



DIVISION OF
CORPORATION FINANCE

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

September 12, 2019

Rohan Palekar
Chief Executive Officer
89bio, Inc.
535 Mission Street, 14th Floor
San Francisco, CA 94105

Re: 89bio, Inc.
Draft Registration Statement on Form S-1
Submitted August 16, 2019
File No. 377-02796

Dear Mr. Palekar:

We have reviewed your 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.

Draft Registration Statement on Form S-1

Prospectus Summary

Our Company

Overview, page 1

1. Please revise here and throughout to remove comparisons of your product candidates with other treatments, product candidates and therapies. For example, on pages 1 and 112, you compare BIO89-100 to other products in development. In addition, please revise here and throughout to eliminate any suggestion that your product candidates have been or will ultimately be determined safe or effective, as only the FDA and foreign government equivalent regulations have the authority to make these determinations. For example, on page 1, you state that you believe that BIO89-100 may be a differentiated therapy based

on, in part, to improved efficacy.

2. We note your disclosure that BIO89-100 may be a differentiated therapy based, in part, on a more convenient dosing regimen. Please balance your disclosure here by disclosing that BIO89-100 must currently be stored as a frozen liquid and is therefore not well-suited to commercialization and that there is not guarantee that you will be able to develop a refrigerated liquid formulation, freeze-dried or lyophilized formulation of BIO89-100.
3. We note your disclosure of page 2 that "[a]pproval of an SHTG treatment, driven by a combination of smaller clinical trials and shorter timelines, can potentially represent a quicker path to market for BIO89-100." Please tell us why you believe that your product candidate for the treatment of SHTG will be approved with smaller clinical trials and shorter timelines. In addition, please disclose whether the FDA has indicated that you may conduct smaller trials for BIO89-100 for the treatment of SHTG as you seek approval from the FDA for this indication.

Our Lead Product Candidate, BIO89-100, page 2

4. We note your disclosure in the second paragraph of this section regarding the results of your preclinical trials of BIO89-100. Please limit the prospectus summary to a description of the endpoints of your clinical trials and whether they were met. To the extent that you do discuss preclinical trials in the prospectus summary, please avoid conclusory statements regarding the results of these studies, and disclose a summary of how the tests were conducted, the number of animal models used, the number of tests conducted and the range of results observed in these tests. In addition, we note your disclosure on page 2 that your single doses of 9.1mg and higher of BIO89-100 in your Phase 1a clinical trial of BIO89-100 demonstrated statistically significant improvements in key lipid parameters measured at Day 8 and Day 15 after dosing on Day 1. Please disclose the p-value used.

Implications of Being an Emerging Growth Company, page 5

5. 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.

Risk Factors

Risks Related to Regulatory Approvals

Even if we are able to obtain regulatory approvals for BIO89-100 or any future product candidate, page 43

6. We note your reference to BIO89-100 approved based upon a surrogate endpoint pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act and the accelerated approval regulations. Please revise to clarify whether the FDA has given you any indication that you may seek approval upon section 506(c) of the Federal Food, Drug, and

Cosmetic Act and the accelerated approval regulations.

Risks Related to this Offering and Ownership of Our Common Stock

Our Amended Certificate provides that the Court of Chancery of the State of Delaware, page 60

7. We note your disclosure on page 60 regarding your exclusive forum provision in your Amended Certificate. However, on page 149, you state that your Amended Bylaws will contain the exclusive forum provision. Please revise for clarity and consistency. In addition, we note your disclosure that the exclusive forum provision identifies the federal district courts as the exclusive forum for Securities Act claims. Please state that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. In that regard, we note that 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. To the extent that your exclusive forum provision does not apply to actions arising under the Exchange Act, please 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 Exchange Act.

Management's Discussion and Analysis of Financial Conditions and Results of Operations

Agreements with Teva, page 72

8. Your discussion regarding your Teva agreements on page 72 differs from that disclosed on pages 113 and F-14 with respect to the number of agreements entered into and the associated milestone payments. Please revise to correct this apparent inconsistency.

Critical Accounting Policies and Estimates

Share-Based Compensation , page 79

9. Once you have an estimated offering price or range, please explain to us the reasons for any differences between the recent valuations of your common stock and the estimated offering price. This information will help facilitate our review of your accounting for equity issuance including stock compensation and beneficial conversion features.

Business

Overview, page 81

10. Please disclose the material terms of the Sublicense Agreement with ratiopharm GMBH in an appropriate section of your Business section.
11. We note your disclosure on page 82 that, in diabetic obese cynomolgus monkeys with elevated triglycerides, BIO89-100 showed significant effects on triglycerides at doses as low as 0.1mg/kg/week with a 78% reduction from baseline observed at the highest dose level of 1.0 mg/kg/week. Please revise to disclose here the number of monkeys used in this study, the range of results observed and when the measurements of triglycerides were

measured. Similarly, please disclose the number of mice and diabetic obese cynomolgus in each preclinical study described on pages 98 to 105, and disclose whether the data in the charts on pages 99 to 105 demonstrates the high, low or average results. In addition, we note your disclosure regarding the reduction of tryclycerides in your Phase 1a SAD study. Please disclose here the range of results observed as well as the dose of BIO89-100.

12. We note your disclosure on page 82 regarding the patents for BIO89-100. Please clarify here, if true, that the patents and know-how related to glycoPEGylation technology for use in the research, development, manufacture and commercialization of BIO89-100 are licensed from TEVA.

Agreements with Teva
FASN Agreements, page 113

13. Please disclose any payments and royalties that must be paid in addition to the payments and royalties that must be paid pursuant to the FGF21 Agreement with Teva. In this regard, we note your disclosure that the provisions in the FASN regarding milestones and royalties are analogous to the provisions contained in the FGF21 Agreement.

Manufacturing and Supply, page 126

14. Please disclose the material terms of your Master Services Agreement with Biotechpharma UAB.

You may contact Andi Carpenter at 202-551-3645 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Sonia Bednarowski at 202-551-3666 or Dietrich King at 202-551-8071 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Healthcare & Insurance