



DIVISION OF  
CORPORATION FINANCE

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

May 16, 2019

Christopher Peetz  
Chief Executive Officer  
Mirum Pharmaceuticals, Inc.  
950 Tower Lane, Suite 1050  
Foster City, CA 94404

**Re: Mirum Pharmaceuticals, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted April 18, 2019**  
**CIK No. 0001759425**

Dear Mr. Peetz:

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 Solution, page 2

1. Please revise to define the term "xanthomas" the first time it is used in terms a lay person would understand.
2. We refer to your statements on pages 2 to 3 that trial data from the Phase 2 INDIGO trial demonstrated multi-parameter response and supported maralixibat's breakthrough therapy designation for PFIC2. Please balance your discussion by disclosing that the primary endpoint of sBA change was not met for the overall group. In addition, expand your disclosure to explain that this designation may not lead to a faster development or regulatory process, and that it does not increase the likelihood that it will receive

approval. Similarly, in your discussion of maralixibat trials in ALGS on page 3, please balance your disclosure to explain that there were other Phase 2 trials that did not meet their primary endpoints.

3. Please revise your last paragraph on page 2 to clarify that your Phase 3 MARCH trial will evaluate maralixibat at a higher dose of up to 600µg/kg twice daily compared to the INDIGO trial dosage of 280µg/kg once daily, and disclose the highest dosage previously tested on a long-term basis.
4. Please revise the last paragraph in this section to explain that volixibat has been evaluated primarily for the treatment of non-alcoholic steatohepatitis, and has not been evaluated in either PSC or ICP, which you discuss in your risk factors on page 12.
5. Your product candidate table discloses that you intend to initiate a Phase 3 trial for biliary atresia. We also note your disclosure on page 14 that you have not had any meeting with the FDA regarding a Phase 3 trial, you do not have any safety data for patients under the age of 12 months, which is the target age group you would seek to treat, and the FDA may require you to first conduct such safety studies. Please explain why you believe it is appropriate to indicate that you expect to initiate a Phase 3 trial in this table.

Our Company, page 3

6. You state that you are well-positioned to deliver on your mission of developing therapies for patients suffering from debilitating liver diseases. Please balance your disclosure by explaining that you have not yet completed a clinical trial as a company, and also that you do not currently have the necessary internal research and development capabilities, as you explain on pages 10 and 29.

Implications of Being an Emerging Growth Company and Smaller Reporting Company, page 4

7. 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.

Risks Associated with Our Business, page 4

8. Expand your discussion to add a bullet disclosing that even if approved, the FDA may only approve maralixibat for the narrower indication of pruritus associated with PFIC, or a subset of the PFIC patient population, rather than for the treatment of PFIC generally, as you more fully explain on page 11.

Our principal stockholders and management own a significant percentage. . . , page 56

9. Expand your disclosure to explain that all of your current directors have been appointed by investors pursuant to a voting agreement, as you more fully explain on page 129.

Use of Proceeds, page 65

10. Please revise to state the approximate amount of net proceeds intended to be used for your development of maralixibat and volixibat. Refer to Item 504 of Regulation S-K.

Business

Our Product Pipeline, page 84

11. We refer to your statements on pages 86 and 87 that volixibat has a favorable safety profile. Given that safety determinations are within the authority of the FDA and other regulatory authorities, please revise to remove these statements. Similarly, please delete your reference in the last paragraph on page 102 to the "durable efficacy" for maralixibat in the treatment of ALGS.

Historical Clinical Development of Maralixibat, page 92

12. For the INDIGO trial, expand your discussion of the pruritus results to explain whether this endpoint was met. As we also note that you state in the chart that the INDIGO trial is ongoing, please update your narrative disclosures accordingly to discuss the ongoing portion of this trial, including when you expect the results from the ongoing portion.

Phase 2 INDIGO Trial, page 94

13. You state that PFIC2 responders demonstrated improvement in pruritus and an increase in quality of life. However, the patient represented by the green line appears to show an increase in the itch score and a decrease in the quality of life. Please revise your disclosures to clarify this discrepancy.

Future Clinical Development of Maralixibat, page 103

14. Please revise to discuss the secondary endpoints you intend to measure in the MARCH trial. Also revise to explain the meaning of submitting data together with natural history data set comparisons, and whether this approach has been previously discussed with the FDA in connection with this trial. Provide similar disclosure for the ALGS trial.

Safety and Tolerability Data for Maralixibat, page 103

15. Please revise to disclose all serious adverse events, not only those that were the most commonly reported. Also provide similar disclosure for volixibat on page 104.

License Agreements, page 105

16. You state in the last paragraph on page 105 that in addition to the disclosed milestones, you are required to also pay an additional amount upon regulatory approval of maralixibat for each and every other indication. Please revise your disclosure of the total aggregate development and regulatory milestones that may be payable to include these amounts.

Christopher Peetz  
Mirum Pharmaceuticals, Inc.  
May 16, 2019  
Page 4

17. For each of your license agreements, to the extent not otherwise disclosed, please revise to clarify the duration of the royalty obligations and the terms of the agreements, including by disclosing the expiration dates of the underlying patents and patent applications.

Phase 2 NASH Clinical Trial, page 105

18. Please expand on your disclosure in the first paragraph to explain the "clinical proof of mechanism" to which you refer.

Intellectual Property, page 109

19. Please revise to disclose the foreign jurisdictions in which you have issued or pending patent applications.

General

20. 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 IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and asset acquisitions.
21. 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 Paul Cline at 202-551-3851 or Angela Connell at 202-551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Dorrie Yale at 202-551-8776 or Mary Beth Breslin at 202-551-3625 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Healthcare & Insurance

cc: Jason L. Kent - Cooley LLP