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): April 23, 2026

Connect Biopharma Holdings Limited

(Exact name of Registrant as Specified in Its Charter)

Cayman Islands	**001-40212**	**Not Applicable**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3580 Carmel Mountain Road, Suite 200	
San Diego, California	**92130**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (877) 245-2787

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**
Ordinary Shares, par value $0.000174 per Share	CNTB	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 7.01 Regulation FD Disclosure.

On April 23, 2026, the Company issued a press release announcing that the independent Data Monitoring Committee overseeing its Phase 2 Seabreeze STAT asthma and COPD trials evaluating rademikibart, the Company's next-generation, potentially best-in-class anti-interleukin-4-receptor alpha (IL-4Rα) antibody (the "DMC"), has completed its review of the pre-specified interim analysis of efficacy with no recommendation for change in sample size. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01, including Exhibit 99.1, 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 or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On April 23, 2026, the Company issued a press release announcing that the DMC has completed its review of the pre-specified interim analysis of efficacy with no recommendation for change in sample size.

Forward-Looking Statements

This disclosure, including the press release furnished herewith as Exhibit 99.1, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "plan," "potential," "aim," "expect," "anticipate," "promising" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this Current Report on Form 8-K. Forward-looking statements contained herein include, but are not limited to, statements regarding the Company's strategy and plans, the potential clinical effects, benefits, safety and efficacy of rademikibart, the timing, nature and significance of enrollment and data from the Company's trials evaluating rademikibart, the timing of any further releases of data or of any presentations or investor conference calls, statements regarding any interim analysis or interim, topline or preliminary data and whether the same is indicative of safety, efficacy, final trial results or likelihood of regulatory approval for our product candidates, the Company's plans and expectations for its asthma and COPD program, and risks and uncertainties associated with drug development and commercialization. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data or results observed during clinical trials or in data readouts; the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; difficulties in collaborating with other companies; successful development and/or commercialization of alternative product candidates by the Company's competitors; changes in expected or existing competition; delays in or disruptions to the Company's business or clinical trials due to geopolitical changes or other external factors; and unexpected litigation or other disputes. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements herein are discussed in the Company's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein, including in our annual report on Form 10-K for the year ended December 31, 2025, and any subsequent filings with the SEC. Except as required by law, the Company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated April 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.

CONNECT BIOPHARMA HOLDINGS LIMITED

Date: April 23, 2026

By: /s/ David Szekeres

Name: David Szekeres

Title: President

Connect Biopharma Announces Enrollment in Phase 2 Seabreeze STAT Studies Will Continue as Planned Following Pre-Specified Interim Analysis

– Expect to report topline data from both studies mid-2026 –

SAN DIEGO, April 23, 2026 (GLOBE NEWSWIRE) -- Connect Biopharma Holdings Limited (Nasdaq: CNTB) (Connect Biopharma, Connect or the Company), a clinical-stage biopharmaceutical company focused on transforming care for the treatment of inflammatory diseases, today announced that the independent Data Monitoring Committee (DMC) overseeing its Phase 2 Seabreeze STAT asthma and COPD trials evaluating rademikibart, the Company's next-generation, potentially best-in-class anti-interleukin-4-receptor alpha (IL-4Rα) antibody, has completed its review of the pre-specified interim analysis of efficacy with no recommendation for change in the sample size.

"Based on the DMC's review of interim efficacy results from our ongoing Seabreeze STAT acute asthma and COPD studies, enrollment will continue as planned with no change in sample size," said Barry Quart, Pharm.D., CEO and Director of Connect Biopharma. Rademikibart continues to be well tolerated in these studies of patients experiencing acute exacerbations. We continue to believe that rademikibart has the potential to deliver differentiated efficacy and safety in patients with type 2 asthma and COPD experiencing acute exacerbations. We remain on track to report topline results from both Seabreeze STAT studies mid-year."

The independent DMC reviewed interim data based on a pre-specified analysis of treatment failure at 28 days, the rate of new exacerbations through 28 days, and the change from baseline in FEV_1 following treatment of a minimum of 50 patients in each study with at least 28 days of follow-up.

The DMC also conducts a review of the safety data for both studies on a regular basis and indicated that it has no safety concerns. To date, there have been no treatment-related serious adverse events or severe adverse events, and no discontinuations due to an adverse event in either study.

Connect expects to report topline data from both ongoing Phase 2 Seabreeze STAT studies of rademikibart for acute exacerbations of asthma and of COPD in mid-2026 and plans to move quickly to meet with the U.S. Food and Drug Administration (FDA) to gain alignment on a Phase 3 program.

