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

DIVISION OF
CORPORATION FINANCE

July 20, 2023

Ken Song, M.D.
President and Chief Executive Officer
RayzeBio, Inc.
5505 Morehouse Drive, Suite 300
San Diego, CA 92121

Re: RayzeBio, Inc.
Amendment No. 2 to Draft Registration Statement on Form S-1
Submitted June 23, 2023
CIK No. 0001825367

Dear Ken Song:

We have reviewed your amended draft registration statement 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 this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Amendment No. 2 to Draft Registration Statement on Form S-1, submitted June 23, 2023

Cover Page

1. Please revise the disclosure on the cover page to clarify whether the offering is contingent upon final approval of your Nasdaq listing. Please ensure that the disclosure is consistent with your underwriting agreement.

Prospectus Summary, page 1

2. We note your disclosure on page 1 that "SSTR2 is a clinically validated target that is expressed in multiple solid tumors" and that "DOTATATE" is a "clinically-validated peptide binder, and a chelator[.]" Please clarify your disclosure here, and elsewhere as appropriate, to explain what is meant by "clinically validated" in both of these contexts.

3. We note your disclosure on page 1 that you have "established a leadership position in the emerging radiopharmaceutical therapeutics modality[.]" Please revise your disclosure here and elsewhere as appropriate to provide a basis for this claim. To the extent this statement reflects management's belief, please revise your disclosure accordingly.

4. We note your disclosure on page 2 that "partial response" "has been confirmed in five of the 17 patients enrolled, representing an objective response rate, or ORR, of 29%." Please revise your disclosure here, and elsewhere as appropriate, to explain what is meant by "partial response" and "objective response rate."

Our programs, page 2

5. With regard to your pipeline table here, on page 119 and page 125, please tell us what the difference is between the "discovery" stage and the "IND enabling" stage. To the extent that both of these stages are meant to characterize pre-clinical work, please revise your pipeline table to remove the distinction between the discovery stage and the IND enabling stage and clarify which drug candidates are still in the pre-clinical stage and which candidates are now in clinical trials. Additionally, please revise the arrows in your pipeline tables in the hepatocellular carcinoma row to clarify that you have not yet obtained an IND for any other indications aside from GEP-NETs and ES-SCLC. We also note the row for SSTR2 - RYZ101 for "other cancers" and the row for "next generation binder - multiple cancers." No specific types of cancer are identified and there does not appear to be any detailed disclosure regarding these programs. Additionally, CA9 for "small molecule targeting" for renal cell cancer has no product candidate named and it does not appear to have begun development. The "other" row is similarly unsubstantiated. It appears these programs should be removed as they are not material enough to be included in your pipeline table. Please revise to provide additional disclosure that justifies the inclusion of these programs in your pipeline table and demonstrates their materiality or remove them from your table.

Our team and investors, page 4

6. We note your disclosure on pages 4 and 122 that you have raised $418 million in equity capital "from a group of premier life sciences investors[.]" Please limit your disclosure of specific investors to those identified in the Principal Stockholder table on page 194. Additionally, please indicate that prospective investors should not rely on the named investors' investment decisions and that these investors may have different investment strategies and risk tolerances.

   We also note that on page 103 you state that you have received gross proceeds of approximately $418 million from the sale of your convertible preferred stock. If true, please disclose here, and elsewhere as appropriate, that the preferred stock offering(s) in which such investors purchased shares were conducted at a significant discount to the IPO price.

Our strategy, page 5

7. We note that one of the key elements of your strategy is to "[b]uild the market leading sustainable SSTR2 franchise in multiple cancers." This implies the likelihood of regulatory approval and comparisons to other products and product candidates. This statement is speculative in light of your product candidates' regulatory status, please remove the references to building a market leading franchise. We also note your disclosure that RYZ101 has "applicability across several cancer indications." Please clarify here, and elsewhere as appropriate, that, to date, RYZ101 has not yet received FDA approval for the treatment of any cancer indications or, alternatively, please remove your reference to RYZ101's "applicability across several cancer indications."

Risk Factors

Risks related to our limited operating history, financial condition and need for additional capital

Our limited operating history may make it difficult for you to evaluate our prospects and likelihood of success, page 12

8. We note your disclosure here that you "have not demonstrated [y]our ability to successfully complete any clinical trials[.]" Please clarify throughout your registration statement, including in the prospectus summary and business sections, how you were able to obtain an IND for a Phase 3 trial even though, according to your disclosure, you have not yet demonstrated the ability to successfully complete any clinical trials. To the extent that you have not completed any clinical trials to date please revise your pipeline tables on pages 2 and 119 to make this clear.

