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

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of February 2025

Commission File Number 001-38807

CHEMOMAB THERAPEUTICS LTD.

(Translation of registrant's name into English)

Kiryat Atidim, Building 7, Tel-Aviv, Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

EXPLANATORY NOTE

On February 19, 2025, Chemomab Therapeutics Ltd. (the “Registrant”) issued a press release titled “Chemomab Completes Successful End-of-Phase 2 Meeting and Aligns with FDA on Clear and Efficient Path to Potential Regulatory Approval for Nebokitug (CM-101) in Primary Sclerosing Cholangitis”, a copy of which is furnished as Exhibit 99.1 herewith.

This Report on Form 6-K and the press release attached as Exhibit 99.1 to this Report on Form 6-K are hereby incorporated by reference into the Registrant’s Registration Statements on Form F-3 (File No. 333-275002 and 333-281750) and Form S-8 (File No. 333-259489 and No. 333-266868).

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
----------------	--------------------

99.1	Press release, dated February 19, 2025, titled "Chemomab Completes Successful End-of-Phase 2 Meeting and Aligns with FDA on Clear and Efficient Path to Potential Regulatory Approval for Nebokitug (CM-101) in Primary Sclerosing Cholangitis"
------	---

SIGNATURE

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, thereunto duly authorized.

CHEMOMAB THERAPEUTICS LTD.

Date: February 19, 2025

By: /s/ Sigal Fattal
Sigal Fattal
Chief Financial Officer



Chemomab Completes Successful End-of-Phase 2 Meeting and Aligns with FDA on Clear and Efficient Path to Potential Regulatory Approval for Nebokitug (CM-101) in Primary Sclerosing Cholangitis

Single Positive Phase 3 Trial Designed to Support Full Regulatory Approval, For the First Time Providing Regulatory Clarity in PSC and Positioning Nebokitug to Potentially Become the First FDA-Approved Treatment for PSC

No Liver Biopsies or Additional Confirmatory Studies Required—Phase 3 Trial Endpoint Is Based on Well-Characterized Clinical Events Associated with PSC Disease Progression

Derisked Phase 3 Program Leverages Published PSC Data Associating Reductions in Clinical Events with the Types of Biomarker Improvements Seen in Nebokitug Phase 2 SPRING Trial

Advancing Discussions with Potential Strategic Partners Post-FDA Feedback While Preparing for Nebokitug Phase 3 Trial

TEL AVIV, Israel - February 19, 2025 - Chemomab Therapeutics Ltd. (Nasdaq: CMMB) (Chemomab), a clinical stage biotechnology company developing innovative therapeutics for fibro-inflammatory diseases with high unmet need, today announced the successful completion of its End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA) and alignment with FDA on the design of a single Phase 3 registration study for its lead product candidate nebokitug (CM-101) for the treatment of primary sclerosing cholangitis (PSC). Nebokitug is the drug name recently assigned to CM-101 by the International Nonproprietary Names (INN) program of the World Health Organization.

“Successful completion of this major milestone is a huge achievement for Chemomab, for patients and for the larger community combatting PSC, a debilitating and often lethal disorder that has no FDA-approved therapies,” said Adi Mor, PhD, co-founder and Chief Executive Officer of Chemomab. “The design of our Phase 3 trial provides, for the first time, regulatory clarity on a streamlined path to potential full regulatory approval based on a single pivotal trial that does not require liver biopsy and includes the most relevant primary efficacy endpoint in PSC. This design allows us to significantly accelerate the potential timeline to full approval since there is no need for additional confirmatory studies. This is also the first time that FDA has agreed to the use of a primary endpoint for PSC comprised of clinical events associated with disease progression, which we and leading experts believe is practical, feasible and well-aligned with clinical practice and the natural history of the disease.”

Dr. Mor continued, “Importantly, key publications have shown that the reductions in PSC biomarkers in our nebokitug Phase 2 SPRING trial, especially the Enhanced Liver Fibrosis (ELF) and liver stiffness elastography measures, are associated with reductions in clinical events, increasing our confidence in the relevance of this approach for nebokitug and decreasing risk. We are looking forward to reporting topline data from the open label extension portion of the SPRING trial, which is primarily intended to provide additional data on nebokitug’s long term safety, before the end of the first quarter. The company is currently in active discussions with potential strategic partners while laying the groundwork for the Phase 3 program, which we could potentially launch before the end of the year.”

