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 23, 2026

Climb Bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40708**	**83-2273741**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

20 William Street **Suite G50** **Wellesley Hills, Massachusetts**	**02481**
(Address of Principal Executive Offices)	**(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

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 7.01 Regulation FD Disclosure.

On October 23, 2026, Climb Bio, Inc. (the "Company") and Beijing Mabworks Biotech Co., Ltd. ("Mabworks"), issued a press release announcing results for additional Phase 1 data in healthy volunteers for CLYM116/MIL116, an anti-APRIL monoclonal antibody, in development for IgA nephropathy ("IgAN"). These data were presented at the American Society of Nephrology (ASN) Kidney Week 2026, which is taking place October 21-25, 2026, in Denver, Colorado.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information contained in Item 7.01 of this Current Report on Form 8-K, including the exhibit furnished under Item 7.01 of this Current Report on Form 8-K, shall not be deemed to be "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 Exchange Act or the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On October 23, 2026, the Company announced additional data from the Phase 1 clinical development program of CLYM116 in healthy volunteers. CLYM116 was engineered as a pH-dependent "sweeper" antibody intended to facilitate the clearance of a proliferation-inducing ligand ("APRIL") while recycling the antibody, which the Company believes supports deep and durable APRIL suppression with extended dosing intervals. CLYM116 is being evaluated in complementary Phase 1 trials in Australia and China. Both are randomized, double-blind, placebo-controlled, ascending-dose studies designed to evaluate safety, tolerability, pharmacokinetics ("PK"), and pharmacodynamics ("PD") of subcutaneous ("SC") CLYM116 in healthy volunteers and enrolled 46 and 42 participants respectively.

The additional data build on previously reported initial Phase 1 results from the trial, with data further supporting the prolonged half-life, deep and durable APRIL suppression, and every-12-week ("Q12W") dosing potential of CLYM116 in IgAN.

CLYM116 showed an estimated half-life of approximately 33 days based on the 800 mg dose and 320 mg multiple-ascending dose ("MAD") cohort. PK was consistent across both studies, with linear exposure and no target-mediated drug disposition observed at doses of 160 mg or higher, consistent with sweeper-mediated degradation of APRIL.

The additional data also extend the previously reported PD findings. As previously reported, a single 320 mg dose produced greater than 90% suppression of free APRIL and approximately 60-75% suppression of IgA, galactose-deficient IgA1 ("GD-IgA1"), maintained through 12 weeks. In the expanded dataset, a single subcutaneous ("SC") injection of 480 mg or higher produced free APRIL suppression of 90% or more through the full 12-week dosing interval, and a single SC injection of 800 mg, the selected loading dose for the NAVIGATE-2 Phase 2 trial, produced reductions of approximately 70% in Gd-IgA1 and approximately 60% in IgA at 12 weeks.

CLYM116 has been generally well tolerated across all dose levels evaluated with no serious adverse events, dose-limiting toxicities, or hypogammaglobulinemia. Injection site reactions occurred in 5 of 88 participants across both studies, which were all Grade 1 and resolved without intervention.

The Company is enrolling patients with IgAN in its ongoing NAVIGATE-2 Phase 2 trial intended to support the Q12W dosing regimen and remains on track to report initial data in the first half of 2027. The Company and Mabworks also expect to initiate a global Phase 3 trial in 2027, pending regulatory feedback.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" including, without limitation, statements regarding: future expectations, plans and prospects for Climb Bio; expectations regarding the therapeutic benefits, clinical potential and clinical development of CLYM116; the anticipated timelines for announcing data from Climb Bio's ongoing and planned clinical trials; the anticipated timelines for enrolling patients in planned clinical trials; the anticipated benefits of Climb Bio's technology transfer and exclusive license agreement with Mabworks; and other statements containing the words "anticipate," "continue," "expect," "may," "plan," "potential," "predict," "project," "target," "will," 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 technology transfer and exclusive license agreement with Mabworks; 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 or nonclinical studies; 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; changes in applicable laws or regulations; the possibility that Climb Bio may be adversely affected by other economic, business and/or competitive factors; 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 Current Report on Form 8-K 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 23, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Climb Bio, Inc.

