



DIVISION OF  
CORPORATION FINANCE

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

February 10, 2013

Via E-mail

Dr. Yaron Daniely  
Chief Executive Officer, President and Director  
Alcobra Ltd.  
65 Rothschild Blvd.  
Tel Aviv 65785 Israel

**Re: Alcobra Ltd.  
Registration Statement on Form F-1  
Filed January 14, 2013  
File No. 333-186003**

Dear Dr. Daniely:

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.

Registration Statement on Form F-1

General

1. 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 if you price below \$10 and 20% if you price above \$10.
2. 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.

3. Please provide us 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.

Prospectus Cover Page

4. Please delete your statements that the industry publications and reports do not guarantee the accuracy or completeness of the information and that you have not independently verified any third-party information. It is not appropriate to directly or indirectly disclaim liability for information in the registration statement.

Prospectus Summary, page 1

5. We note that both here, in your MD&A, and in your Business section you state that MG01CI has been observed to be “effective” in clinical studies conducted to date. See pages 1, 30, 36, and 41. Please be advised that the determination of product efficacy is within the purview of the FDA or comparable regulatory body in jurisdictions outside the United States and the company may not substitute its own judgment or conclusions about product safety for the applicable regulatory authority. Therefore, please revise your disclosure to remove use of the word “effective” where it may presuppose a finding of product safety for MG01CI by the appropriate regulatory authority.
6. You disclose that MG01CI potentially represents a safer alternative to stimulant-based treatments and a more tolerable and effective treatment than the non-stimulants which are currently in the market. If controversy remains in the scientific community as to any of your hypotheses, you should amend your disclosure to note this and to discuss any potential ramifications, particularly how these uncertainties cast doubt upon the possibility of developing MG01CI. Any such controversy should also be addressed wherever else appropriate in your registration statement, including the relevant risk factors and your Business section.
7. Please expand your disclosure to disclose the significance of MG01CI being neither dopaminergic (related to dopamine) nor noradrenergic (related to norepinephrine).
8. Please add the following bullet points to the subsection “Risks Associated with Our Business” on page 2:
  - Please briefly describe the risks associated with being a public company; and
  - Please state that you have no issued patents relating to MG01CI’s technology.

Corporate Information, page 2

9. On pages 2 and 31, you disclose that you have not made a decision whether to take advantage of any or all of the exemptions for emerging growth companies. This does not appear to be consistent with your disclosure on pages 21-22 and other disclosures on page 31. Please revise your disclosure for consistency.

Risk Factors, page 5

10. In the introductory paragraph of this section, you state “[t]he risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business.” Please note that the Risk Factors section must describe all material risks facing your company and offering and should not reference risks that are not material. Please revise these sentences accordingly.
11. Please add a risk factor addressing the risks and conflicts of interest regarding the fact that as a foreign private issuer, you are permitted to follow certain home country corporate governance practices instead of applicable Securities and Exchange Commission and Nasdaq Stock Market requirements, which may result in less protection than is accorded to investors under rules applicable to domestic issuers.

“The commencement and completion of clinical trials can be delayed . . .,” page 5

12. To the extent that you have experienced any problems with your clinical trials such as those described in this risk factor, or have been forced to suspend or terminate one or more trials, please revise to describe such events.

“We intend to rely primarily on third parties to market and sell MG01CI,” page 11

13. Please clearly state in this risk factor that you have no manufacturing, sales, or distribution capabilities at this time.

“We have a limited operating history and we have incurred significant operating losses since our inception...” page 12

14. Please include in this risk factor and in the risk factor entitled, “The requirements associated with being a public company will require significant company resources and management attention” on page 21, an estimate of the annual compliance costs you will incur as a result of your reporting obligations as a public company.

