



DIVISION OF
CORPORATION FINANCE

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

August 30, 2013

Via E-mail

Michael D. Clayman, M.D.
Chief Executive Officer
Flexion Therapeutics, Inc.
10 Mall Road, Suite 301
Burlington, MA 01803

**Re: Flexion Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted August 2, 2013
CIK No. 0001419600**

Dear Dr. Clayman:

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. We note that there are a number of additional exhibits that still need to be filed. Please provide these exhibits as promptly as possible. Please note that we may have comments on these materials once they are provided.
2. We note that you intend to seek confidential treatment for several of your exhibits. Please note that comments on your confidential treatment request will be sent under separate cover.
3. Please confirm that the graphics included in your draft registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.

4. 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. 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.

Summary

Overview, page 1

5. Please describe Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act the first time you refer to it in this section.

The Flexion Portfolio, page 2

6. We note that your objective is to develop long-lasting injectable pain therapies while avoiding systemic and other serious side effects. In your discussion of your product candidates throughout the draft registration statement, we also note that you refer at various times to the fact that current therapies are associated with numerous systemic and serious side effects. In some cases, you specify certain side effects that have been linked with existing treatments, but in other cases you refer to significant side effects in only general terms. Therefore, where applicable, please revise your draft registration statement to disclose the specific side effects to which you refer when discussing the limitations of current treatments. In addition, when you discuss the safety profile of your product candidates or compare them to the safety of other treatments, please disclose any serious side effects associated with your product candidates that have been observed in your trials.

The Offering, page 6

7. We note that your disclosure assumes the conversion of all your outstanding convertible preferred stock into an aggregate of 72,780,250 shares of common stock in connection with the closing of this offering. We also note, however, that on pages F-7 and F-20 you indicate that the mandatory conversion of your issued and outstanding preferred stock is contingent on the completion of a qualifying initial public offering. According to your disclosure, a qualifying initial public offering is defined as an initial public offering in which (i) the per share price is at least \$3.38 and (ii) the gross cash proceeds to the Company are at least \$40,000,000. As there is no guarantee that you will be successful in completing this offering on terms that would trigger mandatory conversion, please revise your disclosure in this section and throughout your draft registration statement, if true, to clarify that the assumed conversion of preferred shares is based on the completion of a qualifying offering that would trigger the mandatory conversion feature of your Series A

and B Preferred Stock. Please also describe the terms of this conversion feature in sufficient detail.

In addition, if failure to trigger the mandatory conversion feature could have a material impact on the Company, please describe such consequences and, as applicable, provide a new risk factor that addresses this issue.

Risk Factors

If we fail to obtain additional financing, we would be forced to delay..., page 10

8. Please disclose the amount of your cash, cash equivalents and working capital and how long these funds will allow you to continue your operations if additional capital is not obtained.

Our product candidates may cause adverse events or have other properties..., page 14

9. We note that you have provided two examples of adverse events related to your product candidates. Please expand your disclosure here to discuss all adverse events related to each of your product candidates.

We face potential product liability, and, if successful claims are brought..., page 30

10. Please quantify the amount of product liability insurance coverage that you carry. For any other types of insurance coverage discussed in your prospectus, please quantify the amount of the coverage.

If we are unable to obtain or protect intellectual property rights related to..., page 31

11. Please expand your risk factor to provide a cross reference to the section entitled “Patents and Patent Applications” which provides a discussion of your material patents and patent applications.

Our ability to use our net operating loss carryforwards and certain other tax..., page 38

12. Please quantify the amount of your net operating loss carryforwards and your federal and state research and development tax credit carryforwards and provide the expiration dates for the carryforwards in this risk factor.

Management’s Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Valuation of Common Stock, page 55

13. Please clarify in your disclosure if your valuations were performed retrospectively or contemporaneously.

14. To gain a better understanding of your determination of the fair market value of your common stock at each valuation date, please provide us the following information in revised disclosure, as applicable:
 - For each valuation date, tell us the guideline public companies that you selected and what similarities existed between you and the guideline public companies selected such as number of products, types of products, size, working capital, liquidity, etc. Specify any adjustments that were made to reflect differences between you and the public companies selected;
 - Disclose the methodology used to determine your assumed volatility factor from the historical trading volatility for the selected publicly traded peer companies. Tell us the public companies that you selected and what similarities existed between you and the public companies and the volatility determined for each peer company.
 - For each valuation date, disclose how you determined the risk-adjusted discount rate and the discount for lack of marketability assumption and why the discounts are appropriate.
 - With regard to your December 31, 2012 and May 20, 2013 valuations, you state that you considered both an average of pre-money values and the median multiple of invested capital for selected life sciences companies that completed IPO's from 2011 to 2012 to determine your enterprise value. Please tell us why these methodologies were used to compute your enterprise value.
 - On page 60 you indicate that subsequent to the May 20, 2013 option grant, you received the valuation analysis prepared as of May 20, 2013. Please clarify if the "valuation analysis received" was from a third party valuation expert. If not true, please clarify your disclosure here and with regards to the other valuation periods disclosed.
15. In explaining the change in fair value of your common stock, quantify the enterprise value, implied equity value, and value of the common stock before discounts that were determined at each date.
16. Please note the following once your IPO price has been determined:
 - Please provide quantitative and qualitative disclosures explaining the difference between the estimated offering price and the fair value of each equity issuance.
 - Confirm that no additional equity issuances were made subsequent to the latest balance sheet or provide additional disclosure in that regard.
 - We may have additional comments on your accounting for stock compensation and related disclosure once you have disclosed an estimated offering price.

