



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

April 27, 2023

Nassim Usman, Ph.D.
President and Chief Executive Officer
Catalyst Biosciences, Inc.
611 Gateway Blvd
Suite 120
South San Francisco, CA 94080

Re: Catalyst Biosciences, Inc.
Preliminary Proxy Statement on Schedule 14A
Filed March 30, 2023
File No. 000-51173

Dear Nassim Usman:

We have reviewed your filing and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments.

Preliminary Proxy Statement on Schedule 14A filed March 30, 2023

Letter to Stockholders, page 1

1. Provide prominent disclosure about the legal and operational risks associated with BC being based in and having the majority of its operations in China. Your disclosure should make clear whether these risks could result in a material change in the combined company's operations and/or the value of its securities or could significantly limit or completely hinder its ability to offer securities to investors and cause the value of its securities to significantly decline or be worthless if the business combination is executed. Your disclosure should address how recent statements and regulatory actions by China's government, such as those related to the use of variable interest entities and data security or anti-monopoly concerns, have or may impact the combined company's ability to conduct its business, accept foreign investments, or list on a U.S. or other foreign exchange following the business combination.

2. Please prominently disclose whether the auditor for the PRC-operations portion of the combined company's audit would be subject to the determinations announced by the PCAOB on December 16, 2021 and whether and how the Holding Foreign Companies Accountable Act and related regulations will affect the combined company. In addition, disclose that trading in your securities may be prohibited under the Holding Foreign Companies Accountable Act if the PCAOB determines that it cannot inspect or investigate completely your auditor, and that as a result an exchange may determine to delist your securities.
3. Provide a description of how cash is transferred through BC's organization and disclose your intentions to distribute earnings. Regarding BC, state whether any transfers, dividends, or distributions have been made to date between the holding company, its subsidiaries, or to investors, and quantify the amounts where applicable. Provide a cross-reference to the consolidated financial statements.
4. Where discussing the transaction consideration in the fourth paragraph of the letter to stockholders, please include the valuation expressed as a dollar figure, as you have done on page 3.
5. Where discussing the percentages of outstanding shares to be held post-Contribution, please clearly state that the pre-Contribution Catalyst stockholders will go from owning 83.4% of outstanding shares, as shown on the organizational chart on page 18, to owning 2.5% and 2.0%, the latter taking into consideration the conversion of Convertible Preferred Stock and the outstanding options of Catalyst and Gyre Options to be granted.

Questions and Answers About the Contributions

Who will be the executive officers of the combined company..., page 4

6. Please revise the table listing the executive officers of the combined company to indicate from which pre-Contribution entity each individual originates.

Catalyst Bioscience, Inc., page 9

7. We note your statement that a Phase 1 clinical trial of Hydronidone was completed in the U.S.; however, you also state that the company does not anticipate filing an IND for the treatment of NASH in the U.S. until late 2023. Please revise your disclosure to clarify whether an IND was filed with the FDA prior to commencement of the referenced Phase 1 clinical trial. In addition, we note your statements that Catalyst plans to commence a Phase 2a proof-of-concept clinical study. However, it remains unclear whether the company has engaged with the FDA and has received approval to progress as described. Please explain.

Summary of the Proxy Statement

The Companies, page 9

8. Disclose each permission or approval that you, your subsidiaries, BC or its subsidiaries are required to obtain from Chinese authorities to operate their businesses and to offer securities. State whether you, your subsidiaries, BC or its subsidiaries are covered by permissions requirements from the China Securities Regulatory Commission (CSRC), Cyberspace Administration of China (CAC) or any other governmental agency that is required to approve your or BC's operations, and state affirmatively whether you and BC have received all requisite permissions or approvals and whether any permissions or approvals have been denied. Please also describe the consequences to you and your investors if you, your subsidiaries, BC or its subsidiaries: (i) do not receive or maintain such permissions or approvals, (ii) inadvertently conclude that such permissions or approvals are not required, or (iii) applicable laws, regulations, or interpretations change and you are required to obtain such permissions or approvals in the future.

Beijing Continent Pharmaceuticals Co., Ltd, page 10

9. Provide a clear description of how cash is transferred through BC's organization. Disclose your intentions to distribute earnings after the business combination. Quantify any cash flows and transfers of other assets by type that have occurred between the holding company and BC's subsidiaries, and direction of transfer. Quantify any dividends or distributions that a subsidiary have made to the holding company and which entity made such transfer, and their tax consequences. Similarly quantify dividends or distributions made to U.S. investors, the source, and their tax consequences. Your disclosure should make clear if no transfers, dividends, or distributions have been made to date. Describe any restrictions on foreign exchange and BC's ability to transfer cash between entities, across borders, and to U.S. investors. Describe any restrictions and limitations on BC's ability to distribute earnings from the company, including its subsidiaries, to the parent company and U.S. investors.
10. We note the following statement on page 10: "The prevalence of IPF in the PRC increased from 83,002 in 2017 to 131,654 in 2022..." Please revise this statement to clarify the meaning of the numbers cited (i.e., number of cases, number of new patients, etc.).
11. Please remove the statement on page 10 that the company may "quickly obtain marketing approvals" for the treatment of rare diseases and further expand the use of drugs, as the timing of regulatory approvals is not within the company's control and cannot be predicted.
12. We note the disclosure on page 10 that Hydronidone was granted Breakthrough Therapy designation by the CDE in March 2021. Please define "CDE" here and disclose that your Breakthrough Therapy designation does not increase the likelihood that Hydronidone will ultimately receive approval.