“We may need substantial additional capital in the future. . . .” page 13

15. Please clearly state in the heading and in the first sentence of the risk factor and on page 2 that you “will” need substantial additional capital to fund your operations and develop and commercialize MG01CI.
16. Please expand this risk factor to quantify your current working capital, and your existing cash and cash equivalents.
17. On page 7, you disclose that before you can submit an NDA to the FDA, you must conduct at least two Phase III clinical trials that will be substantially broader than your Phase II trial. On page 14, you disclose that you believe that your available funds will allow you to complete a Phase III trial and begin the process of attempting to obtain seek marketing approval for MG01CI. On page 26, you disclose that you do not expect that the funds from this offering will be adequate to complete your proposed Phase III trials, which will require you to raise additional funds for this purpose. Please revise your disclose throughout the filing to clarify:
  - whether you will need to complete one or two Phase III trials prior to submitting an NDA to the FDA; and
  - what you believe your available funds and the funds from this offering will enable you to complete.

“We have no manufacturing capacity and anticipate reliance on third-party . . .” page 14

18. To the extent that you have experienced any problems with your existing contract manufacturer such as those described in this risk factor, please revise to describe those problems. For example, please refer to your disclosure regarding the discovery of a contaminated lot of MG01CI on page 44. Please similarly revise your risk factor entitled, “We currently depend on third parties to conduct our clinical trials,” on page 15.

“Any collaboration arrangements that we may enter into in the future may not be successful...” page 15

19. Please expand this risk factor to disclose your prior relationship with Teva Pharmaceuticals that you discuss on page 43.

“We may be unable to adequately prevent disclosure of trade secrets . . .” page 17

20. Please supplementally provide the Staff with a copy of the confidentiality agreement you enter into with employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect your proprietary information. We may have further comment.

“We manage our business through a small number of employees . . .,” page 18

21. Please revise this risk factor to identify your key employees and consultants.
22. Please revise this risk factor to state that although you have employment agreements in place with management, these agreements are terminable at will with minimal notice.

“The recently enacted JOBS Act and our status as a foreign private issuer . . .,” page 21

23. Combining in one risk factor the “emerging growth company” exemptions with those stemming from your status as a foreign private issuer is confusing for investors. Discuss these exemptions in two separate risk factors.
24. Regarding the “emerging growth company” risk factor, since a foreign private issuer is not subject to Exchange Act Section 14’s proxy requirements, and since the level of a foreign private issuer’s disclosure concerning executive compensation is governed by its home country’s rules, it is misleading to state that you intend to take advantage of the exemption from the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Exchange Act. Revise accordingly.
25. Regarding the “foreign private issuer” risk factor, provide examples of the exemptions from “certain governance requirements” under Nasdaq regulations of which you intend to take advantage.

“Our operations may be disrupted as a result of the obligation of management...” page 23

26. Please expand your disclosure to disclose that your sole employee and chief executive officer, Yaron Daniely, is 37 years old. In addition, to the extent you have experienced any problems related to disruptions of service, please revise to describe those problems.

“Exchange rate fluctuations between the U.S. dollar and the New Israeli Shekel . . .,” page 23

27. Please disclose the exchange rate between the U.S. dollar and the New Israeli Shekel as of the latest practicable date.
28. Please expand this risk factor to quantify how a hypothetical change in the exchange rate will affect your earnings as of the latest practicable date.
29. Supplementally advise whether, during the three most recent years, the New Israeli Shekel has been devalued relative to the U.S. dollar and, if so, whether the rate of inflation in Israel has exceeded the rate of devaluation.

“In the past, we received Israeli government grants for certain of our research . . .,” page 23

30. Please file any agreements related to your receipt of royalty-bearing grants from OCS as exhibits to your registration statement, pursuant to Item 8 of Form F-1 and Item 601(b)(10) of Regulation S-K.

“Your rights and responsibilities as a shareholder will be governed . . .,” page 24

31. Please revise the risk factor heading to reference obligations rather than rights, and to indicate that Israeli law may impose obligations and liabilities on a shareholder of an Israeli corporation that U.S. states do not impose upon shareholders of corporations incorporated in their respective states.

Dilution, page 28

32. Please revise the table to begin with your historical net tangible book value per share, instead of pro forma net tangible book value per share.

