



DIVISION OF  
CORPORATION FINANCE

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

May 1, 2012

Via E-Mail

Ivan Bergstein, M.D.  
Chairman, President and Chief Executive Officer  
Stemline Therapeutics, Inc.  
750 Lexington Avenue, Sixth Floor  
New York, New York 10022

**Re: Stemline Therapeutics, Inc.  
Registration Statement on Form S-1  
Filed April 2, 2012  
File No. 333-180515**

Dear Dr. Bergstein:

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.

General

1. Since you appear to qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act (“the Act”), please disclose on your prospectus cover page that you are an emerging growth company, and revise your prospectus to provide the following additional disclosures:
  - Describe how and when a company may lose emerging growth company status;
  - A brief description of the various exemptions that are available to you, such as exemptions from Section 404(b) of the Sarbanes-Oxley Act of 2002 and Section 14A(a) and (b) of the Securities Exchange Act of 1934; and
  - Your election under Section 107(b) of the Act:

- If you have elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the Act, include a statement that the election is irrevocable; or
  - If you have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the Act, provide a risk factor explaining that this election allows you to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Please state in your risk factor that, as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates. Include a similar statement in your critical accounting policy disclosures in MD&A.
2. 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.
  3. 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 \$2.00 if your minimum price is \$10.00 or less, and may not exceed 20% if your price is above \$10.00.
  4. Please file your remaining exhibits as promptly as possible. We will need time to review these documents once they are filed.
  5. Please note that we will not be able to declare your registration statement effective until we have also completed our review of the related confidential treatment request you filed in conjunction with this Form S-1.
  6. Please provide us with proofs of all graphic, 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.
  7. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not exhaustive lists. If our comments are applicable to portions of the filing that we have not cited as examples, make the appropriate changes in accordance with our comments.

8. We note that you use technical jargon throughout your prospectus. Wherever you first use a technical term, please define or explain that term so that an investor can better understand your disclosure. Please provide a definition or explanation for the following terms used in your prospectus:
- “biologic-drug conjugate”;
  - “cell-based assay”;
  - “development plan designed to culminate in registration”;
  - “durable complete responses”;
  - “high throughput screening”
  - “human interleukin-3 (IL-3) genetically linked to a truncated version of diphtheria toxin”;
  - “overexpressed”;
  - “patient-harvested dendritic cells”;
  - “single agent activity”; and
  - “synthetic peptide vaccine that targets several epitopes.”

Prospectus Summary, page 1

9. Please provide support for your statements that you are, “developing the most clinically advanced pipeline of anti-CSC therapeutics,” and that your pipeline establishes you, “as a leader in the CSC field.” Please also provide a basis for the similar disclosure elsewhere in your prospectus, including: the Overview section on page 49; the Overview section on page 65; and the Strategy section on page 67. We also note that on page 19 that you identify other companies with substantial resources and experience that are developing CSC-directed compounds. Given that, please provide a reasonable basis for these statements and, if you cannot, please consider removing the statements.

Risk Factors

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, page 9

10. The risks you discuss under this caption appear to be similar to the risks you discuss under the caption, “Any failure or delay in completing clinical trials for our product candidates may prevent us from obtaining regulatory approval or commercializing product candidates on a timely basis, or at all, which would require us to incur additional costs and delay receipt of any product revenue” on page 15. Please consider combining these two risk factors and eliminating any duplication while addressing the potential adverse consequences of delays or failures in clinical trials.

If, in the future, we are unable to establish our own sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in commercializing our product candidates, page 24

11. Please expand this risk factor to clarify if any of your current executive officers has experience establishing the marketing and distribution capabilities you discuss.

Risks Related to Our Dependence on Third Parties, page 28

12. Please expand your risk factors here to address any potential risks or delays as a result of becoming the sponsor for the INDs you currently license or filing your own INDs. For example, please disclose the extent to which your drug development process may change as a result of acquiring the INDs, and whether your company may be required to: manage clinical trials; engage CROs, collaboration partners, manufacturers or others to assist you in designing, conducting or managing trials; communicate with regulatory bodies; or supply products. If becoming the sponsor for the INDs you currently license or filing your own INDs could cause a major disruption to your research and development processes, please consider adding a separate risk factor discussing that risk.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives, page 38

13. Please expand this risk factor to disclose your estimated costs of compliance as a reporting company.

Capitalization, page 44

14. Please revise your disclosure to highlight the charges to earnings that will occur upon the completion of your offering, including, but not limited to, the stock-based compensation referred to in the last paragraph of Note 8 on page F-19 and the beneficial conversion feature on your 1.27% Convertible Notes disclosed in Note 12 on page F-24. In addition, please clarify whether any of the almost \$1 million in contingent bonuses and salary increases disclosed in Note 10 in the first paragraph on page F-23 will be payable upon the completion of your offering. Please ensure you include all such earnings charges in your dilution computation and MD&A disclosures as well.

