



DIVISION OF  
CORPORATION FINANCE

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

August 28, 2019

Steven Nichtberger  
Chief Executive Officer and President  
Cabaletta Bio, Inc.  
2929 Arch Street, Suite 600  
Philadelphia, PA 19104

**Re: Cabaletta Bio, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted August 2, 2019**  
**CIK No. 0001759138**

Dear Mr. Nichtberger:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Draft Registration Statement on Form S-1

Prospectus Summary, page 1

1. Please revise the disclosure in the first paragraph of the Overview to clarify what you mean by "IND-ready."

Pipeline, page 2

2. We note your disclosure regarding "*in vivo* evidence of efficacy and safety in an animal model..." We also note other examples of statements regarding safety and efficacy on pages 3, 117, 119, and 124. Since none of your product candidates has received FDA approval, please revise your disclosure regarding safety and efficacy in the summary and throughout your prospectus to clarify this point.

3. We note your statement on page 13 that you are early in your development efforts and have not initiated clinical trials for any product candidates. Please expand the table on page 2 to include more information about the progress of the company's pre-clinical trials, and to clarify in the table that no products are past the phase of IND enabling studies. In addition, please include columns for Phase 1, 2 and 3 testing that are equally prominent with the pre-clinical columns, and clarify that these columns refer to clinical testing. In this regard, our concern is that potential investors see a balanced graphical presentation of where you are in the drug development process, and that the table adequately depict, if true, that you have not yet filed an IND application for any product. Please make conforming changes in the Business section as well.

Implications of Being an Emerging Growth Company, page 7

4. Please supplementally 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, page 12

5. We note that there are references to foreign regulators and foreign markets throughout the Risk Factors and other sections of your prospectus. Please revise to explain what non-U.S. markets, if any, you plan to enter, and what steps you have taken to attain the necessary regulatory approvals.
6. Please provide us with a basis for your statement on page 21 that although clinical trials for cell-based therapies have historically included "a lymphodepleting chemotherapeutic regime to condition the patient prior to infusion [with CAR T-cell based therapies]," and that such infusions have resulted in neurotoxicity and other serious side effects, you believe that the use of CAR T cell therapies without preconditioning will avoid neurotoxicity or other side effects. We note your statement that "Based on evidence from other CAR T cell clinical trials demonstrating clinical activity without prior conditioning and the levels of certain cytokines that promote T cell expansion in the patients we are treating relative to cancer patients, as well as data from engineered T cell therapy in the setting of HIV without conditioning, we believe that CAAR T cell therapy may be functional in our autoimmune target patient populations without preconditioning regimens. Based on preclinical studies where DSG3-CAART is combined with stimulatory DSG3 antibodies, we observed these antibodies generate a modest level of cytokine activity that is an order of magnitude less than what was observed when DSG3-CAART engaged with target B cells. We believe this data indicates the presence of soluble DSG3 antibodies could stimulate DSG3-CAART expansion and potentially facilitate engraftment. This information coupled with the risks associated with certain lymphodepleting regimens used for preconditioning, we believe exposing autoimmune patients to these regimens without data to support the benefit is difficult to justify." Please

expand your disclosure to include references to the specific studies on which you base your beliefs, and clarify the reasons for your belief that preconditioning is not necessary for your product candidate.

7. We note your disclosure on page 80 and on page 184 that your exclusive forum provision does not apply to actions arising under the Securities Act or the Exchange Act. Please also ensure that the exclusive forum provision in the bylaws (as effective on the closing of the offering) 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.
8. Please refer to the Risk Factor on page 36 which states that you expect to grow the size of your organization by expanding your employee base. Please explain, here and in the Use of Proceeds section on page 84, what portion of the proceeds of this offering you plan to spend on this endeavor, how long you expect that application of proceeds to last, or what additional source of funds you expect to use in growing your employee base.
9. Please revise your risk factor disclosure to address more specifically the fact that 88.7% of the company will be held by the current stockholders following the offering, and detail more clearly the dilutive impact on investors in this offering that the conversion of outstanding convertible notes, convertible preferred stock, and the exercise of outstanding stock options would have, or tell us why you believe this is not a material risk.

Use of Proceeds, page 84

10. Please revise to clarify whether you believe the net proceeds will be sufficient to complete the Phase 1 clinical trials for your four product candidates, and if not, how far into those trials you expect the proceeds to last.

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

Components of Operating Results

Research and Development, page 95

11. Please quantify the research and development expenses by types of costs incurred for each of the periods presented.

Critical Accounting Policies and Significant Judgements and Estimates

Stock-Based Compensation, page 103

12. 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 leading up to the initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Financial Statements

Steven Nichtberger  
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Page 4

Statements of Operations, page F-4

13. Please provide us your computation of weighted-average number of shares used in computing net loss per share for all periods presented. Also, tell us your consideration of disclosing in the financial statements how you determined weighted-average number of shares used in computing net loss per share.

Notes to the Financial Statements

6. Commitments and Contingencies

Operating Lease Agreement, page F-14

14. Please tell us how you recognize rental expense for leases in which the rent varies from year to year.

The Regents of the University of California, page F-15

15. Please quantify the obligation you are committed to fund. If no such amount is defined in the contract, disclose the estimate of such obligations and whether there is a limit to such obligations.

General

16. Please provide us mockups of any pages that include any additional pictures or graphics to be presented, including any accompanying captions. Please keep in mind, in scheduling your printing and distribution of the preliminary prospectus, that we may have comments after our review of these materials.

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.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Keira Nakada at 202-551-3659 or Lisa Vanjoske at 202-551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Julia Griffith at 202-551-3267 or Dietrich King at 202-551-8071 with any other questions.

Sincerely,

Division of Corporation Finance

Steven Nichtberger  
Cabaletta Bio, Inc.  
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Office of Healthcare & Insurance