Date: October 23, 2026

By: /s/ Aoife Brennan

Aoife Brennan, M.B., Ch.B.
President and Chief Executive Officer

Exhibit 99.1

Climb Bio and Mabworks Announce CLYM116/MIL116 Data Demonstrating Deep, Durable APRIL Suppression and ~70% Gd-IgA1 Reduction at ASN Kidney Week 2026

>90% free APRIL suppression sustained through 12 weeks, supporting Q12W dosing interval

~70% reduction in Gd-IgA1 at 12 weeks

~33-day half-life

NAVIGATE-2 Phase 2 trial enrolling, with initial data expected in the first half of 2027

Global Phase 3 trial expected to initiate in 2027

WELLESLEY HILLS, USA, and BEIJING, China, October 23, 2026 (GLOBE NEWSWIRE) – Climb Bio, Inc. (Nasdaq: CLYM, "Climb Bio") and Beijing Mabworks Biotech Co., Ltd. ("Mabworks"), today announced additional Phase 1 data in healthy volunteers for CLYM116/MIL116, an anti-APRIL monoclonal antibody (mAb), in development for IgA nephropathy (IgAN). These data were presented at the American Society of Nephrology (ASN) Kidney Week 2026, which is taking place October 21-25, 2026, in Denver, Colorado.

CLYM116/MIL116 is being evaluated in complementary Phase 1 trials in Australia and China. Both are randomized, double-blind, placebo-controlled, ascending-dose studies designed to evaluate safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of subcutaneous (SC) CLYM116/MIL116 in healthy volunteers and enrolled 46 and 42 participants respectively.

Near-complete free APRIL suppression was sustained through 12 weeks following a single SC dose ≥480 mg. Following a single 800 mg dose, ~70% reduction in Gd-IgA1 and ~60% reduction in IgA were observed at 12 weeks. PK was consistent across both studies. Exposure was linear, with no target-mediated drug disposition (TMDD) observed across the effective dose range. Together, these PK and PD data support an every 12-week (Q12W) dosing regimen. CLYM116/MIL116 has been generally well tolerated, with no dose limiting toxicities, treatment-related serious adverse events (SAEs), or hypogammaglobulinemia. The NAVIGATE-2 Phase 2 trial is currently enrolling IgAN patients to confirm the Q12W dosing regimen, and a global Phase 3 trial is expected to initiate in 2027, pending regulatory feedback.

"What excites us most about these two datasets is that they offer complementary validation of what we view as a best-in-class anti-APRIL profile for IgA nephropathy," said Aoife Brennan, M.B., Ch.B., President and Chief Executive Officer of Climb Bio. "CLYM116 was engineered as a sweeper antibody, and we've now seen this mechanism translate into superior *in vivo* potency, extended half-life, and predictable, linear exposure across two, parallel clinical studies. This differentiated pharmacokinetic profile drives deep and durable APRIL suppression, leading to substantial reductions in IgA and Gd-IgA1, a key pathogenic driver of IgAN. Our ability to rapidly generate this body of evidence reflects the strength of our partnership with Mabworks and allows us to accelerate this potentially transformative program into later-stage development."

"We are encouraged by the consistency of the findings across both studies, and we continue to move with urgency to generate data in patients," said Feng Li, Ph.D., Chairman of the Board, Chief Executive Officer and General Manager of Mabworks. "IgA nephropathy affects patients worldwide, carrying a particularly high burden in patients of Asian descent. Clinicians and patients have responded with real enthusiasm to the prospect of a highly effective anti-APRIL therapy with an extended dosing interval, and that enthusiasm has translated into strong enrollment momentum in the NAVIGATE-2 trial. Patient data from this ongoing study will allow us to confirm our target Q12W dosing interval and move a single dosing regimen into Phase 3. Together with Climb Bio, we are planning a global registrational study designed to bring MIL116 to patients across geographies as efficiently as possible."

