

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

January 19, 2011

Mr. Jack A. Khattar President and Chief Executive Officer Supernus Pharmaceuticals, Inc. 1550 East Gude Drive Rockville, Maryland 20850

Re: Supernus Pharmaceuticals, Inc.
Registration Statement on Form S-1
Filed December 23, 2010
File No. 333-171375

Dear Mr. Khattar:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

FORM S-1

General

- 1. Please provide us proofs of all graphic, visual, or photographic information you will provide in the printed prospectus prior to its use. Please note we may have comments regarding these materials.
- 2. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not complete lists. If our comments are applicable to portions of the filing that we have not cited as examples, please make the appropriate changes in accordance with our comments.
- 3. Please update the discussion in your prospectus to the most recent date practicable.

- 4. Please be advised that in the event you submit a request for confidential treatment with respect to any of the exhibits yet to be filed, we will not be in a position to consider a request for acceleration of effectiveness of the registration statement until we resolve all issues concerning the confidential treatment request.
- 5. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments. As you are likely aware, you must file this amendment prior to circulating the prospectus.
- 6. Please note that when you file a pre-effective amendment that includes your price range, it must be bona fide. We interpret this to mean that your range may not exceed \$2 if you price below \$20 and 10% if you price above \$20.

Cover Page

7. Please eliminate the term "joint book-running managers."

<u>Summary – Supernus Pharmaceuticals, Inc.</u>

8. Please disclose when you filed the IND for SPN-809.

Our Late-Stage Neurology Portfolio, page 1

- 9. Please disclose the source for the estimated number of people worldwide affected by epilepsy and, if known, the number of such individuals in the United States.
- 10. Please disclose the source for the following statements on page 2:
 - Extended release products have been shown to improve compliance and reduce breakthrough seizures;
 - Extended release products have been shown to reduce side effects and improve tolerability;
 - Managed care plans have not limited the success of extended release products;
 and
 - Extended release products have performed well in the market.

Our Psychiatry Portfolio, page 3

- 11. Please disclose the source for the following statements:
 - ADHD affects an estimated 6.9% of all school-age children and 4.4% of adults in the United States;
 - An estimated 60% to 80% of children with ADHD continue to meet the criteria of ADHD into adolescence;

- As many as 67% of children who have ADHD may have coexisting conditions such as oppositional defiant disorder, defiant disorder, conduct disorder, anxiety disorder and depression; and
- Approximately 25% of children with ADHD also exhibit persistent conduct problems, such as impulsive aggression.

Risk Factors

"Delays or failures in the completion of testing of our product candidates...," page 12

12. Please expand the discussion to explain and quantify the extent to which you have experienced the events described in the bulleted examples, if material.

"If we do not obtain marketing exclusivity for our product candidates...," page 13

13. Please relocate this risk factor to immediately follow the risk factor entitled "if other versions of extended or controlled release..."

"We rely and will continue to rely on outsourcing arrangements for certain of our activities...," page 23

14. Based on the disclosure in this risk factor and in the "Manufacturing" section on page 92, it appears that the company has entered into manufacturing and supply agreements with third party manufacturers for required raw materials, drug substance and finished product for its preclinical research and clinical trials. Please disclose the name of the respective manufacturers and/or suppliers in this risk factor. Also, please identify the raw material that is the subject of the risk factor, whether the company has any agreements in place for the raw material, and, if known, the name of the manufacturer and/or supplier. If you have entered into manufacturing or supply agreements, please file them as exhibits and describe them in an appropriate location in your document. Alternatively, please provide us with an analysis that supports your conclusion that the agreements are not required to be filed pursuant to Item 601(b)(10) of Regulation S-K.

"We may not be able to manage our business effectively if we are unable to attract and motivate key personnel...," page 28

15. To the extent you have experienced problems attracting and retaining qualified management, scientific and administrative personnel in the recent past, please expand your disclosure to describe these problems. Similarly, to the extent applicable, please expand the discussion under the risk factors on page 31 pertaining to disclosure of alleged trade secrets and system failures to describe the problems you have experienced.

"We have operated as a private company and have no experience..." Page 34

16. Please expand the discussion to quantify the additional costs you expect to incur as a public company.

Use of Proceeds, page 43

17. Please expand the discussion to indicate each of the product candidates for which you intend to allocate proceeds, general and administrative expenses, working capital, prosecution and maintenance of intellectual property, and the potential investment in or acquisition of technologies or products that complement your business. With regard to the amounts you anticipate to allocate to specific pipeline products, please state the stage of development you expect the additional funding will enable you to attain as to each such pipeline product.

Management's Discussion and Analysis of Financial Condition and Results of Operations, Overview, page 51

18. Please disclose the source for the statement on page 52 that SPN-812 "may provide increased benefit to an estimated 40% of ADHD patients who suffer from depression."

