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VIA EDGAR

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United States Securities and Exchange Commission
Division of Corporation Finance, Office of Life Sciences
100 F Street, NE
Washington, DC 20549
Attn: Jenn Do
Lynn Dicker
Daniel Crawford
Laura Crotty

Re: Catalyst Biosciences, Inc.
Amendment No. 1 to Preliminary Proxy Statement on Schedule 14A
Filed May 15, 2023
File No. 000-51173

Ladies and Gentlemen:

On behalf of Catalyst Biosciences, Inc., a Delaware corporation (the "Company"), set forth below is the response of the Company to the comments of the staff of the Division of Corporation Finance, Office of Life Sciences (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") contained in the letter dated May 31, 2023 (the "Comment Letter") regarding the Company's Preliminary Proxy Statement on Schedule 14A initially filed with the Commission on March 30, 2023 and amended on May 15, 2023 (the "Proxy Statement").

Concurrently with this response letter, the Company is filing Amendment No. 2 to the Proxy Statement ("Amendment No. 2") via EDGAR. Amendment No. 2 includes revisions made in response to the comments of the Staff in the Comment Letter, as well as additional changes to update certain disclosure contained in the Proxy Statement.

To facilitate your review, we have reproduced the text of the Staff's comments in boldfaced print below, followed by the Company's response.

Amendment No. 1 to Preliminary Proxy Statement on Schedule 14A

Organizational Structure, page 21

1. Please revise to enlarge or otherwise alter the graphics on page 21 so all text is legible.

Response:

The Company has revised the disclosure on pages 23-24 of Amendment No. 2 to address the Staff's comment.

Risk Factor Summary, page 24

2. We note your response to our prior comment 9. Please revise here to add a summary risk factor discussing the risks regarding the transfer of cash out of China. In addition, please revise your discussion regarding dividends, distributions and other transfers on page 264 to include a cross-reference to the Unaudited Pro Forma Condensed Combined Financial Information on page 306.

Response:

The Company has revised the disclosure in the Letter to Stockholders and on pages 15, 28, 31, and 103 of Amendment No. 2 to address the Staff's comment.

Summary of the Proxy Statement

Regulatory Approvals, page 26

3. We note your response to our prior comment 8 and your statement that you are required to file with the CSRC for the overseas listing application pursuant to the Trial Measures. Please provide updated disclosure, when available, regarding the status of this filing.

Response:

The Company has revised the disclosure on pages 29, 140, and 271 of Amendment No. 2 to address the Staff's comment.

Opinion of Catalyst's Financial Advisor, page 124

4. We note your response to our prior comment 29 and reissue in part. Please revise to disclose whether Raymond James excluded any companies or transactions meeting the selection criteria from its selected companies analysis and its selected transaction analysis. If so, revise to state why Raymond James excluded the companies or transactions. Revise to provide the valuations for each of the selected companies and transactions. Revise to provide the growth rate used for the projections and the assumptions and bases relied on in calculating the growth rate.

Response:

The Company has revised the disclosure on pages 129-130 and 135 of Amendment No. 2 to address the Staff's comment.

BC's Business

Our Products and Product Pipeline, page 227

5. We note your response to our prior comment 13 and reissue in part. You continue to state on page 229 that pirfenidone exhibited efficacy in preclinical studies. Please revise to remove this reference.

Response:

The Company has revised the disclosure on page 233 of Amendment No. 2 to address the Staff's comment.

Dividends, Distributions and Other Transfers, page 264

6. We note your response and revisions on pages 264-265 related to comment 42. Please identify BC's subsidiary incorporated in the PRC. Also, if this subsidiary is BC's "only" subsidiary, please provide the identity of "our offshore entities" referred to on page 265 and explain your relationship to those entities.

Response:

The Company has revised the disclosure in the Letter to Stockholders and on pages 14-15, 23-24, 29, 245 and 268-269 of Amendment No. 2 to address the Staff's comment.

BC Management's Discussion and Analysis of Financial Condition and Results of Operations, page 277

Results of Operations, page 281

7. We note your response and revisions on page 282 related to comment 41. You state "Our gross profit margin levels are high due to our mature technology and significant cost reduction due to the scale effect." Please further revise to address how you have been able to maintain the low raw materials cost. Tell us your historical gross margin rates when ETUARY was first approved and sold.