Key Highlights from the CLYM116/MIL116 presentations:

- **Long half-life:** ~33-day half-life estimated based on 800 mg and 320 mg MAD, 3.5x that reported for sibeprenlimab
- **Predictable PK:**linear clearance across the effective dose range, with no TMDD at doses ≥160 mg, consistent with the sweeper-mediated degradation of APRIL

- **Robust and durable APRIL suppression:** ≥90% free APRIL suppression through the full 12-week dosing interval following a single SC injection at dose levels ≥480 mg
- **Significant Gd-IgA1 and IgA suppression:** ~70% reduction in Gd-IgA1 and ~60% reduction in IgA at 12 weeks, following a single SC injection of 800 mg, the selected loading dose for the NAVIGATE-2 Phase 2 trial
- **Q12W dosing regimen:** PK/PD modeling supports sustained APRIL suppression with Q12W dosing, now being evaluated in patients with IgAN in the NAVIGATE-2 Phase 2 trial
- **Favorable safety and tolerability profile:** Generally well tolerated across all dose levels evaluated (25 mg to 1280 mg) with no dose-limiting toxicities, treatment-related SAEs, or hypogammaglobulinemia
    - Injection site reactions were infrequent, occurring in 5 of 88 participants across both studies; all five were Grade 1 and resolved without intervention
- **Partnership supports accelerated development:** NAVIGATE-2 Phase 2 trial is enrolling, with initial data expected in the first half of 2027; a global Phase 3 trial is anticipated to initiate in 2027, pending regulatory feedback

About IgA Nephropathy (IgAN)
IgA nephropathy (IgAN) is a progressive autoimmune kidney disease characterized by proteinuria, hematuria, and loss of kidney function. Immune complexes formed by abnormal, galactose-deficient IgA*1 (Gd-IgA1)* and the autoantibodies *that target* Gd-IgA1 *deposit* in the glomeruli, causing inflammation and scarring that can lead to chronic kidney disease and kidney failure. IgAN is the most common primary *glomerulonephritis* worldwide, is often diagnosed in young adults, and approximately 200,000 people in the U.S. live with the disease. While recently approved therapies have expanded treatment options, a significant unmet need remains for treatments that address the underlying cause of disease by reducing the production of abnormal pathogenic IgA and associated autoantibodies.

About CLYM116/MIL116
CLYM116/MIL116 is a clinical-stage monoclonal antibody targeting APRIL (A Proliferation-Inducing Ligand), a key driver of pathogenic B-cell activity in autoimmune diseases. CLYM116/MIL116 employs a novel pH-dependent bind-and-release 'sweeper' mechanism to potently 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/MIL116 is being advanced for the treatment of IgA nephropathy (IgAN) and may also have broader utility across other B-cell mediated diseases where APRIL plays a critical role. Climb Bio retains worldwide rights to CLYM116/MIL116 outside of Greater China; Mabworks retains rights in Greater China.

About Climb Bio, Inc.
Climb Bio, Inc. is a clinical-stage biotechnology company with a mission to deliver high impact, disease-modifying medicines for individuals living with immune-mediated diseases, including those affecting kidney health. The Company's pipeline includes, budoprutug, an anti-CD19 monoclonal antibody that has potential to treat a broad range of B-cell mediated diseases, and CLYM116, an anti-APRIL monoclonal antibody being developed for IgA nephropathy. For more information, please visit climbbio.com.

About Beijing Mabworks Biotech Co., Ltd.
Beijing Mabworks Biotechnology Co., Ltd. focuses on the research, development, and industrialization of innovative antibody-targeted therapeutics, and is committed to bringing innovative treatment options to patients with autoimmune diseases and cancer. The Company translates scientific breakthroughs in immunology and biology into novel antibody-targeted therapies, pursuing product development and technological innovation across various autoimmune disease and oncology markets with substantial unmet medical needs and market potential. The Company is a National High-tech Enterprise, a Beijing "Specialized, Refined, Distinctive and Innovative" SME, and hosts a Beijing Key Laboratory and a Beijing Engineering Laboratory, as well as an enterprise postdoctoral research workstation and an academician expert workstation.

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monitoring boards; replicating in clinical trials positive results found in early-stage clinical trials or nonclinical studies; 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; changes in applicable laws or regulation; the possibility that Climb Bio may be adversely affected by other economic, business and/or competitive factors; 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.

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