13. We note disclosure both here and elsewhere throughout the proxy statement stating or inferring that Catalyst and BC's product candidates are or may be considered safe and/or effective. For example, we note statements that product candidates have "promising efficacy," "potential efficacy," and "favorable safety." Please note that determinations of safety and efficacy are solely within the authority of the FDA and comparable regulatory bodies; therefore, please revise your prospectus to remove all references and/or implications of safety and efficacy for unapproved product candidates. You may summarize data and findings of studies and trials conducted without drawing conclusions as to these matters.

The Contributions, page 12

14. Disclose that trading in the post-Contribution company's securities may be prohibited under the Holding Foreign Companies Accountable Act if the PCAOB determines that it cannot inspect or investigate completely your auditor, and that as a result an exchange may determine to delist your securities. Disclose whether the auditor responsible for the combined company's PRC-operations would be subject to the determinations announced by the PCAOB on December 16, 2021.
15. Please advise us of the exemption you are relying on for the issuance of Catalyst shares pursuant to the Contributions.

Organizational Structure, page 18

16. Please provide the following in this section:
- an organizational chart illustrating BC's structure before the Contributions;
 - graphically indicate how GNI USA, Inc. relates to the shown entities;
 - explain the difference between BJ Continent Pharmaceuticals Limited and BC in the post-Contribution chart, as your disclosure does not clearly discuss two separate entities for BC;
 - indicate who holds the remaining 30.3% of BC post-Contribution.
17. In reference to footnote 2 to the chart, please revise to define "Entities" here rather than referencing the Business Combination Agreement.

Interests of Certain Directors, Officers and Affiliates of Catalyst and the Contributors

Interests of Catalyst, page 19

18. Please quantify the dollar value of the grants of awards of fully vested stock options under the 2023 Omnibus Incentive Plan to be granted to Nassim Usman, Seline Miller and Thomas Eastling, as discussed on page 19.

Risk Factor Summary, page 21

19. Please revise here to describe the dilutive effects to existing Catalyst stockholders of the issuance of stock pursuant to the Contributions.

20. Please disclose here the risk that the holders of Catalyst Convertible Preferred Stock could be entitled to require Catalyst to redeem, in cash, the shares of common stock underlying its Catalyst Convertible Preferred Stock, causing substantial doubt about Catalyst's ability to continue as a going concern within one year from the filing of this proxy statement.
21. In your summary of risk factors, disclose the risks your corporate structure and being based in or having the majority of the company's operations in China after the business combination poses to investors. In particular, describe the significant regulatory, liquidity, and enforcement risks with cross-references to the more detailed discussion of these risks in the proxy statement. For example, specifically discuss risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice; and the risk that the Chinese government may intervene or influence the combined company's operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in the combined company's operations and/or the value of its securities. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder the combined company's ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.

Catalyst stockholders may not realize a benefit from the Contributions commensurate with the ownership dilution, page 29

22. Please revise here to disclose the amounts and sources of dilution pursuant to the Contributions.

Risks Related to BC's Business Operations in the PRC

The Chinese government may intervene in or influence BC's operations at any time, which could result in a change in BC's operations., page 87

23. Please revise here to disclose that the risks discussed under this heading could significantly limit or completely hinder the combined company's ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.
24. We note your disclosure on page 250 where you discuss the CSRC published Trial Measures. Please disclose how, if at all, the Trial Measures apply to this transaction, whether you and relevant parties to this transaction have complied with the obligations under the Trial Measures, and the risks to investors of non-compliance.

Risks Related to the Combined Company

The certificate of incorporation and bylaws of the combined company will provide that the Court of Chancery of the State of Delaware . . . , page 101

25. We note that your forum selection provision of the combined company will identify the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any “derivative action.” Please disclose whether this provision will apply to actions arising under the Securities Act or Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. If the provision applies to Securities Act claims, please also revise your proxy statement to state that there is uncertainty as to whether a court would enforce such provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If this provision does not apply to actions arising under the Securities Act or Exchange Act, please also ensure that the exclusive forum provision in the governing documents states this clearly, or tell us how you will inform investors in future filings that the provision does not apply to any actions arising under the Securities Act or Exchange Act.

The Contributions

Catalyst's Background of the Contributions, page 114

26. Please revise here to discuss the negotiations between the parties leading to Nassim Usman, Ph.D. remaining as a director and Seline Miller remaining as an executive officer of the combined company.

