

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): August 12, 2026

Connect Biopharma Holdings Limited
(Exact name of Registrant as Specified in Its Charter)

Cayman Islands
(State or Other Jurisdiction
of Incorporation)

001-40212
(Commission File Number)

Not Applicable
(IRS Employer
Identification No.)

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

92130
(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 2.02 Results of Operations and Financial Condition.

On August 12, 2026, Connect Biopharma Holdings Limited (the “Company”) issued a press release announcing its financial results for the three and six months ended June 30, 2026. A copy of the press release is attached hereto 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 2.02, including the attached Exhibit 99.1, 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 made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated August 12, 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: August 12, 2026

By: /s/ Lisa Peraza

Name: Lisa Peraza

Title: Senior Vice President, Finance

Connect Biopharma Reports Second Quarter 2026 Financial Results and Provides Business Update

- Completed enrollment in Phase 2 Seabreeze STAT studies for acute exacerbations in asthma and COPD –
- Expect to report topline results from both Phase 2 Seabreeze STAT studies in September 2026 –
- Cash runway expected for a period of at least one year from the date of this release –

SAN DIEGO, AUGUST 12, 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 reported financial results for the three and six months ended June 30, 2026, and provided a business update.

“During the second quarter, we achieved important milestones with the completion of enrollment in both our Phase 2 Seabreeze STAT asthma and chronic obstructive pulmonary disease (COPD) studies. With topline results on track for September 2026, we are approaching a key inflection point with randomized, controlled data of rademikibart in patients experiencing an acute exacerbation,” said Barry Quart, Pharm.D., CEO and Director of Connect Biopharma. “These studies are powered to evaluate the rate of treatment failure over 28 days and will also assess improvement in lung function, providing important insight into rademikibart’s potential to benefit patients in this critical period after an exacerbation. Improved lung function and reduced treatment failure would support rademikibart’s potential to address this significant unmet need for patients. Following these topline readouts, we plan to engage with the U.S. Food and Drug Administration (FDA) on a potential Phase 3 program. Supported by a cash runway expected to extend at least one year from the date of this release, we believe that we are well positioned to begin executing the next phase of development.”

Recent Highlights

Development Highlights

- Completed enrollment of the Phase 2 Seabreeze STAT asthma and COPD studies evaluating the safety and efficacy of rademikibart as an adjunct treatment for acute exacerbations. Topline data from both studies are expected in September 2026, which should help determine a potential Phase 3 endpoint and sample size requirements.
 - Following topline results, the Company plans to meet with the FDA to gain alignment on a Phase 3 program.
- In August 2026, the Company initiated the Phase 2 Seabreeze STAT IV study, an open-label, single-arm trial to evaluate intravenous (IV) rademikibart as an add-on treatment for an acute exacerbation in 40 participants with asthma or COPD with type 2 inflammation who require an urgent healthcare visit, similar to the Phase 2 Seabreeze STAT asthma and COPD studies. The Seabreeze STAT IV study is being conducted at a number of the same clinical sites that completed the Seabreeze STAT asthma and COPD studies and is designed to bridge 600 mg subcutaneous to 300 mg IV push administration for treating acute exacerbations.

Financial Results for the Three and Six Months Ended June 30, 2026

- Cash, cash equivalents and short-term investments were \$31.5 million as of June 30, 2026. Based on the Company's current operating plan and projections, the Company believes that its cash, cash equivalents and short-term investments will be sufficient to meet its anticipated cash requirements for a period of at least one year from the date of this release.
- License and collaboration revenues related to the license agreement with Simcere, under which Simcere has been granted exclusive rights to develop, manufacture, and commercialize rademikibart for all indications in Greater China, including mainland China, Hong Kong, Macau, and Taiwan. License and collaboration revenues for the three and six months ended June 30, 2026 were \$2.8 million and \$2.9 million, respectively, and were primarily related to the achievement of a regulatory-based milestone, net of development cost sharing. License and collaboration revenues for both the three and six months ended June 30, 2025 were \$48,000 for cost reimbursements for clinical materials. As a part of the Simcere license agreement, Connect is eligible to receive remaining milestone payments up to an aggregate amount of approximately \$99 million upon the achievement of certain development, regulatory and commercial milestones.
- Research and development expense for the three and six months ended June 30, 2026 was \$16.3 million and \$31.3 million, respectively, compared with \$8.8 million and \$15.4 million, respectively, for the same periods in 2025. The increase in research and development expense was primarily due to an increase in rademikibart-related development costs as a result of the initiation of the Phase 2 Seabreeze STAT asthma and COPD studies in May 2025.
- General and administrative expense for the three and six months ended June 30, 2026 was \$4.1 million and \$8.8 million, respectively, compared with \$4.7 million and \$9.5 million, respectively, for the same periods in 2025. The decrease in general and administrative expense was primarily due to a decrease in professional fees, as the prior year periods included one-time professional fees to support our efforts to become more U.S.-centric, partially offset by an increase in non-cash, share-based compensation expense.
- Net loss for the three and six months ended June 30, 2026 was \$17.3 million, or (\$0.27) per share, and \$36.7 million, or (\$0.61) per share, respectively, compared with \$12.9 million, or (\$0.23) per share, and \$23.2 million, or (\$0.42) per share, respectively, for the same periods in 2025.