Management's Discussion and Analysis of Financial Condition and results of Operations

<u>Liquidity and Capital Resources</u>

<u>Cash Flows</u>

<u>Operating Activities, page 63</u>

19. Your liquidity discussion largely reiterates what is presented in the statement of cash flows with little explanation of the reason for increases and decreases. Please revise to provide a more detailed discussion to address and quantify the reasons for changes in operating, investing and financing activities. For example, stating that the \$16.2 million increase in net cash used in operations for the year ended December 31, 2008 compared to the same period in 2007 was the result of a \$16.2 million increase in net loss offset by an increase in certain non-cash items does not seem to be sufficiently informative.

<u>Critical Accounting Policies and Estimates</u> Stock-Base Compensation, page 67

20. On November 2, 2010, your board of directors re-priced 255,000 of the options granted on December 15, 2009 from a per share exercise price of \$1.76 to \$0.64. In addition, your board approved the modification of the performance vesting requirements related to 157,697 employee stock options and 411,765 shares of non-vested stock awarded to our chief executive officer. Please clarify why recording an immediate charge related to the re-priced and modified options under ASC 718 was considered not required.

- 21. Please disclose any grants or equity issuances up until the time of effectiveness of your registration statement.
- 22.Please note that once your filing includes an estimated offering price we may have further comments on stock compensation as well as your capitalization and dilution tables.
- 23.Please revise your disclosure to present the intrinsic value of outstanding vested and unvested options as of the most recent balance sheet date based on the estimated IPO price.

Epilepsy, page 76

- 24. Please revise your disclosure to attribute the below statements and other similar statements to the source from which you obtained the information. In addition, where you cite your own estimates or conclusions, please explain how you arrived at those estimates or conclusions and disclose any third-party sources upon which you relied.
 - Page 76: "In addition, a single breakthrough seizure can lead to permanent loss or reduction in overall seizure control. Data suggest that a significant proportion of patients who experience a breakthrough seizure have a lower chance of achieving reliable seizure control."
 - Page 76: "In certain cases, a single breakthrough seizure can develop into *status epilepticus*, a prolonged seizure or a series of repeated seizures, and eventually result in brain damage or death. Data indicate that the risk of sudden unexpected death in epilepsy was 23 times higher in patients who had at least one breakthrough seizure compared to patients who had achieved seizure control."
 - Page 76: "Despite the introduction of new AEDs in the past few years, drug therapy remains ineffective for seizure control in up to 30% of patients with epilepsy."
 - Page 77: "A 2002 survey undertaken by neurologists in the United States revealed that at least once per month...."
 - Page 78: "For example, in a 2008 study, the rates of patients switching back from generics to branded drugs because of adverse events were found to be 20.8% to 44.1% for AEDs compared to 7.7% to 9.1% for non-AEDs."
 - Page 78: "Based on prescription data from 1994 to 2005 for NCE launches for seizure disorders, such NCEs, on average, experienced slow market penetration..."
 - Page 81: "According to a 2009 survey, the total healthcare costs for patients using branded topiramate products were approximately 20% lower than for patients using multiple generic topiramate products."
 - Page 82: "Moreover, prescription data for seizure disorder drugs from 1994 to 2005 shows that extended release products perform better than NCEs during the first five years of their launch."
 - Page 83: "Topamax reached peak worldwide sales of \$2.7 billion in 2008, before generic products entered the U.S. market in March 2009. With approximately 9.1

- million total topiramate prescriptions in 2009, topiramate continues to represent a significant portion of prescriptions with approximately 8.7% of total prescriptions."
- Page 84: "It reached peak worldwide sales of \$721 million in 2006, before generic products entered the U.S. market in October 2007. With approximately 3.3 million total oxcarbazepine prescriptions in 2009, oxcarbazepine represents a portion of prescriptions"

Epliga Development Program, page 84

25. We note the discussion on page 85 relative to the special protocol assessment. Please expand the discussion to indicate when the meeting(s) occurred and when the SPA was submitted. In addition, please disclose whether the SPA has been approved by the FDA and, if not, the nature of any discussions you have had with the FDA concerning the SPA and any special concerns the FDA has with respect to the study design. Similar information should be provided with respect to any other pending SPAs you may have.

ADHD, page 86

- 26. Please revise your disclosure to attribute the below statements and other similar statements to the source from which you obtained the information. In addition, where you cite your own estimates or conclusions, please explain how you arrived at those estimates or conclusions and disclose any third-party sources upon which you relied.
 - Page 86: "In 2008, the U.S. market for ADHD prescription drugs was more than \$4 billion."
 - Page 86: "It is estimated that the annual societal cost of illness for ADHD is more than \$36 billion."
 - Page 86: "Studies indicate that approximately 80% of ADHD patients respond to stimulants. A key difference between older and new oral stimulants is the duration of action. Most of the older stimulants, representing approximately 35% of total oral stimulant prescriptions, are immediate release products that last approximately four hours, requiring multiple administrations throughout the day. In contrast, most of the recently launched products, representing approximately 65% of total oral stimulant prescriptions, are extended release formulations that last up to twelve hours or more."
 - Page 86: "Approximately 30% of patients with ADHD are non-responsive to or non-tolerant of treatment with stimulants."
 - Page 90: "Depression is a serious and common disease affecting approximately 121 million people worldwide. The worldwide market for antidepressants is approximately \$12 billion."
- 27. Please identify the "seminal clinical trial" referred to under "Current Treatments for Impulsive Aggression in Patients with ADHD."