Response:

The Company has revised the disclosure on page 291 of Amendment No. 2 to address the Staff's comment.

Intangible Assets, page F-55

8. We note your response to comment 43. Referring to IAS 38.57, please explain how you have met each of the criteria listed therein for recognition as an intangible asset. In particular, it is unclear to us how, if BC had not yet received regulatory approval for the commercialization of its product candidates, the criteria for use or sale could be satisfied.

Response:

The Company respectfully acknowledges the Staff's comment. Set forth below is our analysis of paragraph 57 of IAS 38 Intangible Assets ("IAS 38") in determining that certain development costs incurred for the development of BC's product candidates meet the criteria for capitalization.

As of December 31, 2022 and 2021, amounts included in "product development in progress" in intangible assets mainly represent certain capitalized development costs incurred for the development of BC's product candidate F351 Hydronidone ("Hydronidone") located in the People's Republic of China (the "PRC").

In September 2020, BC purchased Hydronidone's intellectual property ("IP") rights, including patents, patents applications, and know-how together with Hydronidone-related documents and materials in mainland PRC, from two subsidiaries of GNI Group Ltd. ("GNI"), BC's ultimate holding company. Before BC acquired Hydronidone's IP, GNI had successfully completed the Phase 2 clinical trial for Hydronidone with satisfactory results. The cash consideration in the IP transfer agreement for this transaction was determined and agreed by all involved parties based on a Hydronidone evaluation report prepared by a prominent third-party appraiser in the PRC.

As of December 31, 2022, 66.7% of the intangible assets balance associated with Hydronidone (December 31, 2021: 79.7%) represented the purchase price paid by BC to GNI's subsidiaries according to the IP transfer agreement, while the remaining 33.3% (December 31, 2021: 20.3%) represented the cumulative expenditures incurred by BC for Hydronidone's Phase 3 clinical trials. BC's application to conduct Phase 3 clinical trials for Hydronidone was approved by the Center for Drug Evaluation of the National Medical Products Administration ("NMPA") in the PRC in July 2021.

Given that the purchase price was determined based on the fair value and that Hydronidone achieved satisfactory results for the Phase 2 clinical trial, BC recognized the purchase price paid to GNI's subsidiaries for Hyrdonidone as intangible assets according to the following accounting standards:

IAS 38.21 *An intangible asset shall be recognised if, and only if:*

(a) it is probable that the expected future economic benefits that are attributable to the asset will flow to the entity; and

(b) the cost of the asset can be measured reliably.

IAS 38.25 *Normally, the price an entity pays to acquire separately an intangible asset will reflect expectations about the probability that the expected future economic benefits embodied in the asset will flow to the entity. In other words, the entity expects there to be an inflow of economic benefits, even if there is uncertainty about the timing or the amount of the inflow. Therefore, the probability recognition criterion in paragraph 21(a) is always considered to be satisfied for separately acquired intangible assets.*

IAS 38.26 In addition, the cost of a separately acquired intangible asset can usually be measured reliably. This is particularly so when the purchase consideration is in the form of cash or other monetary assets.

Regarding the development expenditure capitalized during Hydronidone's Phase 3 clinical trials, BC outlined its consideration of each of the criteria specified in IAS 38.57 below:

According to IAS 38.57 "*An intangible asset arising from development (or from the development phase of an internal project) shall be recognised if, and only if, an entity can demonstrate all of the following:*

(a) the technical feasibility of completing the intangible asset so that it will be available for use or sale.

(b) its intention to complete the intangible asset and use or sell it.

(c) its ability to use or sell the intangible asset.

(d) how the intangible asset will generate probable future economic benefits. Among other things, the entity can demonstrate the existence of a market for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset.

(e) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.

its ability to measure reliably the expenditure attributable to the intangible asset during its development."

(a) Technical feasibility of completing the intangible asset so that it will be available for use or sale.