Dilution, page 46

15. Please revise your historical net tangible book value at December 31, 2011 to remove the parentheses to reflect the amounts as positive or explain to us why it is appropriate to reflect negative amounts. Based on the information on your balance sheet, it appears that you have positive book equity and positive net tangible book value at December 31, 2011.

Selected Financial Data, page 48

16. Please revise the description of your “deficit/earnings accumulated during development stage” to include parentheses around the word “deficit” to properly identify negative numbers. In addition, please add parentheses to each of the amounts on this line in 2007, 2008 and 2009 to be consistent with the deficits presented in your statements of preferred stock and stockholders’ equity (deficit).
17. Please revise your filing to present historical net (loss)/income per common share and the weighted-average number of common shares outstanding for each annual period presented. This comment also applies to your summary financial information on page 8.

Management’s Discussion and Analysis of Financial Condition and Results of Operations  
Financial Operations Overview

Research and Development Expenses, page 51

18. You disclose that you include patent-related legal costs in research and development expenses. Please tell us the nature of these costs and why classification as research and development expenses is not precluded under ASC 730-10-55-2i. Otherwise, please revise your financial statements to reclassify these legal costs to general and administrative expenses.

Critical Accounting Policies and Estimates

Accrued Research and Development Expenses, page 53

19. For each period presented, please disclose the adjustments to your accrued research and development expenses for changes in prior period estimates.

Significant Factors, Assumptions, and Methodologies Used in Estimating Fair Value of Common Stock, page 56

20. Please revise your disclosure to state the amount of additional expense recognized when the retrospective valuation of the common stock as of March 31, 2010 and March 31, 2011 was determined and the period in which the additional expense was recorded.
21. Please update the table and related disclosure on page 57 to include the 2012 option grants you disclose in the second paragraph on page 59. To the extent you grant additional options prior to the completion of this offering, please update the table for those future grants.

22. Once you have determined the proposed price range, please expand your disclosure to include each significant factor contributing to the difference between the fair value as of the date of your most recent equity award on March 9, 2012 and the estimated IPO price.

Results of Operations, page 60

23. You disclose that other income includes amounts associated with the Qualified Therapeutic Discovery grant program from the federal government and the Biotechnology Tax Credit from the City of New York. Please revise your financial statements to provide a policy note discussion indicating how you recognize grant income and separately reference for us the authoritative guidance you rely upon to support your policy. In addition, please revise your disclosure, here or elsewhere in MD&A, to clarify whether you have any continuing performance obligations related to the receipt of these grants and whether there are any refund obligations. If so, please disclose those obligations and their impact on your accounting.

Liquidity and Capital Resources

Cash Flows, page 61

24. Please revise the financing activities line item in the table of primary sources and uses of cash to show net cash (used in) provided by financing activities.

Business, page 65

25. Given your risk factor on page 14 discussing the lack of a consensus as to the role of CSCs in cancer progression, please explain the reasonableness of your statement here that, “there is a large body of evidence indicating that treatment failure, tumor relapse and poor survival are largely the result of the failure of conventional cancer treatments to eradicate CSCs.” Alternatively, please consider deleting this statement.
26. Given your disclosure on page 12 that SL-401 and SL-701 studies were both previously managed by investigators under their own INDs, please disclose in the Business section the investigators that previously managed these studies and sponsored the INDs and the current status of any attempts to transfer sponsorship of these INDs and how that could be accomplished. Alternatively, if your company has the right to file new INDs you should disclose the current status regarding the filing of new INDs.
27. You discuss certain studies such as, “Black in *Leukemia* in 2003” and “Konopleva in *Blood* in 2010” which seem to indicate that certain clinical testing involving your product candidate SL-401 was performed by others in the past. Please expand your disclosure to clarify if these product candidates were licensed to other parties in the past, who conducted earlier testing of the product candidates and what testing was performed.

Design of SL-401 and Mechanism of Action, page 71

28. Please expand your disclosure to explain how, “the mechanism by which SL-401 kills cells differs from that of available therapeutics commonly used to treat AML and other hematologic malignancies.”

Completed Phase 1/2 Clinical Trial – Advanced AML, page 71

29. Please expand your disclosure here to clarify who was responsible for conducting the 401 AHC Study.
30. Please provide a basis for your statement that, “SL-401 does not appear to have overlapping toxicity with traditional hematologic cancer therapies.”
31. We note that the table on page 74 contains the subtitle, “adapted from Konopleva et al. Blood 2010; 116:21: Abstract #3298)”. Please clarify whether the results in this table, which you refer to in your disclosure, are based on your own clinical testing, or are the results of other clinical tests.