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

Financial Overview

Research and Development Expenses, page 30

33. Please separately quantify the research and development expenses by the types of expenses you describe here for the financial statement periods presented.

Critical Accounting Policies and Estimate, page 31

JOBS Act, page 31

34. On page 31, you state that you “are electing to delay such adoption of new or revised accounting standards.” As 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 separately-headed 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.

Results of Operations

Comparison of the Year Ended December 31, 2012 to the Year Ended December 31, 2011, page 32

35. Please revise your discussions to explain the reasons for the underlying expenses fluctuating. For example, you state that the decrease in the research and development expenses is primarily due to the decreases in the number of employees and the clinical

trials. If true, please revise to state that the decreases in the number of employees and the clinical trials were a result of limited funds available during 2012. Otherwise, if the decreases were related to the change in the research and development phase, explain that fact. Please also provide a similar level of discussion for the decrease in your general and administrative expenses.

Liquidity and Capital Resources, page 34

36. Please provide discussions that would address material changes in the drivers underlying your operating cash flows, including the specific cash inflows and outflows generated, for the periods presented. Your discussions should focus on the primary underlying drivers and other material factors necessary in understanding the historical and future cash flows, rather than merely describing items identified on the face of the statement of cash flows. Refer to Section IV of Financial Reporting Release 72.

Quantitative and Qualitative Disclosure About Market Risk, page 35

37. Please provide sensitivity analysis disclosure regarding foreign currency exchange rate risk in accordance with Item 11 of Form 20-F.

Business, page 36

Market Overview, page 36

38. You disclose in this section and elsewhere throughout the filing, various statistics concerning the total ADHD market, including children and adults. Based on your disclosure on page 40, it appears that you have only conducted clinical trials in adults. If you have not conducted clinical trials in children, please advise us why you believe it is appropriate to include children in your target market. In addition, if true, please expand your disclosure throughout your filing, including a separately headed risk factor, to note that you have not conducted any clinical trials in children, but the majority of your target market is children.
39. You disclose in this section and elsewhere throughout the filing, various statistics concerning the U.S., European and Japanese market. Based on your disclosure on pages 41 and 42, your clinical trials have only taken place in Israel. Please expand your disclosure throughout, including a separately headed risk factor, to note that you have only conducted clinical trials in Israel and that you have not yet conducted clinical trials in several of the jurisdictions which you intend to seek regulatory approval. Please also disclose whether it will be more difficult to seek regulatory approval under such circumstances.

Impact of Untreated and Undertreated ADHD, page 37

40. You disclose that ADHD increases health risks, adverse social externalities and economic costs and you provide a table of the effects on page 37. If controversy remains in the scientific community as to these effects on society if ADHD is untreated, you should amend your disclosure to note this and to discuss other potential theories concerning untreated ADHD and the potential causes of these negative societal events.

Diagnosis of ADHD, page 37

41. Please clearly state that “DSM-IV” is the Diagnostic and Statistical Manual of Mental Disorders, fourth edition.

Our Strategy, page 39

42. Please refer to the 6 bulleted points on page 39. To the extent practicable, please indicate when you intend to begin and expect to complete each goal listed.

MG01CI Overview and Mechanism of Action, page 39

43. Some of your disclosure in this subsection includes scientific or statistical jargon or terms of art that may be unfamiliar to lay readers. Where appropriate, please expand your disclosure to include explanations of terminology so that it may be understood by average investors. Portions of your registration statement that include such terminology include:

- “Metadoxine is a specific antagonist of a 5-hydroxytryptamine receptor of the 2b subtype, implicated genetically in ADHD and molecularly in control of dopamine outflow.”
- “MG01CI has the potential to be the first product to affect the serotonergic pathway.”
- “Tested targets included muscarinic, dopaminergic, serotonergic, gabaergic, noradrenergic, opioid and cannabinoid receptors and transporters.”
- “Metadoxine displayed extensive and highly specific receptor binding to only one of the serotonin receptors named 5-HT2B.”
- “The binding had approximately 50-fold selectivity over all other 5-HT receptor subtypes and a variety of other receptors.”
- “No binding was detected to any of the dopaminergic or noradrenergic receptors or transporters.”
- “Other published studies suggest that the 5-HT2B serotonin receptor may be involved ADHD molecular pharmacology, but neither show the benefit of direct modulation of the 5-HT2B serotonin receptor in ADHD treatment as the MG01CI clinical trials demonstrated.”