About the Seabreeze STAT Asthma Study

Seabreeze STAT Asthma is a Phase 2, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of rademikibart as an adjunct to standard of care for acute exacerbations in adult and adolescent participants with asthma and type 2 inflammation. The study has enrolled 160 participants globally with an eosinophil count of ≥ 300 cells/ μ L who have experienced an acute asthma exacerbation. Participants received either a single dose of rademikibart or placebo, administered subcutaneously. The primary endpoint is treatment failure rate over 28 days following an acute exacerbation. The key secondary endpoint is post-bronchodilator (post-BD) forced expiratory volume in one second (FEV₁) at Week 1. Other secondary endpoints include rate and time to new asthma exacerbations, change-from-baseline in asthma symptom score and nocturnal awakenings, post-BD FEV₁ at other timepoints, and incidence of adverse events for 8 weeks after dosing. For more information, please visit clinicaltrials.gov (identifier NCT06940141).

About the Seabreeze STAT COPD Study

Seabreeze STAT COPD is a Phase 2, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of rademikibart as an adjunct to standard of care for acute exacerbations in participants with COPD and type 2 inflammation. The study has enrolled 159 participants globally with an eosinophil count of ≥ 300 cells/ μ L who have experienced an acute COPD exacerbation. Participants received either a single dose of rademikibart or placebo, administered subcutaneously. The primary endpoint is treatment failure rate over 28 days following an acute exacerbation. The key secondary endpoint is post-BD FEV₁ at Week 1. Other secondary endpoints include rate and time to new moderate and severe COPD exacerbations, change-from-baseline in clinical respiratory symptoms of COPD, post-BD FEV₁, at other timepoints, and incidence of adverse events for 8 weeks after dosing. For more information, please visit clinicaltrials.gov (identifier NCT06940154).

About Rademikibart

Rademikibart is a fully human monoclonal antibody targeting interleukin-4 receptor alpha (IL-4R α), a common subunit of interleukin-4 receptor (IL-4) and interleukin-13 receptor (IL-13). We believe that by binding with IL-4R α , 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-4R α . 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 \$99 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. Forward-looking statements are statements that are not of historical fact and include, without limitation, statements regarding future events, our cash balance and cash runway, financial guidance, future financial and operating results and related expectations, 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 the timing or results of any interim analysis or interim, topline or preliminary data and whether such analysis or data is indicative of safety, efficacy, final trial results or likelihood of regulatory approval for our product candidates, planned or expected meetings with the FDA or any other regulatory authorities, planned or expected product approval applications or approvals, anticipated milestones and milestone payments, expected data readouts and enrollments and the timing thereof, 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, market opportunities and potential pricing strategies for our prospective products, if approved, our plans for rademikibart, including potential indications, 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 sufficiency of our current cash, cash equivalents and short-term investments to fund our operations for a period of at least one year from the date of this release; the timing and amount of actual expenses, including, without limitation, our anticipated combined U.S. GAAP R&D and G&A expenses; the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results; whether we will need expanded or additional trials in order to obtain regulatory approval for our product candidates; the timing and outcome of any meetings with the FDA or other regulatory authorities regarding further development of our product candidates, including with respect to a potential Phase 3 program for rademikibart; whether the National Medical Products Administration (NMPA) approves Simcere's pending New Drug Application for rademikibart for atopic dermatitis in China; 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; 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; the degree of market acceptance of our product candidates, if approved, by physicians, patients, healthcare payors and others in the medical community; the impact on our business of adverse global macroeconomic and geopolitical conditions, including high interest rates, the inflationary environment, recessionary fears, foreign exchange rate volatility, instability in financial institutions, government shutdowns, changes in monetary policy, changes in trade policies, including tariffs and other trade restrictions or the threat of such actions, and rising geopolitical instability, including the conflicts in the Middle East and the related volatility in the price of oil and other commodity prices; as well as the risks and uncertainties described in Part I, "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2025, our subsequent Quarterly Reports on Form 10-Q and our other filings with the SEC. Words such as "aim," "anticipate," "believe," "commitments," "continue," "could," "design," "estimate," "expect," "feel," "goal," "intend," "may," "might," "objective," "optimistic," "plan," "potential," "predict," "promising," "seek," "should," "target," "will," "would," 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 or outcomes, or the timing of such results or outcomes, may differ materially from those expressed or implied in our forward-looking statements due to the risks and uncertainties described above. 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 herein. 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 hereof. 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.

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 NMPA, 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.

Connect Biopharma Holdings Limited
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
License and collaboration revenues	\$ 2,768	\$ 48	\$ 2,937	\$ 48
Operating expenses:				
Research and development expense	16,273	8,773	31,303	15,406
General and administrative expense	4,099	4,699	8,845	9,513
Total operating expenses	20,372	13,472	40,148	24,919
Loss from operations	(17,604)	(13,424)	(37,211)	(24,871)
Total other income, net	380	580	637	1,809
Net loss before income tax	(17,224)	(12,844)	(36,574)	(23,062)
Income tax expense	60	55	108	109
Net loss	\$ (17,284)	\$ (12,899)	\$ (36,682)	\$ (23,171)
Basic and diluted net loss per ordinary share	\$ (0.27)	\$ (0.23)	\$ (0.61)	\$ (0.42)
Weighted-average ordinary shares outstanding, basic and diluted	62,884	55,498	59,732	55,426

Connect Biopharma Holdings Limited
Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	June 30, 2026		December 31, 2025	
Cash, cash equivalents and short-term investments	\$	31,486	\$	44,342
Total assets	\$	43,472	\$	56,075
Total shareholders' equity	\$	26,861	\$	41,980

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