

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

January 10, 2014

Via E-mail
Jason B. Shandell
President
Amphastar Pharmaceuticals, Inc.
11570 6th Street
Rancho Cucamonga, California 91730

Re: Amphastar Pharmaceuticals, Inc.
Draft Registration Statement on Form S-1
Submitted December 16, 2013
CIK No. 0001297184

Dear Dr. Shandell:

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 any written materials that you or anyone authorized to do so on your behalf provides in reliance on Section 5(d) of the Securities Act to potential investors that are qualified institutional buyers or institutional accredited investors. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act

of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

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

Prospectus Summary, page 1

- 5. Please define "characterizing complex molecules."
- 6. Please explain the meaning and significance of a PDUFA date.

Risk Factors, page 10

7. We note that ANP is your wholly-owned subsidiary in China. Please advise us of any risks related to your direct foreign ownership in a Chinese entity.

We depend upon our key personnel . . ., page 17

8. Please expand your discussion to identify your key personnel, describe the extent to which you have employment agreements with such personnel, and discuss the extent to which departures have affected you in the past.

We may be exposed to product liability claims . . ., page 19

9. Please disclose the amount of product liability coverage you currently have.

Our products may be subject to federal and state laws . . ., page 36

10. Please expand your disclosure on page 36 and 63 to identify your products that are subject to increasing pricing pressures, and how this pricing pressure has impacted your business to date.

Some of our products are marketed without FDA approval . . ., page 37

11. We note that you did not initially discontinue all of your products that were subject to the Prescription Drug Wrap-Up Program. Please expand your disclosure to state the products that you elected to continue after making a cost-benefit analysis. Additionally, please expand your disclosure to provide the revenues generated from the products you elected to continue to market, and the quantified risk based on your cost-benefit analysis of continuing to market these products. Alternatively, if the FDA also requested that you continue to commercialize these products, please disclose this request.

Market and Industry Data, page 53

12. Please remove the two sentences beginning with "While we are not aware of any misstatements . . ." It is not appropriate to directly or indirectly disclaim liability for information in the registration statement.

Use of Proceeds, page 54

- 13. Please amend your disclosure to include the estimated amount of proceeds you plan to allocate for each of the uses identified on page 54, and for each individual product candidate. Additionally, please expand your disclosure to state the stage of development for each product candidate that you expect to reach using the allocated proceeds.
- 14. Please expand your disclosure to provide a description of the facility expansion. Additionally, please clarify if the facility expansion includes the land development related to a facility expansion in China, and include the investment in land development related to a facility expansion in China as one of the bulleted intended uses on page 54.
- 15. We note that you have commitments to invest in China. If you intend to use any proceeds to fulfill these commitments, please include such commitments in your use of proceeds.

Management's Discussion and Analysis of Financial Condition and Results of Operations Net Revenues, page 64

16. Please separately disclose any significant product revenue included in "Other Products" such as Cortrosyn.

Research and Development, page 65

- 17. You state that you have made, and expect to continue to make, substantial investments in research and development to expand your product portfolio and grow your business. On page 98, you disclose that you currently manufacture and sell 15 products in the U.S. and are developing a portfolio of 13 generic and seven proprietary injectable and inhalation product candidates. Please provide us with the following information and revise your disclosures as appropriate:
 - For your key research and development projects, please tell us the following:
 - The nature, objective, and current status of the project;
 - The costs incurred during each period presented and to date;
 - The nature of efforts and steps necessary to complete the project;
 - The risks and uncertainties associated with completing development;
 - The extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project; and