Christopher Bowlus, MD, the Lena Valente Professor and Chief of the Division of Gastroenterology and Hepatology at the University of California Davis School of Medicine, commented, “Until now, the pathway to drug approval in PSC has been problematic due to the lack of validated surrogate endpoints and clarity around primary efficacy endpoints for PSC registration trials. This has been a major hinderance to the development of effective therapies for PSC. I am delighted that the FDA and Chemomab have aligned on a

Phase 3 trial design that focuses on the clinical events that we encounter in caring for PSC patients. These events are clinically relevant and impact our patients' lives. The agreed composite endpoint approach for the nebokitug trial enhances our chances of efficiently and accurately identifying the potential clinical benefits of this promising new drug. Our patients with PSC are in urgent need of disease-modifying treatments and I look forward to the launch of the nebokitug Phase 3 trial."

The PSC pivotal trial design is focused on a set of clinically meaningful events that occur over time as the disease progresses. The trial's primary endpoint will assess changes in the time-to-first-event of any one of a number of well-characterized PSC clinical events. Chemomab plans to enroll approximately 350 PSC patients to collect the requisite number of clinical events needed to demonstrate statistically significant changes between the treatment and placebo arms. It is estimated that in the absence of intervention, participants would require on average about two years to experience a clinically-meaningful event. The trial will also capture data on key biomarkers such as elastography, ELF score and cholangiography as additional indicators of clinical outcomes, which allows for possible inclusion of an interim analysis during the study.

Chemomab Chief Medical Officer Matt Frankel, MD, noted, "We are very pleased with the strong engagement and collaborative spirit expressed by FDA during our End-of-Phase 2 meeting. The planned study is an events-driven design that is similar to the approach used in many oncology registration trials. This design eliminates the need for invasive liver biopsies and costly, difficult-to-execute confirmatory studies. The results of this trial could also support ex-U.S. global marketing authorizations. Furthermore, given the potentially disease-modifying activity demonstrated by nebokitug, the focus on disease progression-related events may allow us to achieve a broad label in PSC, in contrast to more limited symptom-related endpoints such as pruritus."

About the Nebokitug Phase 3 Trial for the Treatment of PSC

The trial is a randomized placebo-controlled (2:1 active to placebo ratio) clinical event-driven study. Patients in the active treatment arm will receive 20 mg/kg of nebokitug administered intravenously every three weeks. The primary endpoint is the time-to-first clinical event. The endpoint is a composite encompassing multiple, equally-weighted adverse clinical events associated with PSC disease progression, which may include acute cholangitis, biliary strictures requiring intervention, portal hypertension, hepatic decompensation, elevated MELD score (a measure associated with the need for liver transplant), liver transplantation, cholangiocarcinoma and death. Enrolled patients remain in the trial until they experience an event, and the trial continues until the requisite number of events has been collected. It is estimated that in the absence of intervention, participants would require on average about two years to achieve a clinically meaningful event. Clinical events will be assessed in a blinded fashion by an independent clinical endpoint adjudication committee. Approximately 350 PSC patients will be enrolled in the trial, and the study population will be enriched for patients with moderate and advanced disease. Chemomab expects to leverage the strong relationships with global clinical investigators it developed during its successful Phase 2 SPRING study to facilitate enrollment in the nebokitug pivotal trial.

About Nebokitug (CM-101)

Nebokitug is a first-in-class dual activity monoclonal antibody that neutralizes CCL24, a soluble protein that helps drive the inflammatory and fibrotic pathways central to PSC and other fibro-inflammatory diseases. By inhibiting CCL24, nebokitug blocks both immune cell recruitment and fibroblast activation, thereby interrupting the self-reinforcing fibro-inflammatory cycle that results in fibrosis. In clinical and preclinical studies, nebokitug has been shown to have a favorable safety profile, with the potential to treat multiple severe and life-threatening fibro-inflammatory diseases. Chemomab has reported positive results from four clinical trials of nebokitug in patients, including the Phase 2 SPRING trial in patients with PSC. This study achieved the primary safety endpoint and nebokitug-treated patients with moderate to advanced disease showed improvements on a wide range of disease-related secondary endpoints. A consistent pattern of greater improvement on the secondary endpoints was observed in the study arm receiving the higher 20 mg/kg dose of nebokitug. The open label extension portion of the SPRING trial is continuing, with results expected in the first quarter of 2025. Nebokitug has received FDA and EMA Orphan Drug and FDA Fast Track designations for the treatment of PSC in adults.

