



DIVISION OF
CORPORATION FINANCE

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

May 13, 2018

Torben Straight Nissen, Ph.D.
President
Rubius Therapeutics, Inc.
325 Vassar Street, Suite 1A
Cambridge, MA 02139

Re: Rubius Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted April 13, 2018
CIK No. 0001709401

Dear Dr. Nissen:

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 submitted April 13, 2018

Prospectus Summary, page 1

1. The prospectus summary should include a balanced presentation of your business, including your competitive position in the industry. In the presentation of your business, you present your organization as a "leading research and development organization" and include several performance claims as to your proprietary RED Platform on page 1 notwithstanding the preclinical stage of your development. Please tell us the basis for your performance claims and balance your summary

presentation by providing equally prominent disclosure about the competitive, regulatory, technical challenges you face.

Our proprietary RED Platform, page 1

2. Please revise to balance your statement on page 2 that you “have and continue to build a robust intellectual property portfolio..., the breadth and depth of which is a strategic asset with the potential to provide [you] with a significant competitive advantage” with your disclosure on page 49 that you do not own or in-license any issued patents directed to the composition of matter of any of the RCT product candidates that you have thus far developed using the RED Platform, and that you have in some cases only filed provisional patent applications.
3. Please revise to clarify the terms “immuno-privileged” and “well-characterized biodistribution” where you first mention them on page 1.
4. We note your statements on pages 1, 110, and elsewhere that RCTs have an “advantageous safety profile” and “may represent the ideal cell type for the creation of versatile, safe and effective...” We further note disclosure such as your belief that your product candidates will “have enhanced efficacy and avoid immune-driven adverse events...,” “could provide a cure,” and other similar statements. Statements regarding efficacy and safety are determinations that only the FDA and foreign government equivalent regulations have the authority to make. Please revise your disclosure here and elsewhere to eliminate any suggestion that your product candidates have been or will ultimately be determined safe and effective or to have demonstrated safety and efficacy for purposes of granting marketing approval by the FDA or comparable agency.

Our Product Candidate Pipeline, page 3

5. Please revise your pipeline tables on pages 3 and 118 to include a column for each of Phases 1, 2, and 3.

Our Strategy, page 4

6. Please revise the second bullet point, here and in the Business section, to put into context your statement concerning your goal to “rapidly advance” multiple additional RCTs. In this regard, we note your risk factor disclosure on pages 14, 15, and 16 which indicates that the drug development process is uncertain, lengthy, and expensive.

Risk Factors

Our rights to develop and commercialize our product candidates..., page 52

7. Please present as a separate risk factor the risk concerning “march-in rights” mentioned in this risk factor.

Use of Proceeds, page 81

8. Please revise the discussion to identify the stage of development you expect to achieve for RTX-134 and each of your product candidates referenced in your second bullet point with the proceeds of the offering. To the extent you expect to begin particular stage of development but do not expect to complete it, please indicate that you will need to raise additional funding to complete that stage of development.

Management's discussion and analysis of financial condition and results of operations

Results of operations

Comparison of the years ended December 31, 2016 and 2017

General and administrative expenses, page 97

9. Your disclosure on page 98 states that you recognized \$15.7 million for stock-based awards granted to the chairman of your board of directors during the year ended December 31, 2017 and that you accounted for these awards as non-employee stock-based awards because these awards were issued for his services as a consultant. Disclosures on page 174 appear to suggest that other awards to Mr. Epstein were also given as his role as principal executive officer. Please address the following:
- Tell us how you considered awards issued to Mr. Epstein under the guidance in the Glossary definition of Employee in ASC 718 which states that "nonemployee directors acting in their role as members of a board of directors are treated as employees if those directors were elected by the employer's shareholders or appointed to a board position that will be filled by shareholder election when the existing term expires. However, that requirement applies only to awards granted to nonemployee directors for their services as directors. Awards granted to those individuals for other services shall be accounted for as awards to nonemployees." Clarify how you evaluated which of his actions and awards were as an officer of Rubius versus his actions and awards as a nonemployee director. Further explain how you considered the above guidance for his awards as a nonemployee consultant.
 - Provide us a schedule separately showing awards given to Mr. Epstein under his role as a non-employee (and therefore accounted for under ASC 505-50) and as an officer/employee of the Company (and therefore accounted for under ASC 718) based on the guidance in the Glossary of ASC 718.
 - Clearly identify the respective time periods for which he acted as an officer, director, and consultant. Clearly identify his activities in and related awards for each role.
 - Tell us whether the \$15.7 million expense referred to on page 98 and any other amounts of nonemployee awards to Mr. Epstein are included in the compensation amounts in the table on page 174. Revise the footnotes to the table to more clearly quantify all such nonemployee awards pursuant to Instruction 3 to Item 402(c) of Regulation S-K.
 - Provide similar information for any other employee(s) that also had a non-employee director status for certain awards (e.g., Dr. Straight Nissen).

Critical accounting policies and significant judgments and estimates

Stock-based compensation

Determination of fair value of common stock, page 104

10. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and 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.

Business

RTX-Uricase/URAT1 for treatment of chronic refractory gout, page 122

11. We note your use of the term "significant unmet need" on page 123 and elsewhere in the document. Use of such a term might imply that your product would be eligible for fast track designation or priority review granted by the FDA for products that treat certain serious unmet medical needs. Please remove your use of this term throughout or otherwise please explain why you believe use of this term is appropriate.

Disease-related intellectual property, page 141

12. For each program identified in this section, please clarify whether you directly own or license the patents and patent applications. If licensed from a third party, please identify the third party.

Licenses, page 145

13. Please quantify the total potential milestone obligations pursuant to your Exclusive Patent License Agreement with Whitehead Institute for Biomedical Research.

Management, page 166

14. Please revise to disclose any arrangements or understandings pursuant to which Mr. Epstein, Dr. Nissen or Dr. Afeyan was selected as a director, or tell us why such disclosure is not required. Refer to Item 401(a) of Regulation S-K.

Employment and consulting arrangements with our named executive officers, page 175

15. We note that in connection with the offering, you are evaluating entering into amended and restated agreements with your named executive officers. Please file your current employment agreements as an exhibit to your registration statement. Please refer to Item 601(b)(10)(iii)(A) of Regulation S-K.

14. Related parties, page F-33

16. Regarding the promissory notes issued to purchase your common stock, please address the following:
- Revise to clearly disclose your accounting for the notes and purchase of common stock and where these promissory notes are classified in your financial statements.
 - Tell us how you considered the guidance of Staff Accounting Bulletin Topic 4:E.
 - Considering that one of the provisions regarding the maturity date of the promissory notes occurs immediately prior to your initial filing of a registration statement, tell us your consideration of this transaction in the capitalization table.

Exhibits

17. Please file the consulting agreement with Mr. Epstein referenced on page 174. Refer to Item 601(b)(10)(iii)(A) of Regulation S-K. In addition, we note that Dr. Cagnoni, who will join your board of directors in June 2018 when he assumes the role of Chief Executive Officer, is currently serving as an advisor. Please also file any agreement with Dr. Cagnoni as an exhibit.

General

18. 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.
19. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

You may contact Sasha Parikh at 202-551-3627 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Jeffrey Gabor at 202-551-2544 or Mary Beth Breslin at 202-551-3625 with any other questions.

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Arthur R. McGivern