About Rademikibart

Rademikibart is a fully human monoclonal antibody targeting interleukin-4 receptor alpha (IL-4Rα), a common subunit of interleukin-4 receptor (IL-4) and interleukin-13 receptor (IL-13). We believe that by binding with IL-4Rα, rademikibart can block the functions of IL-4 and IL-13 effectively, thereby blocking the T helper 2 (Th2) inflammatory pathway to achieving the goal of treating Th2 related inflammatory diseases such as atopic dermatitis, asthma and COPD.

About Connect Biopharma

Connect Biopharma is a clinical-stage biopharmaceutical company dedicated to transforming care for asthma and COPD. Headquartered in San Diego, California, the Company is advancing rademikibart, a next-generation, potentially best-in-class antibody designed to target IL-4Rα. The Company is currently conducting global clinical studies of rademikibart for the treatment of acute exacerbations of asthma and COPD, areas with significant unmet need. Connect has granted an exclusive license to Simcere Pharmaceutical Co., Ltd., for rademikibart in Greater China. Under the exclusive license and collaboration agreement, Connect is eligible to receive remaining milestone payments up to an aggregate amount of approximately $110 million upon the achievement of certain development, regulatory and commercial milestones. Connect is also eligible to receive royalties at tiered percentage rates up to low double-digit percentages on net sales in Greater China.

For more information visit www.connectbiopharma.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended (the Act). Forward-looking statements are statements that are not of historical fact and include, without limitation, statements regarding future events, our future financial condition, results of operations, business strategy and plans, prospective products (as well as their potential to achieve a differentiated, competitive, or favorable benefit or profile or trend, including on safety, tolerability, improvement, maintenance, clinical response, dosing, efficacy and/or convenience), statements regarding any interim analysis or interim, topline or preliminary data and whether the same is indicative of safety, efficacy, final trial results or likelihood of regulatory approval for our product candidates, planned or expected product approval applications or approvals, anticipated milestones and royalties, expected data readouts and enrollments, research and development plans and costs, potential future partnerships, expectations about existing partnerships, timing and likelihood of success, objectives of management for future operations, future results of anticipated product development efforts, adequacy of existing cash and potential partnership funding to fund operations and capital expenditure requirements, anticipated patient populations or market opportunities for our prospective products, if approved, as well as statements regarding industry trends. These statements are based on management’s current expectations of future events only as of the date of this press release and are inherently subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond our control, including, among other things: the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results; whether we or our current or future partners will need expanded or additional trials in order to obtain regulatory approval for our product candidates; the timing and results of any planned interactions with the FDA; our ability to obtain and maintain regulatory approval of our product candidates; existing regulations and regulatory developments in the U.S., the People’s Republic of China, Europe and other jurisdictions; the ability of our current cash and investments position to support planned operations; our plans and ability to obtain, maintain, protect and enforce our intellectual property rights and our proprietary technologies, including extensions of existing patent terms where available; our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials; and the degree of market acceptance of our product candidates, if approved, by physicians, patients, healthcare payors and others in the medical community.

Words such as “aim,” “anticipate,” “believe,” “could,” “expect,” “feel,” “goal,” “intend,” “may,” “optimistic,” “plan,” “potential,” “promising,” “will,” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. The inclusion of forward-looking statements should not be regarded as a representation by Connect Biopharma that any of its expectations, projections or plans will be achieved. Actual results may differ materially due to the risks and uncertainties inherent in our business and other risks described in our filings with the U.S. Securities and Exchange Commission (SEC). Further information regarding these and other risks is included under the heading “Risk Factors” in our annual and periodic reports filed with the SEC. These forward-looking statements should not be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such forward-looking statements have been made are correct or exhaustive or, in the case of the assumptions, fully stated in this press release. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You are cautioned not to place undue reliance on the scientific data presented or these forward-looking statements, which speak only as of the date of this press release. Except as required by law, Connect Biopharma undertakes no obligation to publicly update any forward-looking statements, whether because of new information, future events or otherwise. Connect Biopharma claims the protection of the safe harbor for forward-looking statements contained in the Act for all forward-looking statements.

This press release discusses our product candidate, rademikibart, which is under clinical investigation and has not yet been approved for marketing by the FDA, the National Medical Products Administration, or by any other regulatory agency. No representation is made as to the safety or effectiveness of rademikibart for the uses for which it is being studied. The trademarks included herein are the property of the owners thereof and are used for reference purposes only.

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