



DIVISION OF
CORPORATION FINANCE

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

July 19, 2019

John Kollins
President and Chief Executive Officer
Satsuma Pharmaceuticals, Inc.
400 Oyster Point Boulevard, Suite 221
South San Francisco, CA 94080

Re: Satsuma Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted June 21, 2019
CIK No. 0001692830

Dear Mr. Kollins:

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 June 21, 2019

Prospectus Summary

Overview, page 1

1. We note your statements throughout the prospectus that you believe STS101 has the potential to be a "best-in-class" acute treatment for migraine. This term suggests that your product candidate is effective, likely to be approved and compares favorably to competitive products. It is premature and inappropriate for you to make such statements or implications. Accordingly, please delete all references throughout your registration statement to STS101 as having the potential to become a best-in-class therapy. If you wish to distinguish STS101 from other acute treatments for migraine that are marketed or are being developed for your target indication, such disclosure should be accompanied by

cautionary language that the statements are not intended to give any indication that your product candidate has been proven effective or that it will receive regulatory approval.

2. We note the disclosure that STS101 was designed to be "effective" and "safe." As your product candidate has not received FDA approval, it is premature to suggest or imply that it is safe or effective. Please revise your disclosure here and any similar statements throughout the prospectus accordingly.
3. We refer to the graphs on page 93 which indicate that DHE mesylate IM injection demonstrated higher plasma concentration than your STS101 candidate. Accordingly, please revise to balance the Summary presentation by clarifying how your product compares to the IM injection alternative. For instance, we refer to disclosures on page 2 indicating that (i) STS101 has a number of key attributes that you believe may provide significant advantages over existing acute treatments for migraine and (ii) DHE exposure levels following STS101 administration exceeded or fell within ranges that previously have demonstrated efficacy with other dosage forms of DHE.
4. Please revise the Prospectus Summary to explain that you rely on a license from SNBL to develop and commercialize STS101. With reference to your January 5, 2017 press release, "Satsuma Pharmaceuticals Spins Out from Shin Nippon Biomedical Laboratories (SNBL) with Funding from Leading Institutional Life Science Investors," it also should be clear from your Summary disclosure that were an SNBL subsidiary at the time that SNBL granted you the original June 2016 license.
5. Please revise the disclosure on page 2 to explain briefly the term "drug exposure." From your disclosure, it should be clear how this measure differs from plasma concentration.

Implications of Being an Emerging Growth Company, page 4

6. 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

STS101 may cause undesirable side effects or have other properties that could delay..., page 19

7. We note your disclosure that unless you can successfully demonstrate by conducting a drug-drug interaction study that the coadministration of DHE and certain other drugs does not result in inhibition of DHE metabolism and elevated DHE levels, the FDA is likely to require a "black box" warning in your label for STS101, which could result in STS101 not achieving its full commercial potential. Please revise your "DHE" disclosure on page 88 and your Development Plan disclosures on pages 96-98 to discuss side effects associated with DHE use and your development plans, if any, to conduct drug-drug interaction studies.

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Our amended and restated certificate of incorporation and amended and restated bylaws will provide for an exclusive forum..., page 59

8. We note that your forum selection provision identifies the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any “derivative action.” Please disclose here and on pages 144-145 whether this provision applies to actions arising under the Securities Act or Exchange Act. In that regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and 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. If the provision applies to Securities Act claims, please also revise your prospectus to specifically state that there is uncertainty as to whether a court would enforce such provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To the extent the provision does not apply to claims arising under the Securities Act and the Exchange Act, please ensure the exclusive forum provision in your governing documents states this clearly.

Use of Proceeds, page 63

9. We note that you intend to use the net proceeds from this offering to fund your Phase 3 EMERGE efficacy trial and your Phase 3 safety trial for STS101 and to further develop STS101. Please revise your disclosure to specify whether additional funds will be necessary to complete the two clinical trials you identify. If a material amount of other funds is necessary to complete these trials, state the amounts and sources of such other funds. Refer to Instruction 3 of Item 504 of Regulation S-K.