Hydronidone is a structural analogue of the approved anti-fibrotic (pulmonary fibrosis) drug pirfenidone, designed to reverse liver fibrosis by inhibiting hepatic stellate cell proliferation while simultaneously blocking the TGF- β signaling pathway, both of which play important roles in the liver fibrosis associated with chronic hepatitis B ("CHB"). For a description of Hydronidone, please refer to the section titled "Our Clinical-Stage Product - Hydronidone: A Drug to Reverse Liver Fibrosis Associated with CHB" beginning on page 236 of CBIO's Proxy Statement dated as of the date hereof (the "Proxy"). According to Hydronidone's Phase 2 clinical trial results, Hydronidone showed better safety results when compared to the placebo in this study and data in improving liver fibrosis associated with CHB after 52 weeks of treatment, with the best efficacy results at 270 mg/day. Please refer to the section titled "Phase 2 Study of Hydronidone for liver fibrosis associated with CHB in the PRC" on page 237 of the Proxy regarding a summary of clinical results of Hydronidone's Phase 2 study.

BC's flagship product ETUARY (pirfenidone capsule) was approved in the PRC in 2011. For a description of ETUARY, please refer to the section titled "ETUARY: National Class 1.1 New Drug for IPF Approved in 2011" beginning on page 231 of the Proxy.

Hydronidone and ETUARY have been both developed for organ fibrosis. Different organ fibrosis diseases share a similar pathogenic mechanism and fibrosis process. The success of ETUARY lays the foundation for BC's development and registration strategy of Hydronidone. Hydronidone and ETUARY share similarities in their chemical structures, albeit with slight structural modifications aimed at minimizing hepatotoxicity. Clinical data suggest that ETUARY could potentially be used for the treatment of liver fibrosis associated with CHB; however, ETUARY's direct application is limited due to its hepatotoxicity. Phase 2 clinical trials in Hydronidone have demonstrated minimal liver damage, making it a promising candidate for the treatment of liver fibrosis.

Based on BC's experience with ETUARY, the primary difficulty encountered in conducting Phase 3 clinical trials for the treatment of idiopathic pulmonary fibrosis was the recruitment of a sufficient number of patients for the trial. However, Hydronidone targets a patient population with liver fibrosis that is larger in scale compared to the population with pulmonary fibrosis targeted by ETUARY. The Phase 2 clinical trial for Hydronidone has already been completed with 240 patients, and the upcoming Phase 3 trial aims to include 248 patients, which is close to the patient number in the Phase 2 trial. Consequently, BC believes that the challenge of recruiting an adequate number of patients and successfully completing the Phase 3 trial for Hydronidone is considerably lower than that of ETUARY.

Based on the positive outcomes obtained through BC's studies as well as the availability of a relatively large scale patient population for the Phase 3 clinical trial, BC considered the technical feasibility including future regulatory approval of Hydronidone as probable.

(b) Intention to complete the intangible asset and use or sell it.

BC is committed to solidifying its leading position in the treatment of fibrosis diseases, enriching its product portfolio and exploring indication expansion. Currently, BC has only one commercialized product, ETUARY, for the treatment of idiopathic pulmonary fibrosis in a relatively small market and is actively developing other drug candidates for the treatment of various fibrosis diseases. As noted above, BC is of the opinion that the technical feasibility of Hydronidone is probable. Furthermore, BC has outlined the preparatory measures it intends to undertake prior to the launch of Hydronidone, including the recruitment of research and development ("R&D") personnel and the expansion of production capacity. In addition, BC has made initial plans for the post-market sales of the new drug, taking into consideration the project budget.

BC commenced the patient enrollment for the Hydronidone Phase 3 clinical trial in January 2022. As of May 9, 2023, BC has completed the enrollment of 124 subjects, which is 50% of the target enrollment. BC expects to submit a NMPA application for Hydronidone in the PRC in the first quarter of 2025.

(c) Ability to use or sell the intangible asset.

In assessing whether BC will have the ability to use or sell Hydronidone, BC performed an assessment to determine that there is no restriction or prohibition for the use or sale of the intangible asset within the PRC. In addition, BC also considered any other restrictions and noted that BC was not restricted in its ability to use or sell Hydronidone by any contractual obligations to third parties within the PRC.

(d) How the intangible asset will generate probable future economic benefits.

Hydronidone, BC's Phase 3 clinical-stage product candidate has the potential to become the first approved drug to treat liver fibrosis associated with CHB. According to Frost & Sullivan, CHB is the number one cause of liver fibrosis in the PRC and the number of patients with liver fibrosis in the PRC reached approximately 140.3 million in 2022, of which approximately 45.3% were caused by CHB. To date, there is no effective clinical therapy for liver fibrosis and no specific therapeutic drugs have been approved worldwide.