Risks related to our dependence on third parties

We may be unable to obtain a sufficient supply of radioisotopes to support clinical development or manufacturing at commercial scale, page 48

9. We note your disclosure here that one of your suppliers of Ac224 is located in Russia, your dependence on this supplier is increased in the near term, and you must rely on your supplier in Russia for your international operations. Please revise to discuss whether the conflict between Russia and Ukraine has impacted you ability to source this supply and its cost.

Results of Operations

Research and Development Expenses, page 108

10. For each period presented, please revise to provide a breakdown of the amount of research and development expense incurred for each of your lead product candidates by program. For product candidates with more than one application, provide a breakdown by indication. To the extent that you do not track expenses by product candidate, program, or indication, please disclose that fact and explain why you do not maintain and evaluate research and development cost in this manner. For all unallocated research and

development expense, provide a breakdown by type or nature of expense such that the sum reconciles to total research and development expense for the period.

Business

Overview, page 116

11. We note your disclosure that "[b]y using the RPT construct as a diagnostic imaging agent, one can visualize in each patient the uptake of the RPT construct in tumor and normal tissues to appropriately select those patients who would more likely benefit from treatment of a therapeutic radioisotope." Please revise your disclosure here, and elsewhere as appropriate, to note whether the FDA, to date, has approved the use of the RPT construct as a diagnostic imaging agent. In this regard, we note your disclosure on page 20 that your "development of a diagnostic imaging agent will be subject to FDA review and approval[.]"

Our Strategy, page 122

12. We note your statement on page 122: "RYZ101 is enrolling in a Phase 3 clinical trial in patients with refractory GEP-NETs, having demonstrated a favorable safety profile in the Phase 1b portion of the ACTION-1 trial." Please revise this and any similar statements in your prospectus that state or imply that your development product candidates are safe as this determination is solely within the authority of the FDA and comparable regulatory bodies. We would not object if you state that the treatment was well-tolerated.

Phase 1b portion of the ACTION-1 trial in patients with GEP-NETs, page 127

13. On page 52 you state that you took advantage of the opportunity to have physicians administer RYZ101 under a compassionate use program and that the starting dose for your ACTION-1 trial for GEP-NETs was selected based on prior clinical experience with Ac225 DOTATATE outside the United States via compassionate use. On page 26 you state that “prior clinical experience in treating patients with GEP-NETs with Ac225 DOTATATE, the same active ingredient as RYZ101, has been presented by an academic nuclear medicine group” and, on page 126, that “academic medical centers outside the United States have already demonstrated clinical response using Ac225 DOTATATE in patients with GEP-NETs.” Please revise to clarify the development of Ac225 DOTATATE and RYZ-101, including the data produced by third parties and through your compassionate use program.

RYZ801 clinical development plans, page 135

14. We note your disclosure that "several clinical sites outside of the United States have imaged a total of 14 HCC patients with [y]our binder." Please revise your disclosure here to note whether any serious adverse events were observed during the imaging of the HCC patients.

License Agreement with Ablaze Pharmaceuticals Inc., page 140

15. We note your disclosure that Ablaze has agreed to pay you up to a percentage in the "low double digits" of certain sublicense revenue it receives, depending on the time when the sublicense agreement is executed. Please revise your description of this sublicense revenue percentage to a figure within ten percentage points. We also note that the maximum number of selected products under the Ablaze Agreement is limited to a certain number and Ablaze's right to select products will expire upon the earlier of (a) Ablaze selecting the maximum number of products allowed to be selected under the agreement; (b) you presenting a certain number of products for consideration by Ablaze to license or (c) a certain date. Please revise to provide the "certain date."

License and Research Collaboration Agreement with PeptiDream, Inc., page 141

16. We note your disclosure that certain royalty payments set forth in the PeptiDream Agreement could be reduced by a percentage in the "low double digits" or "mid-double digits," that you must pay some percentages in the "low double-digit[s,]" and that there is a commitment from PeptiDream to enter into good faith business discussions concerning the funding of up to a percentage in the "mid-double digits" of the costs related to IND-enabling studies, manufacturing of clinical supply and clinical trials for certain licensed products. For each of these percentages, please revise to a figure that is within ten percentage points.

    We also note your statement on page 141: "Unless earlier terminated, the PeptiDream Agreement will expire on the first to occur of (a) the instance that, at any time from and after the expiration of the research term, there are no selected conjugates under active development or commercialization by us or (b) on a licensed product-by-licensed product and country-by-country basis upon the expiration of the applicable royalty term for such licensed product." Please revise to provide the royalty term(s).

General

17. Please tell us why the agreement with Niowave, Inc. was deleted from the prospectus disclosure and considered not a material contract required to be filed under Item 601(b)(10) of Regulation S-K.

18. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications

You may contact Gary Newberry at 202-551-3761 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Joshua Gorsky at 202-551-7836 or Margaret Schwartz at 202-551-7153 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Terren J. O'Connor, Esq.