



DIVISION OF  
CORPORATION FINANCE

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

October 14, 2014

Via E-mail

Jonathan M.N. Rigby  
President and Chief Executive Officer  
SteadyMed Therapeutics, Inc.  
2410 Camino Ramon  
San Ramon, California 94583

**Re: SteadyMed Ltd.  
Draft Registration Statement on Form S-1  
Submitted September 17, 2014  
CIK No. 0001619087**

Dear Mr. Rigby:

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.

General

1. Please file all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
2. Prior to its use, please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus. Please note that we may have comments regarding this material.
3. 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.

4. Comments to your application for confidential treatment will be delivered under separate cover.

Company Overview, page 1

5. Please expand your disclosure to define “orphan designation” the first time this term is used.
6. Please clarify if you intend to seek orphan designation for Trevyent in the U.S. or EU.
7. Please revise the table on pages 2 and 75 to reflect only the current stage of development for each product candidate and indication. Accordingly, please eliminate columns for planned or hoped for future events or outcomes. These are uncertain or speculative and should be discussed in the text where they can be placed in an appropriate context.
8. Please briefly state that you believe that you are a PFIC and that if you are a PFIC, U.S. holders may be liable for additional taxes and may be required to file an annual information return on IRS Form 8621. Additionally, please include the risk that you believe that you are a PFIC in your “Risk Factors Summary” on page 5.

Risk Factors

If the FDA does not conclude that Trevyent, page 12

9. We note that some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). Please expand your disclosure to explain the nature of such challenges and how, if such challenges were successful, they would impede your planned operations.
10. We note that there are currently six patents published in the Orange Book in connection with Remodulin and that United Therapeutics may initiate a patent infringement lawsuit against you, which would automatically prevent the FDA from approving the NDA for Trevyent for a substantial period of time. Please include this information under a separate risk factor and identify this risk on page 5 under “Risk Factors Summary.” Additionally, please describe any patent infringement lawsuit that United Therapeutics has initiated against Sandoz in response to its ANDA for a generic form of treprostinil.

Special Note Regarding Forward-Looking Statements and Third Party Data, page 48

11. We note your statement that you have not verified any third-party information. Please revise your disclosure to remove this statement as it is inappropriate to directly or indirectly disclaim liability for information provided in your prospectus.

Use of Proceeds, page 50

12. Please expand your disclosure to include the approximate amount you plan to allocate to each of the clinical studies for your existing product candidates that you expect to fund with the proceeds by indication. Additionally, please disclose whether you expect the applicable proceeds will be sufficient to fully fund each clinical trial or state what aspects of such trials you will be able to accomplish using the applicable proceeds.

Capitalization, page 52

13. Please revise the presentation of this table to remove cash and cash equivalents or, alternatively, clearly indicate that it is not a component of capitalization by adding an underline or double underline under the amounts as well as a blank line.

Research and Development Expenses, page 59

14. We note that you plan to continue pre-clinical and clinical trials for SMT-201 and SMT-301. Please identify these product candidates. In this regard, we note that you have two product candidates named Bupivacaine AHPA and Ketorolac AHPA described in your prospectus.

Loan from a Commercial Bank, page 65

15. Please disclose the material terms of the Loan and Security Agreement including interest rate provisions, repayment terms and maturity, restrictions or covenants, security interest and any other material terms.

Contractual Obligations and Commitments, page 67

16. Please revise your presentation to include interest with regard to your bank loan in the table or tell us why your presentation is appropriate.

Stock-based Compensation Expense, page 68

17. We may have additional comments on your accounting for stock compensation or any beneficial conversion features. Once you have disclosed an estimated offering price, please provide us with an analysis explaining significant differences between the estimated offering price and the fair value of material recent equity issuances prior to the date of effectiveness.

Business, page 73

18. Please expand your disclosure to identify your long-lived assets located in all foreign countries and in Israel as required by Regulation S-K Item 101(d)(1)(ii).

19. We note that Trevyent is a combination product that includes a new medical device. We also note that you did not include an IND submission in your table on pages 2 and 75. If applicable, please disclose when each IND for Trevyent was filed, the party who filed the IND, and the specific indication listed therein. If no INDs have been filed to support your clinical trials for Trevyent, please disclose why INDs were not required.
20. Please describe the clinical trials that you are planning to fund with proceeds from this offering. In this regard, please provide a general description of the study including the size, duration, and purpose.

