

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): **March 20, 2023**

Catalyst Biosciences, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-51173
(Commission File Number)

56-2020050
(IRS Employer Identification No.)

611 Gateway Blvd
Suite 120
South San Francisco, CA
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's telephone number, including area code: **(650) 871-0761**
Not Applicable
(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 March 20, 2023, Dr. Nassim Usman, on behalf of Catalyst Biosciences, Inc. (the “Company”), gave a presentation (the “Corporate Presentation”). In addition, the Company posted the Corporate Presentation on its website, ir.catalystbiosciences.com. A copy of the Corporate Presentation is attached hereto as Exhibit 99.1.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and 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. The information in this Current Report shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Description
99.1	Catalyst Biosciences March 20, 2023 Corporate Presentation Slide Deck.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

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.

CATALYST BIOSCIENCES, INC.

Date: March 20, 2023

By: /s/ Nassim Usman, Ph.D.
Nassim Usman, Ph.D.
President and Chief Executive Officer

CATALYST BIOSCIENCES

Corporate Presentation
20 March 2023

CatalystBiosciences.com

Cautionary Note Regarding Forward-Look

This presentation contains “forward-looking statements” within the meaning of the Securities Act of 1933. Forward-looking statements involve substantial risks and uncertainties and are based on estimates and assumptions. While we believe that our forward-looking statements are reasonable as of the date of this presentation, all statements included in this presentation are without limitation, the amount and timing of planned cash distributions under the (“CVR”); expectations regarding the proposed transactions with entities and Beijing Continent Pharmaceuticals Co. Ltd. (“Beijing Continent”), the expected results of the proposed transaction; the potential market opportunity for and expected prevalence of nonalcoholic steatohepatitis (“NASH”) and liver fibrosis; the safety and tolerability of Hydronidone (F351) in NASH and liver fibrosis; the safety and tolerability of the association of clinical data with potential clinical benefit; and statements regarding our plans and expectations regarding, Beijing Continent’s programs. In some cases, you can identify forward-looking statements by the use of words such as “anticipate,” “design,” “expect,” “potential,” “plan,” or the negative of these words, or by the use of phrases such as “may,” “could,” “intend,” “estimate,” “believe,” “project,” “forecast,” “target,” “goal,” “intend,” “anticipate,” “expect,” “plan,” or “intend.” We intend to identify forward-looking statements. Actual results or events could differ materially from our intentions, expectations, and projections disclosed in the forward-looking statements. Factors that could cause actual results or events to differ materially, including, but not limited to, the completion of a combination with Beijing Continent will not be completed in a timely manner, the success of Hydronidone (F351) in NASH and liver fibrosis will not be successful or require additional clinical trials, that results from the Phase 2 trial of Hydronidone (F351) in hepatitis related conditions may not be replicated in subsequent trials, and other risks described in the “Risk Factors” section of our most recent Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (“SEC”) as well as the proxy statement and registration statement on Form S-1 filed with the SEC. We disclaim any obligation to update any forward-looking statements, except as may be required by law.

CBIO corporate strategy

Generate further value for stockholders

December 2022

- + Acquired global rights (excluding China) to Hydronic treat NASH and liver fibrosis
- + Plan to acquire a controlling interest in Beijing Conti biopharmaceutical company based in China, from the parties
- + Announced \$7.5 million special dividend and CVR

2023

- + Completed \$6 million asset sale of compounds designed for neurodegenerative disorders to GC Biopharma, with net proceeds to be used for general corporate purposes
- + Annual Meeting of Stockholders expected to be held in the first half of 2023

CBIO 2023 corporate strategy

Transition Our Focus to Organ Fibrosis

- + Expect to consummate Beijing Continent business co
- + Planning development of Hydronidone (F351) for NA
- + Beijing Continent expected to complete enrollment of (F351) for hepatitis B virus (“HBV”)-associated liver fi
- + Distribute remaining net cash from legacy assets to C

Beijing Continent sales of ETUARY (Pirfer

Consistent growth in revenue & profit

Beijing Continent Financials

(Legal entity, local currency)

	P/L				
	000s RMB				
	FY2020	FY2021	FY2022	20 vs 21	21 vs 22
Revenue	447,002	571,038	688,630	28%	21%
COGS	26,627	25,629	29,299	-4%	14%
Gross profit	420,375	545,409	659,331	30%	21%
SG&A	228,460	314,799	413,936*	38%	31%
R&D	37,212	46,188	53,768	24%	16%
Profit before tax	156,656	188,704	194,193	20%	3%
Profit after tax	127,927	149,387	151,594	17%	1%
Headcount	419	481	523	15%	9%

800,000 —
700,000 —
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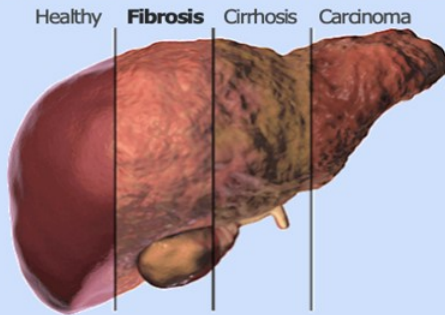
*including writing down of BC's one-time listing expenses of JPY 395M

