

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

July 25, 2012

Via E-mail
Dr. Yuval Cohen
President
Morria Biopharmaceuticals PLC
53 Davies Street
London W1K 5JH
United Kingdom

Re: Morria Biopharmaceuticals PLC

**Registration Statement on Form 20-FR12G** 

Filed June 28, 2012 File No. 000-54749

Dear Dr. Cohen:

We have reviewed your filing 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 within ten business days by amending your filing, 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 or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your filing and the information you provide in response to these comments, we may have additional comments.

## General

- 1. Pursuant to section 12(g)(1) of the Exchange Act, your registration statement will become effective by operation of law on August 27, 2012 at which time you will be required to begin filing all of the reports mandated by Section 12(g) of the Securities Exchange Act of 1934. If the review process has not been completed before that date you should consider withdrawing the registration statement prior to August 27, 2012 to prevent it from becoming effective and refiling it at such time as you are able to respond to any remaining issues or comments.
- 2. Please be advised that your registration statement is concurrently being reviewed by the Office of International Corporate Finance. You will receive comments generated by that Office, if any, at a later date.

- 3. Since you appear to qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, please disclose on your prospectus cover page that you are an emerging growth company, and revise your prospectus to:
  - Describe how and when a company may lose emerging growth company status;
  - Briefly describe the exemption from Section 404(b) of the Sarbanes-Oxley Act of 2002 and update your risk factor on page 33 for this exemption; and
  - State your election under Section 107(b) of the JOBS Act:
    - o If you have elected to opt <u>out</u> of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b), include a statement that the election is irrevocable; or
    - o If you have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1), 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.

#### <u>Item 3. Key Information</u>

#### A. Selected Financial Data, page 4

4. The identification of some columns of selected financial data as "unaudited" may give an investor the impression that the other columns have been audited. We believe your disclosure in the introductory paragraphs of this section is sufficient to highlight to investors which selected financial data have been derived from audited or unaudited financial statements. Please revise your disclosure to remove any label identifying a column as unaudited.

#### D. Risk Factors, page 5

5. Please expand your disclosure in this section to add a risk factor that addresses the risks resulting from the fact that the report of your independent registered public accounting firm on your financial statements states that your recurring operating losses, negative cash flows and dependence on additional financial support raise substantial doubt about your ability to continue as a going concern. Please include in this risk factor the fact that the auditor's going concern opinion may have a detrimental effect on your ability to obtain additional funding.

"We anticipate that we will incur losses for the foreseeable future and we may never achieve or sustain profitability," page 6

6. Please state in this risk factor that your total accumulated deficit as of the end of 2011 was \$12,621,000.

"We will require additional capital to fund our operations, and if we are unable to obtain such capital, we will be unable to successfully develop and commercialize our product candidates," page 6

- 7. Please expand your risk factor to
  - include an estimate of your operating expenses, including your research and development costs, for fiscal year 2012;
  - disclose the amount of your existing cash and investment securities;
  - disclose the amount of all compensation that you anticipate deferring; and
  - disclose the material elements of your current contemplated plan for your fiscal year ended December 31, 2012.

"If we default on our convertible notes, we may lose all of our assets and intellectual property," page 8

- 8. Please expand this risk factor to disclose
  - the list of events of default as defined in your Securities Purchase Agreement dated April 3, 2012; and
  - that you are required to repay your convertible notes by January 4, 2013, the aggregate amount that you expect to be due as of that date, and that you do not currently have sufficient cash available to repay them.

"Our product candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval..." page 10

9. Please expand this risk factor to disclose when you intend to file your IND application for your two product candidates in clinical trials.

"We have not conducted any absorption, distribution, metabolism and excretion (ADME) studies with respect to our clinical and pre-clinical product candidates," page 15

10. In this risk factor, please include the reason you have yet to perform ADME studies and whether or not you intend to conduct such studies in the future.

