

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): **October 26, 2023**

Catalyst Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

000-51173
(Commission File Number)

56-2020050
(IRS Employer Identification No.)

12730 High Bluff Drive
Suite 250
San Diego, CA
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: **(650) 266-8674**

N/A
(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

- 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
Common Stock	CBIO	The Nasdaq Capital 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 October 26, 2023, GNI Group Ltd. (“GNI Japan”) issued a press release announcing that Beijing Continent Pharmaceuticals Co., Ltd., of which GNI Japan holds an indirect controlling interest, completed the subject enrollment of its Phase III clinical trial in China of F351 (Hydronidone) for hepatitis B virus-induced liver fibrosis.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be “filed” for purposes of Section 18 of 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 Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Forward Looking Statements

This report and the press release attached as an exhibit contain statements that pertain to future conditions and events and that are not historic facts are forward-looking statements. Forward-looking statements may include, but are not limited to, words such as “believe,” “plan,” “strategy,” “expect,” “forecast,” “possibility” and similar words that describe future operating activities, business performance, events or conditions, including expectations relating to the performance or effectiveness of F351. Forward-looking statements, whether spoken or written, are based on judgments based on information that is currently available. As such, these forward-looking statements are subject to various risks and uncertainties, and actual business results may vary substantially from the forecasts expressed or implied in forward- looking statements. Consequently, investors are cautioned not to place undue reliance on forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.* The following exhibits are being furnished herewith:

Exhibit Number	Exhibit Title or Description
99.1	Press Release, dated October 26, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

CATALYST BIOSCIENCES, INC.

Date: **October 27, 2023**

By: /s/ Nassim Usman, Ph.D.

Name: Nassim Usman, Ph.D.

Title: President and Chief Financial Officer



October 26, 2023

Company Name: GNI Group Ltd.
Representative: Director, Representative Executive Officer,
President and CEO Ying Luo, PhD
(Security Code: 2160, TSE Growth)
Contact Person: Chief Financial Officer
Toshiya Kitagawa
(TEL. 03-6214-3600)

Subject Enrollment Completed in F351 Phase III Clinical Trial

GNI Group Ltd., (TSE Growth listed code: 2160; “GNI” or “the Company”; “we” or “the Group” including our subsidiaries and affiliates) today announced that Beijing Continent Pharmaceuticals Co., Ltd. (“BC”), one of its core subsidiaries, completed the subject enrollment of Phase III clinical trial in China of F351 (generic name: Hydronidone) for HBV- induced liver fibrosis. The clinical study aims to confirm the efficacy of F351 in treating liver fibrosis associated with chronic hepatitis B (CHB) and to continue to observe its safety. As previously disclosed, China National Medical Products Administration (NMPA) designated F351 as a “Breakthrough Therapy” in 2021, and F351 forms a core of our future drug pipeline. The completion of the registration was achieved more than two months ahead of our initial expectation, thanks to the cooperation of not only the Group but also many others, and we believe that this shows the high expectations for F351 in China.

The completion of this registration is very important for the commercial launch of F351, and the entire group will work together to bring the product to market as soon as possible.

As disclosed on October 24, 2023, BC will become a subsidiary of Catalyst Biosciences, Inc. (“CBIO”). After becoming a subsidiary of CBIO, there will be no change to the fact that it will continue to be fully consolidated by the Group.

Please refer to BC’s press release below for more details.

<https://www.bjcontinent.com/en/news>

After a 52-week data collection period, Beijing Continent plans to publish top-line data and, if the results are as favorable as expected, submit an application to the Chinese authorities for marketing in China. The safety profile of the drug has so far been satisfactory and comparable to that of the Phase II clinical trial in China.

The impact of this news on the Company’s consolidated financial results for the current fiscal year is immaterial.

About F351 (generic name: Hydronidone):

F351 is a New Chemical Entity (NCE) derivation of ETUARY®, which inhibits hepatic stellate cell proliferation and TGF-β signaling pathway, both of which play major roles in the fibrosis of internal organs. BC holds the key patent rights for F351 in mainland China, while Catalyst Biosciences, Inc., an equity method affiliate of the Company, holds its rights in the other countries.

This material contains statements concerning the current plans, expectations and strategies of GNI Group Ltd. (“the Company”). Any statements contained herein that pertain to future operating performance and that are not historic facts are forward-looking statements. Forward-looking statements may include, but are not limited to, words such as “believe,” “plan,” “strategy,” “expect,” “forecast,” “possibility” and similar words that describe future operating activities, business performance, events or conditions. Forward-looking statements, whether spoken or written, are based on judgments made by the management of the Company, based on information that is currently available to it. As such, these forward-looking statements are subject to various risks and uncertainties, and actual business results may vary substantially from the forecasts expressed or implied in forward- looking statements. Consequently, investors are cautioned not to place undue reliance on forward-looking statements.

The information contained in this material does not constitute or form part of any offer for sale or subscription of or solicitation or invitation of any offer to buy or subscribe for any securities, nor shall it or any part of it form the basis of or be relied on in connection with any contract or commitment whatsoever. Any decision to invest in or acquire securities of the Company must be based wholly on the information contained in the preliminary offering circular issued or to be issued by the Company in connection with any such offer and not on the contents hereof.
