

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

June 6, 2013

Via E-mail
Pnina Fishman
Chief Executive Officer
Can-Fite BioPharma Ltd.
10 Bareket Street
Kiryat Matalon, P.O. Box 7537
Petah-Tikva 49170, Israel

Re: Can-Fite BioPharma Ltd.

Amendment No. 1 to Draft Registration Statement on Form 20-F

Filed May 10, 2013 CIK No. 0001536196

Dear Dr. Fishman:

We have reviewed your filing and have the following comments. In our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter within 10 business days by providing the requested information or by advising us when you will provide the requested response. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing 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, please disclose that you are an emerging growth company. In addition, describe how and when a company may lose emerging growth company status.

Forward Looking Statements, page 7

2. You reference "[o]ther unknown or unpredictable factors" that could harm your future results in this section. Please remove this reference, as it is not appropriate to warn investors about risks that are not known to you.

Explanatory Note, page 7

3. We note your statements in this section that you "do not make any representation as to the accuracy of information" in the registration statement that is based on third-party data. We also note your statement that you "cannot guarantee the accuracy or completeness of any such information" contained in the disclosure. It is not appropriate to imply that you are not responsible for statements included in your registration statement. Please delete these sentences or clarify that you are responsible for the statements included in your registration statement.

<u>Item 3. Key Information</u> <u>Selected Financial Data, page 10</u>

4. We note your disclosure of exchange rate information for the periods ending with the previous five years. Please also disclose the high and low exchange rates for each month during the previous six months as required by Item 3.A(3)(b).

Capitalization and Indebtedness, page 10

5. Please revise the information included in the capitalization and indebtedness table on this page to update the information as of a date no earlier than 60 days prior to the date of submission of your registration statement pursuant to Item 3.B.

Risk Factors

"Clinical trials are very expensive...," page 15

6. Please expand this risk factor to disclose instances in which you have actually experienced the risk involved. For example, you should consider disclosing the fact that Phase II trials for CF101 for treatment of RA have twice failed to meet the specified primary clinical endpoints and that you will have to conduct those trials again.

"Developments by competitors may render our products or technologies obsolete...," page 17

- 7. Please provide a brief summary of competitors and competing products that have commercialized or are seeking to commercialize products that address the same indications as your primary product candidates.
- 8. We note the similarity between the risks discussed in this risk factor and those discussed in the risk factor under the heading "[w]e face significant completion and continuous technological change" on page 23. In light of these similarities, please consider consolidating your discussion of these risks into a single risk factor.

"We may suffer losses from product liability claims if our product candidates cause harm to patients...," page 18

9. Please revise your risk factor to discuss the extent to which patients in clinical trials have experienced adverse events and identify any such events.

Risks Related to Our Intellectual Property, page 20

- 10. It appears that you have material patents for primary product candidates, CF101 and CF102, that will expire in the U.S. and in Europe in 2014 and 2015. If true, please consider adding a risk factor stating this fact and explain the ways in which this loss of patent protection over the next two years could negatively affect your operations.
- 11. We note your statements that "[w]e believe that our drugs have certain unique characteristics and advantages over drugs currently available on the market and under development to treat these indications." Please revise your disclosure to describe the unique characteristics and advantages of your products as compared to specified drugs currently on the market. In addition, please highlight that other drugs on the market and new drugs under development may be better established and accepted among patients and physicians in their respective markets, are orally bioavailable, can be efficiently produced and marketed, and are relatively safe.
- 12. We note your stated belief that your product candidates "exhibit a relatively high probability of therapeutic and commercial success for the treatment of autoimmune-inflammatory, oncological and ophthalmic diseases." Please consider deleting this statement in light of the considerable uncertainty of the regulatory approval process, the relatively early development stage of your product candidates and your limited experience in bringing a product candidate to commercialization.

"International patent protection is particularly uncertain..." page 22

13. Identify those foreign countries in which you expect to do business that do not protect a company's intellectual property rights to the same extent as the United States.

