preclinical data (H2 2025) and submission of IND or CTA (H2 2025)

First Quarter 2025 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$197.8 million as of March 31, 2025. Cash, cash equivalents and marketable securities are expected to fund operations through 2027.
- **Research and Development (R&D) expenses:** R&D expenses were \$17.3 million for the three months ended March 31, 2025, including the \$9.0 million upfront payment made to Mabworks in accordance with the license agreement, compared to \$1.1 million for the comparable period in 2024.
- **General and Administrative (G&A) expenses:** G&A expenses were \$5.7 million for the three months ended March 31, 2025, compared to \$1.9 million for the comparable period in 2024.
- **Other income, net:** Other income, net was \$2.2 million for the three months ended March 31, 2025, compared to \$1.3 for the comparable period in 2024.

About Climb Bio, Inc.

Climb Bio, Inc. is a clinical-stage biotechnology company developing therapeutics for patients with immune-mediated diseases. The Company's pipeline includes, budoprutug, an anti-CD19 monoclonal antibody that has demonstrated B-cell depletion and has potential to treat a broad range of B-cell mediated diseases, and CLYM116, an anti-APRIL monoclonal antibody currently in IND-enabling studies for IgA nephropathy. For more information, please visit climbbio.com.

About Budoprutug

Budoprutug is a clinical-stage, anti-CD19 monoclonal antibody being developed by Climb Bio to address a broad range of B-cell mediated, immune-driven diseases. Designed with enhanced effector function and low picomolar affinity, budoprutug targets and depletes CD19-expressing B cells, including plasma blasts that are key sources of pathogenic autoantibodies. Climb Bio plans to evaluate budoprutug in multiple clinical trials across three lead indications—primary membranous nephropathy (pMN), immune thrombocytopenia (ITP), and systemic lupus erythematosus (SLE)—which represent distinct mechanistic subtypes of immune-mediated disease. Early clinical data suggest budoprutug may offer durable B-cell depletion, rapid reductions in autoantibodies, and clinical remission in pMN. A subcutaneous formulation is also in development to enable broader patient access and potential home-based dosing. Budoprutug has been granted orphan drug designation by the FDA for the treatment of pMN.

About CLYM116

CLYM116 is a preclinical-stage monoclonal antibody targeting APRIL (A Proliferation-Inducing Ligand), a key driver of pathogenic B-cell activity in autoimmune diseases. CLYM116 employs a novel pH-dependent bind-and-release mechanism to potentially block APRIL signaling, promote lysosomal degradation of APRIL, and recycle the antibody to extend its half-life. This differentiated design offers the potential for rapid, deep, and durable inhibition of APRIL with a favorable safety profile and less frequent dosing. CLYM116 is being advanced for the treatment of IgA nephropathy (IgAN), with plans to initiate a Phase 1 clinical trial following completion of IND-enabling studies and subject to regulatory clearance. The molecule may also have broader utility across other B-cell mediated diseases where APRIL plays a critical role.

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; expectations regarding the therapeutic benefits, clinical potential and clinical development of budoprutug and CLYM116; the trial design for the planned clinical trials of budoprutug; the anticipated timelines for initiating clinical trials of budoprutug for primary membranous nephropathy, immune thrombocytopenia and systemic lupus erythematosus; plans to optimize the administration of budoprutug; the anticipated benefits of Climb Bio’s license agreement with Mabworks; expectations regarding the timing of an investigational new drug application or clinical trial application submission for CLYM116; 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. and its license agreement with Mabworks; 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 and CLYM116 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; competing successfully with other companies that are seeking to develop treatments for primary membranous nephropathy, immune thrombocytopenia, systemic lupus erythematosus, IgA nephropathy and other immune-mediated diseases; maintaining or protecting intellectual property rights related to budoprutug, CLYM116 and/or its other product candidates; managing expenses; and raising the substantial additional capital needed, on the timeline necessary, to continue development of budoprutug, CLYM116 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.

Investors and Media

Carlo Tanzi, Ph.D.
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Climb Bio, Inc.

Condensed Consolidated Balance Sheets

*(In thousands)
(unaudited)*

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
Assets		
Cash, cash equivalents and marketable securities	\$ 197,845	\$ 212,529
Other assets	2,895	4,658
Total assets	\$ 200,740	\$ 217,187
Liabilities and stockholders' equity		
Liabilities	\$ 7,355	\$ 5,306
Total stockholders' equity	193,385	211,881
Total liabilities and stockholders' equity	\$ 200,740	\$ 217,187

Condensed Consolidated Statements of Operations

*(In thousands, except per share amounts)
(unaudited)*

	<u>Three Months Ended March 31,</u>	
	<u>2025</u>	<u>2024</u>
Operating expenses:		
Research and development	17,327	1,091
General and administrative	5,691	1,914
Total operating expenses	\$ 23,018	\$ 3,005
Loss from operations	(23,018)	(3,005)
Other income, net	2,237	1,308
Net loss	\$ (20,781)	\$ (1,697)
Net loss per share, basic and diluted	\$ (0.31)	\$ (0.06)