- Whether a future milestone such as completion of a development phase, date
 of filing an NDA with a regulatory agency, or approval from a regulatory
 agency can be reliably determined.
- For the remainder of projects not considered individually significant, tell us the composition of the total R&D expense for each period presented. This can take a variety of forms but is mainly driven by how many projects are managed and how they are reported within the organization. We believe disclosure of R&D by your divisional structure would be informative. Also distinguishing between discovery, preclinical and clinical development categories and further by late stage such as phase III development categories along with providing the number of projects in each category helps provide information necessary to understand the pipeline and trends by division. To the extent that management has information available by therapeutic class, we believe that further enhances the understanding of R&D expense and trends.
- If based on a known event, trend, demand, commitment or uncertainty, future R&D expense or the mix of R&D expense is reasonably likely to differ from current trends, please tell us the reasons for and the amount of the expected change.
- For projects that you disclose are in the late stage of development such as phase III, unless management believes that the expected effect on results of operations or financial position from the project when completed will be insignificant, please tell us the following about each project, even if the R&D expenses incurred on the project has not been material, in order to provide insight into expected effects on future operations, financial position or liquidity. Please include:
 - A description of the nature and its indication;
 - The phase the project is in at the end of the reporting period and the month and year it entered that phase;
 - Significant patents associated with the project and their expiration dates as well as other information about the exclusivity period related to the project;
 - Significant developments of the project during the period such as significant milestones, filing for regulatory approval, approval and other responses from regulatory agencies; suspension or termination and their reasons;
 - Future expected milestones such as completion of a development phase, date
 of filing an NDA with a regulatory agency, or approval from a regulatory
 agency if it can be reliably determined. If the extent and timing of these
 future events cannot be reliably determined, please tell us the facts and
 circumstances that prevent their determination.

<u>Critical Accounting Policies</u> <u>Share-Based Compensation, page 72</u>

18. Please revise Management's Discussion and Analysis relating to your issuances of equity instruments as follows:

- Please update the table on page 76 to include the terms of all equity issuances through the date of effectiveness, including options, warrants, preferred stock, deferred stock units, etc.
- Please include a discussion of each significant factor contributing to the difference between the fair value as of the date of each grant and the estimated IPO price. Please note that we are deferring final evaluation of stock compensation and related costs until an amendment including your estimated offering price has been filed.

Agreements with Corporate Partners, page 94

19. Please expand your disclosure to state your share of the gross profits from Andrx's sales and now Watson's sales of enoxaparin in the U.S., within a ten percent range. Additionally, please disclose the material early termination provisions, and the year that the agreement will expire given the patents that are currently outstanding.

Investment in China, page 95

20. We note on page 95 that you entered into agreements to lease land in China. Please expand your disclosure to clarify which of the filed exhibits relate to each of the agreements you entered. Alternatively, please file the agreements as exhibits to the registration statement.

Business, page 98

21. Please advise us of the INDs submitted for Primatene Mist HFA and Amphadase by indication and disclose when these INDs were filed and by whom. Additionally, please clarify whether you or anyone else has filed INDs for Primatene Mist HFA and Amphadase. If so, provide the same information as requested for the INDs that you have submitted.

Our Product Candidates, page 103

22. We note that you have 13 generic product candidates in development. Please expand your disclosure to state the number of candidates that are in early stage development prior to bioequivalence studies.

Intellectual Property, page 122

- 23. Please disclose your products and candidates for which you do not have patent protection.
- 24. Please expand your disclosure to discuss your material patents by material product or product group. Additionally, please expand your disclosure to discuss your material patents for each of Primatene Mist HFA and Amphadase.

25. Please provide similar information with respect to your non-U.S. patent coverage and identify the applicable jurisdictions.

Management, page 124

- 26. Please update the security ownership table to the most recent practicable date.
- 27. Please identify the natural person(s) with voting or investment control over the securities owned by Coller International Partners IV Limited.

Executive and Director Compensation, page 130

- 28. Please update your executive and director compensation disclosure to include the registrant's last completed fiscal year. You should continue to provide 2012 executive compensation information in your Summary Compensation Table. Please refer to Instruction 1 to Item 402(c) of Regulation S-K.
- 29. Once available, please expand your disclosure to include the material terms of the employment agreements between you and your named executive officers. Additionally, please file these agreements as exhibits.

Certain Relationships and Related Transactions, page 140

- 30. We note that the company signed a purchase agreement for the NDRC facility with MSI in October 2012. Please file your purchase agreement as an exhibit pursuant to Item 601(b) of Regulation S-K.
- 31. When available please file your indemnification agreements between the company and its directors.

Shares Eligible for Future Sale, page 146

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

Underwriting

Commissions and Discounts, page 152

33. Please advise us if the company and the selling shareholders will pay the expenses of the offering on a pro rata basis. If the company and the selling shareholders will not pay the expenses of the offering on a pro rata basis, please expand your disclosure to explain the amount the company will pay and the amount the selling shareholders will pay.

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 Ibolya Ignat at (202) 551-3656 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Matthew Jones at (202) 551-3786, John Krug at (202) 551-3862 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

cc: David B. Allen, Esq.

K&L Gates LLP

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Irvine, CA 92618