"If our competitors are better able to develop and market products than any products that we and/or any potential future collaborators may develop . . .," page 21

11. Please include in this risk factor the names of the companies that you believe will be your principal competitors and those products that you believe will compete with yours at such time as yours enter the marketplace.

"We depend on third-party suppliers for key raw materials used in our manufacturing processes . . .," page 22

12. Please include in this risk factor the names of the third-party suppliers you are dependent upon.

"Use of third-party manufacturers may increase the risk that we will not have adequate supplies of our product candidates or products." page 24

13. You disclose that your present or future manufacturing partners may not be able to comply with FDA-mandated current Good Manufacturing Practice regulations or other FDA regulatory requirements. To the extent you are aware that one or more of your current manufacturing partners do not comply with FDA-mandated current Good Manufacturing Practice regulations or other FDA regulatory requirements, please disclose this fact as well as the names of each manufacturing partner that does not comply.

"We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily . . .," page 25

14. Please include in this risk factor the names of the material contract research organizations that have performed your clinical trials to date.

"If we do not establish strategic collaborations, we may have to alter our development plans," page 25

15. This risk factor is substantially similar to the second one on page 22. Please merge them into a single risk factor in order to avoid repetition in your disclosure.

"We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies . . .," page 33

16. Please estimate the costs you will incur as a result of complying with public company laws and regulations over the next fiscal year and on an annual basis thereafter.

## Item 4. Information on the Company

## A. History and Development of the Company

## April 2012 Private Placement of Senior Secured Convertible Notes and Warrants, page 38

- 17. In your "Description of Notes" on page 40 please provide the definition of "material adverse event" in your Securities Purchase Agreement.
- 18. In your description of the Registration Rights Agreement on page 40, please disclose the actual date rather than referring to the "Self Filing Effective Date" and describe the payments you will be required to make to your investors if this registration statement is not filed and/or declared effective on a timely basis.

#### B. Business Overview

## Product Candidates, page 41

- 19. Please state here, as well as in your discussion of your clinical pipeline on page 49 and your Overview on page 68, that the clinical trials your two major product candidates have undergone were performed in Israel and South Africa, and not in the United States.
- 20. Please state here and wherever else applicable in your registration statement whether or not you believe your clinical trials have complied with the rules for such trials set forth by the FDA. If they have not, please specify how your clinical trials have differed from those rules.

#### Steroids and Currently Available Alternatives, page 42

21. In your table on page 44, please indicate in the row describing your product candidates that your studies to date have not advanced beyond Phase 2.

#### Scientific Background to Inflammation and Our Product Candidates, page 45

22. In this discussion, please address whether the research performed by your principal shareholder into the field of lipid conjugates has produced conclusive evidence into their anti-inflammatory properties. If there is any controversy in the greater scientific community as to this assertion, you should note this here and discuss any possible ramifications, particularly how this uncertainty could impact the development of your product candidates. If appropriate, you should amend your disclosure wherever you discuss this research and its implications, including the risk factor on pages 10-11.

## Research and Development, page 45

- 23. Please include in this discussion the amounts you have spent on R&D over the last three fiscal years as well as an estimate of your R&D expenses for fiscal year 2012.
- 24. We note that you disclose the focus of your development plan for fiscal 2012, provided that you raise additional capital. Given your disclosure on page 6 that you believe that your existing cash and investment securities will be sufficient to support your current contemplated operating plan until December 31, 2012, please expand your disclosure to disclose the focus of your development plan for fiscal 2012 if you do not raise additional capital.

## Development of our Clinical Pipeline for our Product Candidates, page 49

25. For each of the trials discussed, please disclose any side effects observed with your product candidates and, where available, please disclose whether the results are statistically significant and provide all p-values that you have available.