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Catalyst Biosciences

Liver fibrosis market opportunity

Liver fibrosis is the build-up of scar tissue in the liver due to chronic liver damage



Main indications

- Non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH)
- Chronic viral hepatitis B and C
- Alcohol-related liver disease
- Autoimmune hepatitis
- Others: PBC, PSC, Hemochromatosis, Wilson's, Alpha-1 deficiency & other liver injuries/diseases

Treatment algorithm

- Treating the underlying cause
- Medications to prevent, slow or reverse fibrosis
- (End stage) Liver transplantation

Available treatments

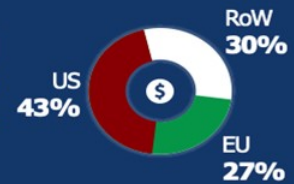
- Antivirals for chronic hepatitis B and C
- Immunosuppressants
- Ursodeoxycholic acid
- Corticosteroids, pentoxifylline, and N-acetylcysteine
- ACE inhibitors, Obeticholic acid, and fibrates

Global Liver Fibrosis Treatment Market

↑ **\$2.7B**
USD 2022 est

↑ **CAGR 13%**
(2023-2030)

Regional Market Share



Drivers

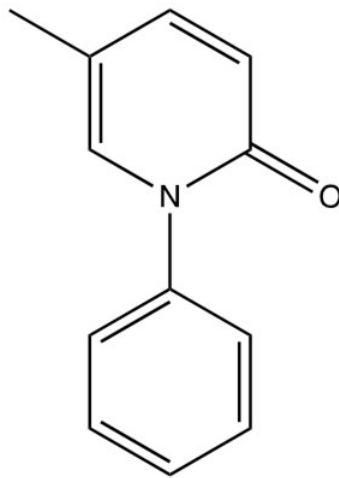
1. High & rising prevalence of liver fibrosis
2. Development of novel therapies
3. Government initiatives and funding

Restraints

1. High cost of treatment
2. Limited efficacy of available treatments
3. Stringent regulatory requirements

Hydronidone's metabolic profile vs Pirfenidone

Pirfenidone



Hydronidone



- + Low potential of Hydronidone and its major metabolites for DDIs in the CYP450, and major transporter systems
- + In contrast to Pirfenidone, the shift toward Phase II metabolism may lead to the formation of reactive metabolites and covalent protein binding, thus increasing the risk of idiosyncratic liver toxicity (*Zhou S et al, J Med Chem 2020*)

Hydronidone's (F351) positive nonclinical Therapeutic effect & favorable safety profile in liver

- + Has shown anti-fibrotic effects across standard models of liver fibrosis
 - More potent than Pirfenidone
- + Pleiotropic mechanism of action designed to target the key drivers of liver fibrosis
 - Independent of initial causative insult
 - Results in inhibition of hematopoietic stem cell proliferation with reduction in liver fibrosis
- + Absorption, distribution, metabolism and excretion profile is favorable with high oral bioavailability, exposure and metabolite profile relevant to human
- + No adverse effects on major organ systems observed
- + Well tolerated upon long-term dosing across species at exposure levels relevant to human with no major organ toxicity
- + No genotoxicity or adverse effects on fertility and reproduction

