Climb Bio Reports Third Quarter 2024 Financial Results and Business Highlights

November 12, 2024

Appointed Douglas Williams, Ph.D. as Chair of the Board of Directors

FDA Clearance of Investigational New Drug Application (IND) for systemic lupus erythematosus (SLE)

Expanded Management Team with the Appointment of Gary Hao, Ph.D. as Vice President of Chemistry, Manufacturing and Controls

Highlights Timing of Key Upcoming Milestones

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

WELLESLEY HILLS, Mass., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Climb Bio, Inc. (Nasdaq: CLYM), a clinical stage biotechnology company developing therapeutics for patients with immune-mediated diseases, today reported financial results for the quarter ended September 30, 2024 and provided a business update.

“We have had a very productive third quarter, successfully completing the rebranding and transition of Climb Bio into a leading immune-mediated diseases company,” said Aoife Brennan, President and CEO of Climb Bio. “At our recent investor event, we outlined our development strategy and the broad potential of budoprutug. We have now received U.S. Food and Drug Administration clearance of our IND for our Phase 1b clinical trial of budoprutug in SLE and expanded our board and management team with the appointment of Dr. Doug Williams as Climb Bio's new board Chair and Dr. Gary Hao as Vice President of CMC. With a strong financial position and continued progress towards building our management team, we believe we are well-positioned to develop improved treatments for the approximately 50 million patients in the U.S. and many more globally living with immune-mediated diseases.”

Recent Highlights

- **FDA Clearance of our IND for budoprutug in SLE.** The U.S. Food and Drug Administration (FDA) has cleared the IND allowing Climb Bio to initiate a Phase 1b open label clinical trial of budoprutug in patients with active lupus. The trial is designed to evaluate the safety and impact of ascending dose regimens on the speed and depth of depletion of circulating B cells, the decline in production of pathogenic autoantibodies, and the nature of B cell subsets that are produced upon recovery of B cells. In addition, patients will be followed for changes in clinical outcomes.

- **Continued focus on building a leading immune-mediated disease company.**
  - **Appointed Doug E. Williams, Ph.D. as Chair of the Board of Directors.** Dr. Williams boasts over 30 years of executive leadership experience in the biotechnology sector. Throughout his career, he has held pivotal research and development roles, contributing significantly to the creation of groundbreaking drugs such as Leukine®, Enbrel®, Adcetris®, Tecfidera®, Alprolix®, Eloctate® and Spinraza®. As a CEO, he has successfully guided both private and public companies, from clinical development to commercial success, and has overseen multiple successful mergers. Additionally, he serves as Chair of the Board for both AC Immune SA and a director of Stablix. Dr. Williams holds a Ph.D. from the State University of New York at Buffalo, Roswell Park Division, and completed a postdoctoral fellowship at Indiana University School of Medicine.
  - **Appointed Gary Hao, Ph.D. as Vice President of Chemistry, Manufacturing and Controls (CMC).** Dr. Hao has over 17 years of experience in biopharmaceutical CMC development, from discovery to commercialization. He has extensive regulatory filing experience and has led cross functional teams. Dr. Hao has held similar roles at multiple biotechnology companies, including Vesigen Therapeutics, Codiak BioSciences, TG Therapeutics, and Alkermes. Dr. Hao received a Ph.D. from the Joan & Sanford I. Weill Medical College of Cornell University and a B.S. in Biochemistry from Nakai University.

- **Presented additional data from the Phase 1b study of budoprutug in primary membranous nephropathy (pMN) at the American Society of Nephrology Kidney Week 2024.** The data presented included the complete remission of proteinuria in 3/5 (60%) of patients dosed with budoprutug in the study. In addition, the data showed a 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. All patients in the study who received budoprutug saw a complete and sustained B-cell depletion, 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.

Program Overview and Anticipated Key Milestones

- **pMN:** pMN is an IgG4 mediated disease, affecting approximately 70,000 people. We have completed a Phase 1b trial in pMN and plan to continue the advancement of budoprutug for pMN to late phase development in 2025.
- **Immune Thrombocytopenia (ITP):** 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. We plan to initiate a Phase 2 clinical trial of budoprutug in ITP in the first half of 2025 subject to regulatory clearance.
- **SLE:** 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. Following the FDA clearance of our IND, we plan to initiate a Phase 1b clinical study of budoprutug for SLE in the first half of 2025.
- **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.

Third Quarter Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $217.9 million as of September 30, 2024, as compared to $106.8 million as of December 31, 2023. Cash is expected to fund operations through 2027.
- **Research and Development (R&D) expenses:** R&D expenses were $6.2 million for the three months ended September 30, 2024, compared to $2.9 million for the same period in 2023.
- **General and Administrative (G&A) expenses:** G&A expenses were $5.5 million for the three months ended September 30, 2024, compared to $2.1 million for the same period in 2023.
- **Other income, net:** Other income, net was $2.8 million for the three months ended September 30, 2024, compared to $1.0 million for the same period in 2023.
- **Net loss:** Net loss was $8.9 million for the three months ended September 30, 2024, compared to $4.0 million for the same period in 2023.

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; 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 primary membranous nephropathy, immune thrombocytopenia, and systemic lupus erythematosus 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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Climb Bio, Inc.
Condensed Consolidated Balance Sheets
(In thousands)
(unaudited)

	September 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents, and marketable securities	$ 217,927	$ 106,798
Other assets	4,272	3,671
Total assets	**$ 222,199**	**$ 110,469**
Liabilities and stockholders' equity		
Liabilities	3,423	2,870
Total stockholders' equity	218,776	107,599
Total liabilities and stockholders' equity	**$ 222,199**	**$ 110,469**

Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Acquired in-process research and development, related party	$ —	$ —	$ 51,659	$ —
Research and development	6,240	2,876	8,377	12,284
General and administrative	5,492	2,125	11,073	22,869
Total operating expenses	**11,732**	**5,001**	**71,109**	**35,153**
Loss from operations	(11,732)	(5,001)	(71,109)	(35,153)
Other income, net	2,837	1,033	5,628	3,675
Net loss	**$ (8,895)**	**$ (3,968)**	**$ (65,481)**	**$ (31,478)**
Net loss per share, basic and diluted	$ (0.13)	$ (0.15)	$ (1.57)	$ (1.17)