"Our ADSs have a limited prior trading history...," page 27

14. In this risk factor, as well as elsewhere in the registration statement (for example, at pages 31 and 104), you state that your ADSs currently trade in the United States on the OTCBB. However, since 1999, as a condition of eligibility to trade on the OTCBB, a company, including a foreign company with ADRs, must have Exchange Act reporting obligations and be current in its Exchange Act reporting. See OTCBB Rule 6530. Accordingly, either revise the registration statement to state that your ADSs currently trade on the OTC (as opposed to the OTCBB) or else explain how you are currently able

to trade your ADSs on the OTCBB although you are not yet an Exchange Act reporting company.

"As a foreign private issuer, we are permitted to follow certain home country corporate governance practices...," page 28

15. Supplementally advise, with a view to disclosure, whether you intend to follow Israeli law regarding the composition of a listed company's board of directors, which, unlike NYSE MKT rules, does not require that a majority of a listed company's board of directors be independent.

"We conduct our operations in Israel...," page 29

16. Disclose whether, during peacetime in addition to during hostilities, Israeli citizens, including your employees, have military service obligations that could interfere with normal business operations.

ADR Holder Risk Factor

17. Add a risk factor that discusses the risks resulting from the fact that an ADR holder's voting and distribution rights, if any, are governed by the deposit agreement and, thus, differ from the rights of an issuer's ordinary shareholders.

<u>Item 4. Information on the Company</u> Our Strategy, page 34

18. We note that you plan to "focus most prominently on advancing our product candidates that are in the most advanced stages." Please elaborate by disclosing the specific clinical products and corresponding indications upon which you plan to primarily focus going forward.

Our Product Pipeline, page 35

- 19. We note disclosure indicating that certain research was conducted pursuant to investigational new drug applications on pages 47 and 50 for CF101 and CF102, respectively. Please expand your disclosure throughout this section to indicate whether you or a third party has filed INDs for the following:
 - CF101 for treatment of psoriasis
 - CF101 for treatment of rheumatoid arthritis
 - CF101 for treatment of osteoarthritis
 - CF101 for treatment of dry eye syndrome
 - CF101 for treatment of glaucoma
 - CF101 for treatment of uveitis
 - CF102 for treatment of hepatocellular carcinoma

• CF602 for treatment of sexual dysfunction

If INDs for these products and for the corresponding treatments indicated have been filed, please additionally disclose the identity of the filers and the dates the applications were filed. Alternately, where no IND has been filed, please explain why.

Clinical Trials of CF101, page 39 Rheumatoid Arthritis page 42

20. Please revise your disclosure to indicate whether any adverse events were experienced by patients in the Phase IIb studies of CF101 in combination with MTX for rheumatoid arthritis.

Clinical Trials of CF102, page 49 Phase I/II Clinical Study, page 50

21. Please revise your disclosure to indicate whether any adverse events were experienced by patients in either of the Phase I/II studies of CF102.

<u>In-Licensing Agreements</u> NIH Agreement, page 52

- 22. We note your disclosure of several payments you are entitled to under the NIH agreement, including "individual payments ranging from \$25,000 to \$500,000" subject to milestone achievement. Please disclose the total aggregate potential milestone payments you are entitled to receive under this agreement.
- 23. You disclose that the NIH agreement will remain in effect "until the last patent licensed" under that agreement expires. Please disclose the date on which the last-to-expire patent expires in this section.

Patents, page 56

24. Please clarify whether the patents you reference on this page, expiring in 2015 and 2014, are composition-of-matter patents covering CF101 and CF102 and whether they expire on those dates in both Europe and the United States. If so, please disclose what response, if any, you have planned to mitigate the loss of composition-of-matter patent protection for your two primary pipeline candidates.

Government Regulation and Funding, page 66

25. We note your discussion of FDA regulations in the United States on page 66. Please expand the discussion to specifically address the following U.S. regulatory issues:

- whether you will seek new drug applications (NDAs) for your product candidates, the purpose behind the NDA, and the regulatory process involved;
- the fact that CF102 was granted orphan drug status and the meaning of and regulatory ramifications of such status.

<u>Item 5. Operating and Financial Review and Prospects</u> Overview, page 74

26. As your registration statement does not seek to register a public offering of securities, please eliminate the reference to "the net proceeds of this offering" in the next-to-last paragraph on this page.