# Intellectual Property, page 52

26. Please indicate the product candidates to which each of your material U.S. and non-U.S. patents relate.

#### Manufacturing, Marketing and Sales of our Drugs, page 55

27. Please disclose the names of your third-party manufacturer(s) here and in the risk factor on page 23. Please also disclose here the material terms of your contractual relationships with them, if any. If you are substantially dependent on an agreement with a third-party for the manufacture of your product candidates, please file this agreement as an exhibit to your registration statement. Alternatively, please provide us with an analysis that supports your determination that you are not substantially dependent on an agreement with a third-party manufacturer.

#### Item 5. Operating and Financial Review and Prospects

## Stock-based Compensation and Fair Value of Ordinary Shares, page 70

- 28. With respect to your common stock valuations, please expand your disclosures to provide the following information relating to your issuances of equity instruments during the past three fiscal years:
  - A discussion of the significant objective and subjective factors, assumptions, and methodologies used in determining fair value of the shares underlying the options, warrants and deferred shares issued;

- Include in your discussion how management determined fair value based on the share price used in equity financing rounds; and
- Identify the recent equity transactions used to determine fair value.

#### C. Research and Development, Patents and Licenses, etc., page 74

29. Please provide disclosure to quantify the amount of costs, both internal and external, incurred during each period presented and incurred to date on each of your major research and development projects. Please reconcile these amounts to the research and development expense reported on your statements of operations. To the extent that you cannot attribute costs to a project, please explain why management does not maintain and evaluate those costs by project.

#### F. Tabular Disclosure of Contractual Obligations, page 75

30. Please expand your disclosure to include the obligation to pay Yissum \$70,000 per year, described in Note 7 to the financial statements, in the table. Also, expand your disclosure here to discuss all future potential royalties, milestones and other fees reasonably likely to be paid relating to this agreement.

# <u>Item 6. Directors, Senior Management and Employees</u>

## **B.** Compensation

#### Other Director Compensation, page 82

31. Please file copies of the agreements you disclose in this section and your agreements with Prof. Saul Yedgar and Dr. Joseph Bondi that you disclose in the section below. See 4(b)(i) and (ii) of the Instructions as to Exhibits.

#### Item 7. Major Shareholders and Related Party Transactions

#### **B.** Related Party Transactions

32. We note that you state "See also "Material Contracts." Please expand your disclosure to provide a brief summary of the related party transactions referenced later in the filing. [

## Item 9. The Offer and Listing

## C. Markets, page 91

33. You state elsewhere in your registration statement that you intend to apply to list your common shares on the NYSE Amex. You should therefore include this information in this section, pursuant to Form 20-F.

#### Item 10. Additional Information

#### A. Share Capital, page 91

34. In your description of your outstanding convertible notes, you refer to them as "debentures." As the term debenture typically refers to unsecured debt, and these notes are secured by your assets, it is not appropriate to use this term to describe the notes. Please amend your disclosure accordingly.

# C. Material Contracts, page 102

35. It does not appear that your sub-license agreement dated February 1, 2005, or your amendment dated April 4, 2012, have been filed as exhibits to your registration statement. Please file these contracts, as they are material to your operations.

## Item 19. Exhibits, page 126

36. Please file complete and executed copies of the agreements filed as Exhibits 4.2, 4.3 and 4.16-4.20. The current version of the respective filed agreement appears to be missing an attachment, appendix, date or disclosures throughout the agreement which appears to indicate that it is not the final agreement. Please file copies of the complete agreements with your next amendment.

#### **Consolidated Financial Statements**

#### Notes To Consolidated Financial Statements

# Note 13: Subsequent Events, page F-24

37. Regarding the Financing completed April 4, 2012, please expand your disclosure to discuss the accounting treatment of the various securities issued in this transaction.

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 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 James Peklenk at (202) 551-3661 or at Donald Abbott at (202) 551-3608 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (2020) 551-3383, Jennifer Riegel at (202) 551-3575 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey Riedler

Jeffrey Riedler Assistant Director

cc: Jeffrey Schultz, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
666 Third Avenue
New York, NY 10017