
**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 December 2022

Commission File Number: 001-40212

Connect Biopharma Holdings Limited
(Translation of registrant's name into English)

12265 El Camino Real, Suite 350
San Diego, CA 92130(Address of principal executive office)

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

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On December 30, 2022, Connect Biopharma Holdings Limited (the “Company”) provided a business and clinical development program update.

The Company disclosed that it had determined, in light of the current macroeconomic climate and challenging funding environment, to commence its Global Phase 3 program for CBP-201 in moderate-to-severe atopic dermatitis (“AD”) after it has secured the partnership necessary to fully complete the program.

Based on this development, the Company anticipates its cash and investments will enable it to meet milestones for its ongoing clinical trials and advance its preclinical assets toward the clinic, while it continues to evaluate partnership opportunities.

The status of the Company’s pivotal CBP-201 AD trial in China remains on track. In October 2022, the Company announced positive topline Stage 1 data on the primary analysis population of 255 patients and is currently conducting the 36-week Stage 2 period, which includes a potentially differentiated once a month dose regimen. The Company expects to have pre-New Drug Application (“NDA”) interactions with the Center for Drug Evaluation of the Chinese National Medical Products Administration in the first quarter of 2023 to discuss the Company’s CBP-201 data package.

The information in the paragraphs above under “Information Contained in this Report on Form 6-K” in this Report on Form 6-K is hereby incorporated by reference into the Company’s Registration Statements on Form F-3 (File No. 333- 264340) and Form S-8 (File No. 333-266006).

On December 30, 2022, the Company issued the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

The furnishing of the attached press release is not an admission as to the materiality of any information therein. The information contained in the press release is summary information that is intended to be considered in the context of more complete information included in the Company’s filings with the Securities and Exchange Commission (the “SEC”) and other public announcements that the Company has made and may make from time to time. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing or furnishing of other reports or documents with the SEC or through other public disclosures.

Forward-Looking Statements

The Company cautions that statements included in this report that are not a description of historical facts are forward-looking statements. Words such as “may,” “could,” “will,” “would,” “should,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “intend,” “predict,” “seek,” “contemplate,” “potential,” “continue” or “project” or the negative of these terms or other comparable terminology are intended to identify forward-looking statements. These statements include the Company’s expectations with respect to how long its current cash position will support its operation needs and capital expenditure requirements, the Company’s plans to advance the development of its product candidates, the Company’s ability to out-license any of its product candidates or to obtain partnership funding for any of its development programs, the timing of achieving any development or regulatory milestones, and the potential of such product candidates, including to achieve any benefit or profile or any product approval. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in the Company’s business and other risks described in the Company’s filings with the SEC, including the Company’s Annual Report on Form 20-F filed with the SEC on March 31, 2022, and its other reports. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to revise or update this report to reflect events or circumstances after the date hereof. Further information regarding these and other risks is included in the Company’s filings with the SEC which are available from the SEC’s website (www.sec.gov) and on the Company’s website (www.connectbiopharm.com) under the heading “Investors.” All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Exhibit Index

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| Exhibit 99.1 | Press release dated December 30, 2022: Connect Biopharma Provides Business and Clinical Development Program Update |

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, thereunto duly authorized.

Dated: December 30, 2022

CONNECT BIOPHARMA HOLDINGS LIMITED

By /s/ Steven Chan

Name: Steven Chan

Title: Chief Financial Officer



Connect Biopharma Provides Business and Clinical Development Program Update

Cash runway now expected to extend into at least 2025 as a result of revised timeline of global Phase 3 program of CBP-201 in atopic dermatitis (AD); Longer cash runway permits continued evaluation of potential partnership opportunities to advance the global AD Phase 3 program

Progress of China pivotal AD trial remains on track with completion of 36-week Stage 2 expected in H2 2023

SAN DIEGO and TAICANG, SUZHOU, China – December 30, 2022 – Connect Biopharma Holdings Limited (Nasdaq: CNTB) (Connect Biopharma or the Company), a global clinical-stage biopharmaceutical company developing T cell-driven therapies to treat inflammatory diseases, today provided a business update for its operations and clinical trial development programs.