Opinion of Catalyst's Financial Advisor, page 118

27. Please revise here to disclose whether there were any material changes made to the draft documents reviewed by Raymond James disclosed on page 119. If so, disclose those changes.
28. We note you state here that the Raymond James fairness opinion is attached to this proxy statement as Annex C. Annex C appears to be an accounting consent and the full text of the opinion does not appear elsewhere in the proxy statement. Please attach the opinion to the proxy statement or otherwise advise.
29. Please revise your disclosure to summarize Raymond James’ discounted cash flow analysis and any other valuation analyses conducted in preparation for rendering the fairness opinion. Please also summarize the projections provided to Raymond James and used in reaching the fairness determination and disclose the assumptions and bases relied related thereto.

30. Please revise to quantify the amount of compensation paid by Catalyst to Raymond James and its affiliates over the past two years.

The Business Combination Agreement

Conditions to the Completion of the Contributions, page 137

31. We note you disclose here that conditions to the completion of the contributions are subject to the satisfaction or waiver by each of the parties. Please revise to state which conditions may be waived and revise your Risk Factors if applicable.

Catalyst's Business

Summary, page 193

32. We note your statement that Hydronidone performed better than Pirfenidone at comparable dose in the murine NASH model. Please revise your disclosure to provide information regarding any head-to-head trials conducted comparing Hydronidone to Pirfenidone directly. If head-to-head trials were not conducted, please remove this statement and any similar comparisons.

Hydronidone Pre-Clinical Development in NASH, page 198

33. We note you plan to use clinical data obtained in the recently completed Phase 2 clinical study of Hydronidone conducted by BC in the PRC. Please revise here to disclose the FDA may not accept the data from this clinical study and provide risk factor disclosure that the FDA may require you to conduct additional trials if it does not accept data from BC's clinical study or believes that additional data is necessary to supplement your clinical study data.

Intellectual Property, page 200

34. Please revise page 201 to disclose all jurisdictions related to the granted patents for your first and second patent families. Please also include the expiration dates or years of each.

Our Clinical-Stage Product - Hydronidone: A Drug to Reverse Liver Fibrosis Associated with CHB, page 218

35. Please remove your statement that "Hydronidone is expected to remain the only approved anti-fibrosis drugs for the treatment of CHB in the PRC, for at least a few years after approval, according to Frost & Sullivan" as such statement is premature at this stage of development and implies not only that regulatory approval will be obtained, which is outside of the control of the company and unknown, but also that no competitors will develop competing products in the interim.

Phase 2 Study of Hydronidone for liver fibrosis associated with CHB in the PRC, page 220

36. Please expand BC's discussion of the SAEs observed in the Phase 2 study of Hydronidone to describe the SAEs.

F573: Potential Category 1 New Drug for ALF/ACLF, page 221

37. Please revise here to summarize the results of the Phase 1 clinical trial for F573. To the extent results are not yet available, state when BC expects to receive them. Regarding the Phase 2 trial, disclose the trial design, primary and secondary endpoints.

Our Preclinical-Stage Product Candidates, page 222

38. Please revise your discussion of the F528 and F230 preclinical studies to state whether results you refer to are statistically significant.

Intellectual Property, page 232

39. Please revise this section to disclose the type of patent protection (e.g., composition of matter, use, or process) and the expected expiration dates, on an individual or patent family basis, for all material patents owned by BC.

BC Management's Discussion and Analysis of Financial Condition and Results of Operations, page 260

Results of Operations, page 264

40. We note from page F-57 that BC's trade receivables increased 70% during 2022, as compared to an increase of 21% in total RMB revenues. Please explain the reason(s) for why trade receivables have increased at a significantly faster rate than revenues. Quantify how much of the balance has been collected subsequent to December 31, 2022.
41. As disclosed on page 265, we note that BC's gross profit margin has approximated 96% in each of the last two years. Please revise the disclosure to explain how BC has maintained such a high level of gross profit margin and/or why raw materials and the remaining components of cost of sales, if applicable, is so low. Additionally, describe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on revenues or gross profit margins. Refer to Item 303(b)(2)(ii) of Regulation S-K.

BC Financial Statements, page F-32

42. Based on the disclosures discussed on pages 94-95 and 248-249 regarding restrictions on the ability of BC's Chinese subsidiaries to remit sufficient foreign currency to offshore entities for such offshore entities to be able to pay dividends, make other payments or otherwise satisfy BC's foreign-currency-denominated obligations, please address the need for BC to provide the Schedule I per Rule 5-04(c) of Regulation S-X.

Nassim Usman, Ph.D.
Catalyst Biosciences, Inc.
April 27, 2023
Page 9

11. Intangible Assets, page F-55

43. We note product development in progress accounts for most of the intangible assets balance. It is not clear to us why such costs are classified as intangible assets. Please identify the transactions that have resulted in these amounts and/or address why these costs, referring to the disclosure on page F-39, are not accounted for as inventories.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

You may contact Jenn Do at 202-551-3743 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Daniel Crawford at 202-551-7767 or Laura Crotty at 202-551-7614 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Stephen B. Thau, Esq.