DHE, page 88

10. We note that your disclosures on pages 2 and 90 compare your STS101 product to Migranal and intravenous-delivered DHE by referencing plasma concentration levels in terms of variability, rapidity, and high peak measurement. Based on these disclosures and others, it appears that these three factors/measures may impact DHE's therapeutic response but also may be associated with negative side effects. Accordingly, please revise appropriate sections of your Business discussion to explain the significance of DHE plasma concentration as it relates to therapeutic response and side effects. From your revised disclosures, it should be clear how your STS101 product compares to Migranal and to IV delivered DHE in terms of the variability, rapidity, and high peak measurements of recorded DHE plasma concentrations.

Our Solution: STS101 for the Acute Treatment of Migraine, page 89

11. We note your disclosure concerning the STS101 development work that SNBL conducted over more than 15 years. Please revise here and elsewhere, as applicable, to clarify whether Satsuma has engaged in any product development efforts since the spin-off and indicate whether any such development efforts are on-going.
12. With reference to your disclosure in the penultimate paragraph on page 90, please revise the Business section to explain the favorable stability properties that STS101 dry-powder formulation has demonstrated.

Business

Safety and Tolerability, page 93

13. Your disclosure indicates that subjects treated with STS101 reported a higher frequency of nasal adverse events than those treated with DHE mesylate IM injection or Migranal DHE mesylate liquid nasal spray. Please expand your disclosure to identify the adverse events experienced by patients undergoing each treatment and the frequency of each adverse event. Provide comparative data for DHE mesylate IM injection and Migranal DHE mesylate liquid nasal spray and also discuss potential reason(s) for the disparate results. Also revise your disclosure on pages 2 or 3 to balance your Summary disclosures on page 2 concerning STS101's safety and tolerability profile.

Comparison of STS101 PK Data to Other DHE Products, page 93

14. We note that in this section captioned, "Comparison of STS101 PK Data to Other DHE Products," you compare STS101 to Migranal DHE mesylate liquid nasal spray and MAP0004, but not to injectable DHE. Accordingly, please revise this caption to clarify that you are comparing STS101 to other DHE nasal sprays.
15. Please revise your disclosure to clarify, if true, that MAP0004 was never approved by the FDA and, therefore, FDA did not make a determination concerning the efficacy or safety of the drug candidate. Please also expand your disclosure to discuss any known differences in trial protocols, conditions and patient populations that could materially impact the comparability of the trial data sets presented.

Phase 3 Efficacy Trial, page 96

16. Please revise to identify the "certain" patient subgroups that you reference in the penultimate sentence on page 96.

Intellectual Property, page 100

17. We refer to your disclosure on page 33 concerning your "solely owned patent portfolio" and your disclosure on page 111 concerning your SNBL license covering

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certain patent rights. Please revise your disclosure on page 100, and elsewhere as applicable, to clarify/distinguish the intellectual property rights that you own and those rights covered by the SNBL license. From your revised disclosures, investors should be able to determine the duration of your royalty obligations and the term of the SNBL license agreement, as it currently stands, for all jurisdictions where you plan to commercialize. Given the close connection between your Intellectual Property discussion and your SNBL license discussion, also consider revising the presentation so that these discussions appear in succession.

Government Regulation, page 101

18. We note your disclosure indicating that FDA will require you to conduct human factors studies to support approval of STS101. Please expand your disclosure to explain what these studies entail and revise your development plan disclosures on pages 96-98 to discuss your plans as they relate to these studies.

Coverage and Reimbursement, page 109

19. Given your disclosed plans to submit an NDA before the end of 2021, please expand your disclosure concerning coverage and reimbursement to discuss the coverage and reimbursement applicable to existing acute migraine treatments, including those using DHE.

Licenses and Collaborations, page 111

20. Please revise to disclose the amounts reimbursed to SNBL pursuant to the license, or advise.

General

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 Mark Brunhofer at (202) 551-3638 or Jim Rosenberg, Senior Assistant Chief Accountant, at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Irene Paik at (202) 551-6553 or Joseph McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Healthcare & Insurance