“We continue to have great confidence in our global development strategy, and particularly in the potential of our lead product candidate, CBP-201, which is currently in development to treat atopic dermatitis and asthma,” said Zheng Wei, PhD, Co-Founder and CEO of Connect Biopharma. “Yet, in light of the current macroeconomic climate and challenging funding environment, we feel that it is necessary and financially prudent to commence our Global Phase 3 program for CBP-201 in moderate-to-severe AD after we have secured the partnership necessary to fully complete the program. The CBP-201 Global Phase 3 program in AD was to commence before the end of the year, and our ongoing pivotal AD trial in China is unaffected and remains on track.”

“With this change in timing for our Global Phase 3 program in AD, we expect our cash runway, without taking into account any additional funding, to extend into at least 2025-more than a year longer than previously forecasted-which is meaningful, particularly under current capital market conditions,” said Steven Chan, CFO of Connect Biopharma. “We anticipate that this longer runway will allow us to meet the milestones for our ongoing clinical trials and advance our preclinical assets toward the clinic, while we continue to evaluate partnership opportunities.”

The Company is actively seeking potential global and regional partners who would be able to provide additional experience and infrastructure to support the next phase of clinical development for CBP-201, including providing potential input into the clinical trial designs that furthers Connect Biopharma’s goal of delivering a differentiated therapeutic program with improved efficacy and dosing convenience. Partnership efforts focus on CBP-201’s potential not only in AD, but also in other disease indications with significant unmet need including asthma, which is in Phase 2, and for which the Company expects to report topline results during the second half of 2023.

CBP-201 Pivotal AD trial in China

In October 2022, Connect Biopharma announced positive topline Stage 1 data on the primary analysis population of 255 patients and is currently conducting the 36-week Stage 2 period, which importantly, includes a potentially differentiated once a month dose regimen. The Company expects to have pre-New Drug Application (NDA) interactions with the Center for Drug Evaluation (CDE) of China’s National Medical Products Administration in the first quarter of 2023 to discuss the Company’s CBP-201 data package for a potential NDA filing as early as 2024 and potential approval in China as early as 2025.

CBP-307 Phase 2 trial in moderate-to-severe Ulcerative Colitis (UC)

The Company also anticipates completing the global Phase 2 maintenance phase for CBP-307 in the first half of 2023. The Company reported efficacy data in May 2022 for the 12-week induction phase of the trial showing CBP-307 0.2 mg once daily administration led to a significantly higher number of patients compared to placebo achieving clinical remission based on adapted Mayo score. The Company is actively seeking to out-license CBP-307 for future trials in UC and Crohn's disease to capitalize on its potential to be a competitive asset and a welcome addition to the gastroenterologist's treatment armamentarium.

CBP-174 in Pruritus associated with AD

The Company previously reported results from its Phase 1 single ascending dose study for CBP-174 in pruritus associated with AD and is continuing to evaluate next steps for clinical development.

Anticipated 2023 Milestones

- **CBP-201 Pivotal China trial in AD:** On track to engage with the CDE in the first quarter of 2023. Anticipate 36-week Stage 2 completion in the second half of 2023
- **CBP-201 in Asthma:** Anticipate completing enrollment for the global Phase 2 trial in the first half of 2023 and reporting top-line results in the second half of 2023
- **CBP-307 in UC:** Anticipate completing Phase 2 maintenance phase and reporting the results in the first half of 2023

About Connect Biopharma Holdings Limited

Connect Biopharma is a U.S. and China-based clinical-stage biopharmaceutical company dedicated to improving the lives of patients with inflammatory diseases through the development of therapies derived from T cell research. The Company is building a rich pipeline of proprietary small molecules and antibodies, using functional T cell assays, to screen and discover potent product candidates against validated immune targets. The Company's lead product candidate, CBP-201, is an antibody designed to target interleukin-4 receptor alpha in development for the treatment of atopic dermatitis and asthma. The Company's second most advanced product candidate, CBP-307, is a modulator of S1P1 T cell receptor and is in development for the treatment of ulcerative colitis. The Company's third product candidate, CBP-174, is a peripherally acting antagonist of histamine receptor 3, in development for the treatment of pruritus associated with atopic dermatitis.

For more information, please visit: <https://www.connectbiopharm.com/>

Forward-Looking Statements

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