Business

Overview, page 69

17. Please briefly explain why you consider your lead product candidate, FX-006, to be “first-in-class.”
18. Please revise your disclosure to clarify the meaning of “systemic” side effects.
19. Please clarify the meaning of the term “concomitant medical conditions.”

The Flexion Portfolio, page 74

20. Please explain the term “concomitant comorbidities” in this section.
21. We note your assertion on page 74 that clinical data suggest FX006 and FX005 “may provide local therapeutic concentrations that could last for at least three months and result in very low systemic concentrations of drug.” However, the basis for this statement is unclear given that patients in your Phase 2a trial for FX006 were evaluated for only six weeks following treatment. While each of your Phase 2b trial for FX006 and your Phase 2a trial for FX005 evaluated patients for at least 12 weeks after injection, your disclosure suggests that neither of these studies were designed to measure drug concentration. Instead, these trials appear to have been principally concerned with an assessment of pain relief, whereas the six-week Phase 2a trial for FX006 collected relevant data on plasma and synovial fluid concentrations of TCA over time. Accordingly, please revise your disclosure to provide the basis for your belief that FX006 and FX005 may sustain therapeutic concentrations lasting at least three months.

FX006-Front Line IA Therapy for Patients with Moderate to Severe OA Pain, page 76

22. You state here and elsewhere in your prospectus that FX006 has been studied in two clinical trials in 196 patients. However, under the section entitled “FX006 Development Program,” you state that your Phase 2b trial had 228 patients and your Phase 2a trial had 24 patients. Please revise your disclosure to account for this apparent discrepancy.

FX006 Development Program

Study FX006-2011-001, page 76

23. Please expand your disclosure to provide the meaning of “responder status” and “rescue medication consumption,” as well as brief descriptions of the WOMAC, PGIC and CGIC scales.
24. Please explain the meaning and significance of p-values in this section.

25. Please explain what you mean by “maximal” plasma concentrations and provide a definition for “synovial fluid” and “serum cortisol.” In addition, please revise as necessary to clarify:

- the therapeutic significance of TCA concentration in synovial fluid;
- the relationship of plasma concentration of TCA to systemic side effects;
- the relationship of circulating serum cortisol levels to the HPA axis; and
- the significance of reductions in serum cortisol

FX005 Development Program, page 80

26. Please define the term “diluent” the first time it appears in your prospectus.

27. We note your disclosure in this section that FX005 has completed a phase 2a clinical trial in 70 patients. However, the subsequent subsection entitled, “Study FX005-2010-001” states that 140 patients participated in the Phase 2a clinical trial. Please revise your disclosure to account for this apparent discrepancy.

Indemnification Agreements, page 123

28. Please file the indemnification agreements, or form of agreement, with your directors and executive officers as exhibits.

Lock-Up Agreements, page 133

29. Please file the lock-up agreements as exhibits.

Market and Industry Data, page 144

30. Please note that it is not appropriate to state or imply that you do not have liability for the statements in your registration statement. Your statements that you have not independently verified market and industry data and that internal company research and market definitions were not verified by any independent source could imply that you are not taking liability for this information. In order to eliminate any inference that you are not liable for all of the information in your registration statement, please delete these statements or include a statement specifically accepting liability for these statements.

Note 9. Convertible Preferred Stock, page F-17

31. Please revise your disclosure to address the following, as applicable:

- State the number of common stock warrants that were issued in the Series B preferred stock issuance in December 2012;

- Clarify what you mean by “(i) the consummation of a qualified initial public offering; and
- Why you did not believe that the warrants would not be issued and therefore no value was assigned to the warrants separately at December 31, 2012 and June 30, 2013. Provide us your accounting basis to support your accounting.

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 Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Johnny Gharib at (202) 551-3170, Daniel Greenspan at (202) 551-3623 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler
Assistant Director

Via E-mail
Sean M. Clayton, Esq.
Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121