General and administrative expenses, page 83

27. Please revise your disclosure to include the amount for each factor that contributed to the increase in general and administrative expenses for both December 31, 2012 compared to December 31, 2011 and December 31, 2011 compared to December 31, 2010. Please clarify in the disclosure if these increases are indicative of a trend that you expect to continue in future periods.

Financial income, net, page 84

28. Please revise your disclosure to clarify the reason for the decrease in the financial net income resulting from the change in fair value of financial liabilities. Please clarify if the change in fair value from December 31, 2011 to 2012 was a result of the change in fair value of the warrants and if so what caused this decrease. For your explanation of December 31, 2011 compared to 2010 please change the heading of Financial expense, net to Financial income, net. Please explain the reason for the decrease in fair value of options. Please tell us why the change in fair value of options is not listed as one of the factors for changes in financial expense and income on page 77.

F. Contractual Obligations, page 86

29. Please revise your table to include any potential future milestone payments.

Compensation, page 89

30. Please explain why Guy Regev, Director, and Ilan Cohn, Vice Chairman of the Board, have been omitted from the annual compensation table included on this page. If the omission was an oversight, please appropriately revise your disclosure.

Board Practices, page 93

31. Clarify the difference between an external and independent director.

Employees, page 100

32. You state that as of December 31, 2012, you had eight employees, "four of whom were employed in management and administration and seven of whom were employed in research and development." Please provide the correct number of employees in each category that add up to the total number of employees disclosed.

Share Ownership, page 100

33. Please explain why Directors Gil Oren and Yechezkel Barenholz have been omitted from the share ownership table included on this page. If the omission was an oversight, please appropriately revise your disclosure.

Major Shareholders, page 102

34. Disclose the number of your U.S. holders and the percentage of your ordinary shares held by them. See Form 20-F Item 7.A.2.

Item 10. Material Contracts, page 112-114 License Agreement, page 114

35. On page 56, in your discussion of patents, you cross-reference to this section for a discussion of "in-licensing agreements." Please either expand this section to include a discussion of all material licensing agreements or delete the cross-reference on page 56.

Certain Israeli Tax Considerations, page 114

36. An investor is entitled to rely on the information disclosed in the registration statement. Accordingly, delete your disclaimer that the ensuing Israeli tax discussion "should not be construed as legal or professional tax advice" as it implies that an investor may not so rely on the information disclosed.

U.S. Federal Income Tax Considerations, page 117

- 37. Similarly delete your disclaimer that the U.S. federal income tax summary "is for general information only and does not constitute tax advice."
- 38. You are required to disclose the material U.S. federal income tax consequences, and not just "certain...considerations," regarding the purchase, ownership and disposition of your ordinary shares and ADSs by U.S. investors. Revise the first paragraph of this section accordingly.

Notes to Consolidated Financial Statements Note 7:- Ophthalix Spin Off, page F-27

39. Please explain to us why this was accounted for as a reverse acquisition and the specific journal entries that were recorded. Please tell us the authoritative literature you relied upon in determining the appropriate accounting treatment.

Note 14:- Contingent Liabilities and Commitments a. Liabilities to pay royalties, page F-40

40. You disclose on page 33 that under your license agreements you are generally obligated to make development milestone payments. Please revise your disclosure in the notes to the financial statements to include the amounts of the potential milestone payments.

b. Commitments, page F-41

- 41. Please revise your disclosure to clarify the nature of the underlying events which will trigger the milestone payments remaining in the development of CF101 in Japan. Please confirm whether there are any additional future milestone payments that have not been included in the disclosure.
- 42. Please revise your disclosure to disaggregate the amount of potential milestones to be received related to CF101 in Korea between development and regulatory milestones. Please clarify the nature of the underlying events which will trigger the milestone payments. Please confirm whether there are any additional future milestone payments that have not been included in the disclosure.

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 all information the Securities Exchange Act of 1934 and all applicable Exchange 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.

In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

You may contact Vanessa Robertson at (202) 551-3649 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192, Bryan Pitko at (202) 551-3203, or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Bryan J. Pitko for

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-mail</u>

Robert L. Grossman, Esq. Greenberg Traurig, P.A.