BC has developed a comprehensive plan for the necessary preparations prior to the commercial launch of Hydronidone, which includes the recruitment of additional R&D personnel, expansion of in-house production capacity, and utilization of BC's existing sales network for ETUARY. In addition, BC has performed a profit forecast for Hydronidone. Given that Hydronidone and ETUARY are both medical products used in the treatment of organ fibrosis with similar chemical mechanisms, and considering BC's intentions to expand Hydronidone products within the existing distribution network of ETUARY, along with the potential market size of Hydronidone exceeding that of ETUARY, BC has utilized the historical sales data from the launch of ETUARY as a reference to forecast the profitability of Hydronidone. It is anticipated that substantial economic gains can be realized through the sales of Hydronidone products.

Based on the factors noted above, BC believes that it is probable that Hydronidone will provide future economic benefits.

(e) Availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.

BC has established a dedicated R&D team for Hydronidone, which comprises clinical medicine experts, regulatory professionals, drug manufacturing specialists, and procurement specialists. The team is led by an individual with over 20 years of experience in the field of drug development, and each member of the research team possesses an average of five to six years of experience in pharmaceutical research and clinical trials.

For the Phase 3 clinical trial, BC has partnered with a prominent Chinese contract research organization ("CRO") specializing in infectious diseases. This CRO is known for its highly skilled project team, proficiency in managing large-scale projects, and efficient patient recruitment across multiple clinical trial sites nationwide. This CRO's trials are highly regarded for their progress and quality within the industry.

BC's main product sales have shown consistent growth, and the market continues to expand. The primary source of BC's funding is from cash flows generated by operating activities. BC held cash and bank balance and bank deposits totaling RMB214.9 million (USD31.2 million) as of December 31, 2022. As BC is still in a growth phase, it is expected that the sales volume of BC's main product, ETUARY, will further increase in the future.

BC plans to expand in-house production capacity and utilize its existing sales network for ETUARY for Hydronidone's production and sales. BC currently has in-house manufacturing facilities located in two cities in China, one of which is undertaking a technology upgrade for capacity expansion. BC's sales and marketing team has market coverage of 30 provinces, autonomous regions and municipalities in the PRC, with an average of more than nine years of experience in pharmaceutical sales. BC's distribution network for ETUARY has supported BC's strong and consistent sales growth over years. By leveraging the existing distribution network for Hydronidone, BC believes that it can quickly enter the market at a relatively low cost if Hydronidone obtains applicable approvals.

Therefore, BC expects that it will have adequate financial support for Hydronidone development, considering its strong internal team, collaboration with a leading domestic CRO, and sufficient funding sources. Thus, BC believes that the criteria of "sufficient technical, financial, and other resources" have been met.

(f) Ability to measure reliably the expenditure attributable to the intangible asset during its development.

Hydronidone's Phase 3 clinical trial has been supported by a prominent CRO. The service engagement contract clearly outlines the allocated R&D expenses and the respective timelines. Due to the thoroughness of the contract plan, BC anticipates that any variances between the actual incurred amounts and the budgeted amounts are expected to be minimal. Furthermore, the R&D team, legal department, and finance department have diligently tracked and documented the R&D expenses associated with Hydronidone, with the goal of ensuring accurate and reliable measurement of each expenditure.

Accordingly, BC considers the measure of these expenditure as straightforward and reliable.

Conclusion

In conclusion, BC believes that all the requirements under IAS 38.57 for capitalizing Hydronidone are met when BC capitalized related development costs.

In addition, we respectfully advise the Staff that we already identified the accounting policy of internally developed intangible assets as one major GAAP difference in the section titled “Summary of Significant IFRS to U.S. GAAP Differences” on page 32 of the Proxy. BC has expensed “product development in progress” in intangible assets in BC’s audited financial statements in conformity with IFRS for the years ended December 31, 2022 and 2021 when converting BC’s financial data into U.S GAAP, which were included on pages 315 to 317 and in the section titled “Selected Unaudited Pro Forma Condensed Combined Financial Data of Catalyst and BC” in the Proxy.

Please direct any questions concerning this letter to the undersigned at (212) 506-5076 or sthau@orrick.com.

Very truly yours,

/s/ Stephen Thau

Stephen Thau

ORRICK, HERRINGTON & SUTCLIFFE LLP

cc: Nassim Usman, Ph.D., President and Chief Executive Officer