About Primary Sclerosing Cholangitis

PSC is a rare, debilitating progressive liver disease characterized by inflammation and fibrosis (scarring) of the bile ducts that can lead to cirrhosis of the liver, liver failure and death. PSC also increases the risk of various cancers, which account for about half of PSC-related mortality. PSC affects an estimated 30,000 patients in the U.S. and about 80,000 worldwide. The underlying cause of PSC is unknown, but about 75% of patients also have inflammatory bowel disease. Liver transplantation is common in end stage disease cases, but even then, PSC re-occurs in about 20% of transplanted patients. With no approved therapies to date, there is a high unmet medical need for new drugs to address the symptoms of PSC and slow or stop the progression of this devastating illness.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release, including statements regarding our future financial condition, results of operations, business strategy and plans, and objectives of management for future operations, as well as statements regarding industry trends, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “estimate,” “intend,” “may,” “plan,” “potentially” “will” or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: the risk that certain acknowledgements from the End-of-Phase 2 (EOP2) meeting with the FDA in connection with PSC regulatory approval will not materialize into a pathway for regulatory approval; that certain conclusions and assumptions drawn from the EOP2 meeting with the FDA discussed in the presentation will prove incorrect and adversely affect the ability for nebokitug to become an FDA fully approved therapy; the risk that the full data set from the nebokitug study or data generated in further clinical trials of nebokitug will not be consistent with the topline results of the nebokitug Phase 2 PSC trial; failure to obtain, or delays in obtaining, regulatory approvals for nebokitug in the U.S., Europe or other territories; failure to successfully commercialize nebokitug, if approved by applicable regulatory authorities, in the U.S., Europe or other territories, or to maintain U.S., European or other territory regulatory approval for nebokitug if approved; uncertainties in the degree of market acceptance of nebokitug by physicians, patients, third-party payors and others in the healthcare community; nebokitug development of unexpected safety or efficacy concerns related to nebokitug; failure to successfully conduct future clinical trials for nebokitug, including due to the Company’s potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval, among other things; risks that the Company’s clinical studies will be delayed or that serious side effects will be identified during drug development; failure of third parties on which the Company is dependent to manufacture sufficient quantities of nebokitug for commercial or clinical needs, to conduct the Company’s clinical trials; changes in laws and regulations applicable to the Company’s business and failure to comply with such laws and regulations; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; and uncertainties with respect to the Company’s need and ability to access future capital; and the intensity and duration of the current war in Israel, and its impact on our operations in Israel. These risks are not exhaustive. You should carefully consider the risks and uncertainties described in the “Risk Factors” sections of our 20-F for the year ended December 31, 2023. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this press release. Before you invest, you should read the documents we have filed and will file with the SEC for more complete information about us. You may get these documents for free by visiting EDGAR on the SEC website at www.sec.gov. This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities law of any such state or jurisdiction.

About Chemomab Therapeutics Ltd.

Chemomab is a clinical stage biotechnology company developing innovative therapeutics for fibro-inflammatory diseases with high unmet need. Based on the unique role of the soluble protein CCL24 in promoting fibrosis and inflammation, Chemomab developed nebokitug (CM-101), a first-in-class dual activity monoclonal antibody that neutralizes CCL24 and has demonstrated disease-modifying potential. In clinical and preclinical studies, nebokitug has been shown to have a favorable safety profile and has been generally well-tolerated, with the potential to treat multiple severe and life-threatening fibro-inflammatory diseases. Chemomab has reported positive results from four clinical trials of nebokitug in patients. Based on recent positive data from its Phase 2 SPRING trial in primary sclerosing cholangitis (PSC), the company is preparing for potential initiation of a PSC nebokitug Phase 3 pivotal trial. Data from the SPRING trial open label extension will be reported in the first quarter of 2025. Nebokitug has received FDA and EMA Orphan Drug and FDA Fast Track designations for the treatment of PSC. Chemomab's nebokitug program for the treatment of systemic sclerosis has an open U.S. IND. For more information, visit: chemomab.com.

Contacts:

Media and Investors:

Barbara Lindheim
Consulting Vice President, Investor & Public Relations,
Strategic Communications
Phone: +1 917-355-9234
barbara.lindheim@chemomab.com
IR@chemomab.com