Trevyent Development Plan, page 80

21. We note on page 80 that you characterize the PatchPump as “safe.” Regulatory approval of the PatchPump and Trevyent is dependent on the FDA making a determination according to criteria specified in law and agency regulations, that your product is both safe and effective. Therefore, it is premature for you to describe Trevyent or the PatchPump as safe. Accordingly, please delete language stating that the PatchPump is safe throughout your prospectus, as applicable.
22. We note that your planned summative usability testing will ensure that Trevyent meets all of the applicable FDA requirements. Please expand your disclosure to discuss this and any additional testing that you are planning to complete prior to submitting Trevyent’s NDA. Additionally, please describe ISO 62366 and discuss any additional testing you are planning to comply with ISO 62366.
23. Please expand your disclosure to briefly describe the formative human factors studies conducted to date with 93 volunteers.
24. Please briefly describe the six patents in connection with Remodulin published in the Orange Book and why you believe that Trevyent does not infringe any of these patents.
25. If applicable, please explain your plans to demonstrate clinical superiority in order to obtain approval of Trevyent as an orphan drug.

Trevyent Sales and Marketing, page 81

26. We note on page 13 that you state that a patent infringement lawsuit could significantly delay the marketing approval of Trevyent in the United States. Please briefly discuss how your anticipated timeline to commercialize Trevyent may be delayed if United Therapeutics initiates a patent infringement lawsuit. In this regard, please discuss how a 30 month stay related to such litigation could impact your marketing approval.

27. We note that Sandoz has filed an ANDA for a generic form of tadalafil. Please expand your disclosure to briefly discuss how a generic form of tadalafil may impact your plan to price Trexymol comparably to Cialis.

Ketorolac AHPA, page 85

28. Please clarify that ketorolac is a generic drug.

Intellectual Property, page 89

29. Please identify the material jurisdictions in which you have significant patent protection, and disclose the expiration dates of your significant patents by jurisdiction.

Review and Approval of Drugs Products in the United States, page 90

30. If applicable, please briefly summarize the FDA's regulatory scheme under the Orphan Drug Act, and expand your disclosure to clarify that you must demonstrate clinical superiority.

Executive Officers, page 102

31. Please expand your disclosure to clarify the period of time that Mr. Rigby worked at Zogenix.

Executive Compensation, page 118

32. Please provide the material terms of each executive officer's employment agreement or arrangement.

Rule 144, page 146

33. Please state the number of shares of common stock that will be restricted securities under Rule 144 upon completion of this offering.

Lock-Up Agreements, page 147

34. Please state the number of shares that are subject to a lock-up.

Consolidated Balance sheet, page F-4

35. Please revise to include the amount of preferred shares issued and outstanding for the period ended December 31, 2012.

36. Please revise to include the liquidation preference of your preferred stock in accordance with ASC 505-10-50-4.

Note 10: Shareholders' Deficit, page F-24

37. In a., please include share capital information for the period ended June 30, 2014 in accordance with ASC 505-10-50-2.

Exhibit Index

38. Please file the employment agreement for each of your managers.
39. We note on page 87 that you have supply agreements with Bespak Europe Ltd., EaglePicher Medical Power, LLC, and Nova Laboratories Limited. Please revise your disclosure to identify the parties to the Supply Agreement filed as Exhibit 10.8. Additionally, please file your two other supply agreement as exhibits pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please provide us with an analysis supporting your determination that these agreements are not material to the company.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at <http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm>.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (<http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm>). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Sasha Parikh at (202) 551-3627 or Joel Parker at (202) 551-3651 if you have questions regarding comments on the financial statements and related matters. Please contact Matthew Jones at (202) 551-3786 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler  
Assistant Director

Jonathan M.N. Rigby  
SteadyMed Ltd.  
October 14, 2014  
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cc: James C. Kitch  
Michael E. Tenta  
Cooley LLP  
3175 Hanover Street  
Palo Alto, CA 94304