Design of SL-701 and Mechanism of Action, page 76

32. The table on page 77 entitled “EphA2 Over-Expression on CSCs of GBM By Flow Cytometry” is illegible. Please increase the size of the table, and below the table please provide a narrative explanation of the data represented in the table.

License and Research Agreements

Scott and White Memorial Hospital, page 88

33. Please expand your disclosure here to clarify who is obligated to conduct and fund the research and to discuss the regulatory milestones and corresponding time periods you must adhere to in order to retain the license under the June 2006 agreement. Please file any separate agreement with Scott and White related to this research and please disclose the material terms of the arrangement.

University of Pittsburgh, page 89

34. Please disclose the amounts of the annual license maintenance fees that you must pay to University of Pittsburgh until your first commercial sale of a licensed products under the license agreements for the IL-13Ra2 peptide and the EphA2 peptide, the amounts of the initial license fee paid and the regulatory milestones, and the corresponding time periods you must adhere to in order to retain the license. Please also disclose who is obligated to conduct and fund the research.

Cambridge University Technical Services Limited, page 91

35. Please disclose the aggregate amount of the regulatory milestone payments and the royalty rate under the Exclusive Patent and Non-Exclusive Know-How License Agreement with Cambridge University. Please note that you may disclose the royalty rate as a range, such as “single digits” or “mid-teens.”

Executive Compensation  
Annual Cash Bonus, page 117

36. Please expand your disclosure here to include each of the factors considered by the board in determining the amount of Dr. Bergstein’s annual cash bonus including whether any performance criteria or targets were set, the extent of achievement of those criteria or targets, and how the board considered this level of achievement and the other factors disclosed in determining the amount of the bonus that was ultimately awarded.

Employment Agreements, page 123

37. We note your disclosure here that if you, “terminate Dr. Rowinsky without "cause" or if he terminates employment with us for "good reason," (each as defined in his employment agreement) including if such termination occurs within 12 months following a change in control, we are obligated to pay Dr. Rowinsky his base salary for 12 months, and up to 24 months, following such termination (in the case of a termination following a change in control, the payment is made in a lump sum)”. However, your disclosure in the Potential Payments Upon Termination or Change in Control tables on page 125 seems to indicate that Mr. Rowinsky is only eligible for twelve months salary payment upon “Termination Without Cause or for Good Reason in Connection With or Following a Change in Control.” Please revise your disclosure to clarify this inconsistency.

Transactions with Related Persons, page 130

38. Please expand your disclosure to clarify the nature of your company’s relationship to Pequot Capital Management.
39. Please file the 2003 license agreement and the assignment agreement related to the transfer of patents effective upon the closing of this offering between your company and Dr. Bergstein.

Note 7. Capital Structure

Redemption of Series A Preferred Stock, page F-16

40. Please tell us how you calculated the \$12.2 million discount resulting from the redemption of your Preferred Shares. In this regard, you state that you recorded the



issuance of the Convertible Note at \$0.9 million and the issuance of common stock at \$1.0 million. When coupled with the \$0.75 million in cash paid, it would appear that the discount resulting from the retirement of \$15.1 million in preferred stock would be approximately \$12.45 million. In your response, please explain why you state that the value of the 227,759 shares of common stock issued in exchange for the Preferred Shares was \$1.2 million but then later disclose that the shares were recorded at their issuance date fair value of \$1 million.

41. Please explain to us why the value of the 227,759 shares of common stock issued in exchange for the Preferred Shares is in the range of \$1.0 to \$1.2 million and not approximately \$13 million. In this regard, it appears that the holders of Preferred Shares accepted the common stock plus \$0.75 million in cash and \$1.25 million in face value of notes in settlement of your obligation to pay them \$15.1 million. In your response, please explain the business purpose for why the holders of Preferred Shares, the Pequot Funds, were apparently willing to forgo approximately \$12 million in value. Also, tell us the original conversion rate in the Preferred Shares and why the Pequot Funds did not merely convert the Preferred Shares into common.

Note 10. Commitments and Contingencies

University of Pittsburgh, page F-21

42. In the first two paragraphs on page F-22 you disclose two additional non-exclusive license agreements entered into in March 2012. Please tell us the amounts of the initial license fees paid to UP and explain why you expect to defer portions of these fees until September 2012 for one agreement and March 2013 for the other.

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

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Page 10

- 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 Dana Hartz at 202-551-3648 or Mark Brunhofer at 202-551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Michael Rosenthal at 202-551-3674 or me at 202-551-3715 with any other questions.

Sincerely,

/s/ Jeffrey Riedler

Jeffrey Riedler  
Assistant Director

cc: James Barrett  
Edwards Wildman Palmer LLP