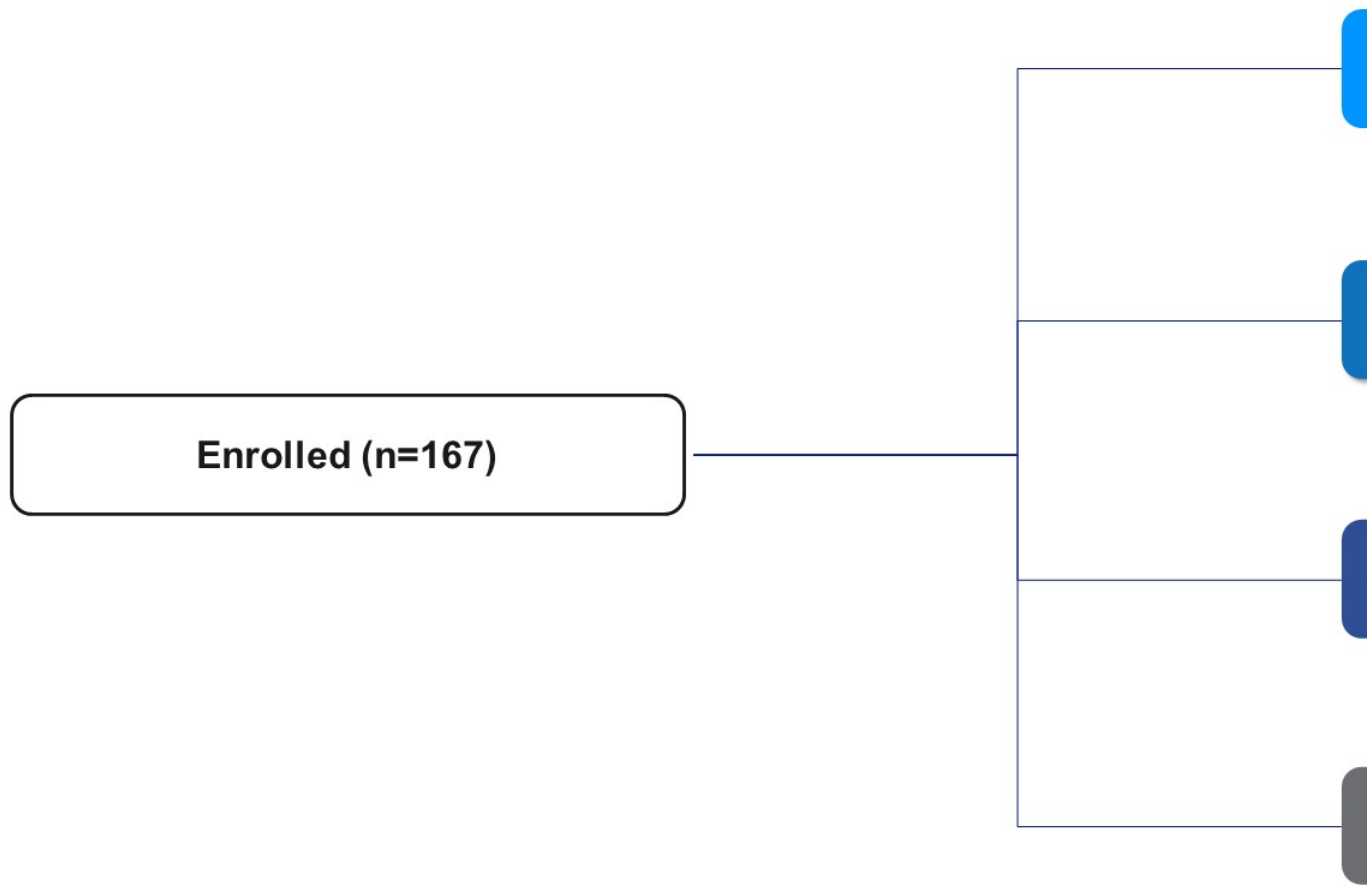
Phase 2 trial results in HBV-induced liver fibrosis

Double blind, randomized, placebo-controlled + standard of care

Design	<ul style="list-style-type: none">▪ A randomized, double-blind, placebo-controlled, dose-exploration phase 2 trial of Hydronidone treatment of liver fibrosis associated with HBV (Beijing Contingent)
Basic Treatment	<ul style="list-style-type: none">▪ *Entecavir administered continuously for 52 weeks
Primary Endpoint	<ul style="list-style-type: none">▪ Proportion of liver fibrosis Ishak scores decreased at 52 weeks of treatment
Secondary Endpoint	<ul style="list-style-type: none">▪ Conversion rate and decrease of HBV DNA▪ Proportion of decrease in liver transient elastography compared to pre-treatment▪ Proportion of liver tissue inflammation grade improvement compared to pre-treatment without treatment▪ Improvement of liver function alanine aminotransferase

Phase 2 trial results in HBV-induced liver t

Double blind, randomized, placebo-controlled + ent



Phase 2 trial results in HBV-induced liver fibrosis

Double blind, randomized, placebo-controlled + ent

Therapeutic Effect

P = 0.024

Primary Endpoint:

The proportion of Ishak of liver fibrosis decreased by ≥ 1 point (fibrosis regression) from baseline after 52 weeks treatment

Safety Profile

Positive safety profile. There was **no statistical difference** in the occurrence of adverse events, adverse reactions and serious adverse events between the four groups during the trial



Clinical risk/benefit profile of Hydronidone

Potential treatment of liver fibrosis of different etiologies

- + Positive results in a subpopulation of patients with significant liver fibrosis; Hydronidone's (F351) potential in preventing progression of liver fibrosis
- + No statistical difference in the occurrence of adverse or serious adverse events between the four groups during treatment
- + Good safety profile demonstrated in subjects with mild to moderate liver fibrosis
- + No adverse effects nor prolongation of QT interval
- + Food consumption slows down absorption of Hydronidone and its metabolites and reduces the C_{max} values; therefore, administration with food is recommended
 - No clinically relevant DDIs observed

CBIO Summary

Transitioning Our Focus to Organ Fibrosis

- + Acquired global rights (excluding China) to Hydronidone to treat NASH and liver fibrosis and demonstrating promise
- + Anticipate completing a business combination with BeiGene, a late stage biopharmaceutical company based in China in 2021
- + Hydronidone (F351) clinical readouts expected in 2021 for liver fibrosis and NASH
- + Planned additional cash distributions to CVR holders

Thank you

Nasdaq: CBIO

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