EnSoTrol (osmotic delivery system), page 91

28. Please expand the discussion to address the term and termination provisions of the United Therapeutics license agreement. In addition, please disclose the potential range within ten percent for royalties, i.e. single digits, teens, twenties, etc.

Management, page 105

- 29. Please state whether you currently have charters for the compensation, audit, and governance committees. In this regard, please note instruction 2 to Item 407 of Regulation S-K.
- 30. Please include a discussion of your board leadership structure and risk oversight function. See Item 407(c) of Regulation S-K.

Executive Compensation, page 110

- 31. We note the discussion on pages 114-115 that disclosure of your corporate goals would cause serious competitive harm. Please provide us with an analysis of the potential competitive harm you anticipate as a result of such disclosure. See CD&I Question 118.04.
- 32. Please disclose the individual goals for each of the four NEOs whose cash awards were 40% based upon individual goals. In addition, please disclose the Committee's assessment of the extent of achievement of each of the individual goals.
- 33. Please expand the discussion of equity awards on page 115 to discuss the factors related to awards made to the two NEOs in 2009.
- 34. Please update the discussion and related tables to reflect the fiscal year ended December 31, 2010. In addition, to the extent the company awards or has awarded equity or cash incentive awards for 2010 performance, or adjusts or has adjusted base salaries, the compensation discussion and analysis should be revised accordingly.

Certain Relationships and Related Party Transactions, page 126

35. Please update the discussion to describe the policies and procedures your board will use to review and approve related party transactions subsequent to the consummation of the proposed offering.

Principal Stockholders, page 127

36. Please revise the footnotes to disclose the natural persons with voting and/or investment power over the shares held by New Enterprise Associates 11, Limited and its affiliates, OrbiMed Private Investments II, L.P. and its affiliates, and Shire LLC, respectively.

<u>Consolidated Financial Statements</u> <u>Consolidated Statement of Cash Flows, page F-6</u>

37. Please clarify how purchases of marketable securities during the nine months ended September 30, 2010 would result in cash inflows of \$45,297,692 and how sales and maturities of marketable securities during the nine months ended September 30, 2010 would result in \$30,746,029 cash outflows.

Notes to Consolidated Financial Statements
Summary of Significant Accounting Policies
Revenues, page F-14

- 38. It is unclear how your accounting policies described here are applied to the one-time payment of approximately \$36.9 million received from Shire plc as consideration for "a royalty-free, fully paid-up license to Intuniv." Revise your accounting policy footnote disclosure to include a discussion of the accounting policy applied to the one-time payment received from Shire plc and your basis in the accounting literature for your accounting treatment.
- 39. Please disclose the basis for recognizing development revenue as the related costs are incurred and reference for us the authoritative literature you relied upon to support your accounting.

Exhibits

- 40. We note the disclosure indicating there are two in-licensing agreements with Afecta, however only one such agreement has been filed as an exhibit. Please advise whether there is, in fact, more than one agreement with Afecta and, if so, file this second agreement as an exhibit. Alternatively, please provide an analysis that supports your conclusion that the agreement does not have to be filed pursuant to Item 601(b)(10) of Regulation S-K.
- 41. We note that once the non-recourse notes are retired, your right to receive royalties will resume pursuant to the agreements with Endo/Indevus and Royalty Sub and Collagenex/Galderma and Royalty Sub. Please file these agreements as exhibits. Alternatively, please provide an analysis that supports your conclusion that the agreements do not have to be filed pursuant to Item 601(b)(10) of Regulation S-K.
- 42. Please file the non-recourse not agreement as an exhibit. In addition, please expand the disclosure in the prospectus where appropriate to identify the holder of the non-recourse note.
- 43. Please file your remaining exhibits, including the legal opinion, as soon as practicable. We will need time to review these exhibits prior to any request for acceleration of effectiveness.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Act of 1933 and

all applicable Securities Act rules require. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please refer to Rules 460 and 461 regarding requests for acceleration. We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Iboyla Ignat, Staff Accountant, at (202) 551-3656, or Melissa Rocha, Branch Chief, at (202) 551-3854 if you have questions regarding comments on the financial statements and related matters. Please contact John Krug, Senior Counsel, at (202) 551-3862, or me at (202) 551-3715 with any other questions.

Sincerely,

Jeffrey Riedler Assistant Director

cc: Paul M. Kinsella, Esq.
Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199-3600