

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

November 25, 2014

Via E-Mail
Rob Hadfield, Esq.
General Counsel
Flex Pharma, Inc.
800 Boylston Street, 24th floor
Boston, MA 02110

Re: Flex Pharma, Inc.

Confidential Draft Registration Statement on Form S-1

Submitted October 29, 2014

CIK No. 0001615219

Dear Mr. Hadfield:

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.

# Prospectus Summary Clinical Development, page 2

1. Disclose in the Summary when and where your Flex-001, Flex-002 and Flex-003 trials were conducted and who conducted them. Further, disclose in the Summary where you plan to conduct the planned proof-of concept trial, whether you will test the product as a drug or dietary supplement and whether you will file an IND before commencing trials. If not, disclose why no such IND will be necessary.

# Prospectus Summary Product Development, page 3

- 2. Please remove the tabular information about drug product candidates on page 3 and page 76. As discussed on page 77, the company has no definitive plans at this time to conduct the drug candidate tests described in that table and such a decision will be made at a later date based upon the results of the proof-of-concept study of the dietary supplement.
- 3. Provide more information in the Summary section about both the potential drug version and the dietary supplement version of your product. You should indicate the form and method of delivery of both versions, what factors would affect your decision to market one or the other or both versions and to whom and how the drug and/or dietary supplement versions would be marketed.

#### Risk Factors

# Clinical development involves..., page 15

4. It may appear to the reader that the disclosure on page 16 indicating the registrant has not commenced or completed any clinical trials of any drug product candidates is inconsistent with disclosure elsewhere in the prospectus describing statistically significant results of clinical trials. As all studies to date have been of the dietary supplement version of the product, please provide additional explanatory disclosure on page 16 to eliminate this confusion.

#### **Risk Factors**

# Our drug product candidates..., page 19

5. We note capsaicin is one of the three active ingredients in your proprietary treatment. Briefly discuss the current scientific evidence concerning the possible carcinogenic or co-carcinogenic effects of capsaicin ingestion as reported in animal or human studies. Also discuss known adverse reactions to capsaicin in humans such as those experienced from the use of capsaicin-containing creams for topical use in the treatment of pain.

#### Risk Factors

### We will incur significant increased costs, page 40

6. Please expand this risk factor to include an estimate of the additional legal, accounting and other costs you expect to incur as public company.

#### Industry and Market Data, page 45

7. We note that you state that neither the registrant nor the underwriters "have independently verified the accuracy or completeness of any third-party information". You should delete this statement. You should not provide any information that may cause the

reader to conclude that you are not responsible for all of the information included in the prospectus.

# Use of Proceeds, page 46

- 8. Please identify to what stage of development you expect the application of the proceeds will bring you regarding both the clinical product and the dietary supplement.
- 9. In view of the fact that the company has no definitive plans to test the drug product candidate, please provide alternate use of proceeds disclosure assuming you do not pursue the drug product candidate.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation, page 60

10. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to the IPO and the estimated offering price.

#### **Business**

#### Clinical Development, page 72

- 11. Provide additional information as to each study including:
  - The symptomatic and demographic characteristics of the persons who were studied and how they were recruited;
  - The version(s) and dosage(s) of the product that were administered;
  - What the subjects in the control group received; and
  - The number of subjects receiving the product and receiving the control.
- 12. In view of the small number of subjects tested in the three completed studies, please provide additional disclosure wherever you discuss the statistical significance of the results in order to put it in an appropriate context. That disclosure should disclose that because of the small number of subjects receiving the product and the control, the p-values calculated are relatively unreliable. Furthermore, because of the small number of subjects tested, the results of future trials that include more subjects are more likely to show differing results. You should also cite the small number of subjects and the resulting unreliability in the bulleted list of risks in the summary and in the risk factors section as a separate risk factor.
- 13. Where you mention the planned "proof-of concept" trial, you should disclose how that trial will be designed differently from the three completed studies. You should include:

- The symptomatic and demographic characteristics of the subjects you will recruit;
- The nature and target size of cohorts and control groups;
- The version(s) and dosage(s) of the product that will be administered;
- How the study will be controlled;
- Endpoints; and
- Methods of measuring the results and analyzing the differences between the control group and the group who will receive the product.

#### **Business**

# Consumer Brand and Products, page 78

14. Disclose that you will be required by the FDA to comply with GMP for the dietary product. Also, disclose whether you will choose to pursue an organic designation for same.

# <u>Certain Relationships and Related Party Transactions</u> Founders Agreement, page 120

15. Please provide a detailed description of the Founders' anti-dilution rights.

# Financial Statements, page F-1

- 16. Please tell us why it is appropriate to present financial statements only since your inception on February 26, 2014 and reference for us the authoritative literature you rely upon to support your presentation. In your response, at a minimum, address the following:
  - Tell us why you do not present any predecessor financial statements.
  - If you have no predecessor, tell us:
    - How your Scientific Founders and Christoph Westphal, as identified on page 120, discovered or obtained your intellectual property underlying the royalty agreement;
    - When this intellectual property was discovered;
    - How long this intellectual property is in development;
    - When your Flex-001, Flex-002 and Flex-003 cross-over studies completed in 2014, as disclosed on page 72, began;
    - Who funded discovery and development prior to your inception; and
    - How much money was spent on discovery and development prior to your inception.

### Balance Sheets, page F-3

17. Please remove the issuance and conversion of your Series B convertible preferred stock issued after the balance sheet date from your pro forma financial information presented alongside your historical balance sheet. Otherwise, reference for us the authoritative literature you rely upon to support your presentation.

#### Notes to Financial Statements

Note 2: Summary of significant accounting policies Research and development expenses, page F-9

18. Please tell us the types of overhead costs you include in research and development expenses and how they are properly classified. In your response, demonstrate to us how they are not general and administrative costs that are not clearly related to research and development activities as stipulated in ASC 730-10-25-2e.

#### Exhibit Index

19. We note the first page of the Royalty Agreement, which will be filed as Exhibit 10.9, makes reference to a Founders Agreement, a Patent Assignment Agreement and a Technology Assignment Agreement. It appears that the registrant is either a party to these agreements or the agreements were negotiated by other parties on the registrant's behalf. You should file all three of these agreements as exhibits to the registration statement. You should also describe their material terms of the Technology Assignment Agreement and the Patent Assignment Agreement in the prospectus.

#### General

- 20. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 21. Please confirm that the graphics included in your registration statement are the only graphic, visual, or photographic information 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.
- 22. 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.

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 Scott Wuenschell at (202) 551-3705 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Preston Brewer at (202) 551-3969 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-Mail</u> Marc Recht, Esq. Cooley LLP