44. Please expand your disclosure to identify the adverse events related to Metadoxine.



Clinical Data, page 40  
Clinical Results, page 40

45. It is unclear if you have submitted an Investigational New Drug application to the FDA. On page 42 of your filing, you state that you intend to initiate discussions with the FDA in 2013, and that your Phase IIb trial was modeled based on regulatory requirements and on trial characteristics that have been acceptable to FDA in recent development programs. However, on page 46, you refer to your “existing IND application.” If you have submitted an Investigational New Drug application to the FDA, please disclose this fact, state when you filed this application and whether or not the IND has been approved.
46. In your prospectus, you describe clinical trials that you conducted in September 2011. If true, please clearly indicate in your filing, wherever you discuss these clinical trials, that these clinical trials have not been sanctioned by the FDA nor conducted under the guidance of the FDA, and disclose any FDA guidance you have received on whether the results of these clinical trials will impact your ability to receive regulatory approval in the U.S.
47. Please expand your discussion to provide more detail regarding the clinical trials conducted by you regarding MG01CI. Your description should include the following information:
- When the clinical study was held;
  - How long the clinical study was active;
  - How you targeted patients to enroll;
  - Whether you conducted this study with any other parties; and
  - The steps taken to ensure the accuracy of the results.
48. Please expand your disclosure of your Phase IIa study to disclose any relevant p values. Please also disclose the meaning and significance of p values.
49. You disclose that secondary outcome measures were subtests from the Weschler (WAIS-R) test. Please expand your disclosure to describe this test.
50. You provide a graph of the mean TOVA scores in your extension study. Please disclose the number of subjects that were evaluated in this extension study.
51. Please refer to the tables on pages 41 and 42 and the accompanying explanatory text on pages 40-42 under the subheadings “Clinical Results” and Summary of Clinical Data and Key Conclusions.” Much of the description in the explanatory text and the disclosure intended to give context to the data reflected in the tables makes use of highly technical statistical terminology that may not be readily understood by the lay reader. Therefore, please revise pages 40-42 to explain, in simple terms, the meaning and significance of:

- The ADHD Score, TOVA Omission Score, TOVA Commission Score, TOVA Response Time Score, and TOVA RT Variability Score. Please also disclose the scale used for each score to give context to the score achieved.
- “Clinically profound with a calculated effect size of 0.9.”

Research and Development, page 43

52. You state that you sponsor and conduct clinical research activities with investigators and institutions to measure key clinical outcomes. Please expand your discussion to provide additional disclosure regarding your relationship with these investigators and institutions. For example, please disclose the following:

- Please identify the investigators and institutions with whom you conduct clinical research activities;
- Please indicate when you entered into these arrangements with each party;
- Please discuss each parties’ obligations with respect to the clinical research activities;
- Please disclose any financial provisions in these arrangements; and
- Please discuss any term and termination provisions related to each arrangement.

If any arrangements with investigators and/or institutions have been memorialized in a written agreement, please file each agreement as an exhibit to your registration statement, or provide us with a legal analysis as to why these agreements are not material pursuant to Item 8 of Form F-1 and Item 601(b)(10) of Regulation S-K.

Former Strategic Relationship with Teva Pharmaceuticals, page 43

53. Please disclose whether you or Teva Pharmaceuticals have any continuing obligations to each other due to Teva’s equity investment or funding of a stage of MG01CI’s clinical development. These continuing obligations may include the payment of royalties, milestones, etc.

Manufacturing, page 43

54. You state in this subsection that you currently rely on one third-party manufacturer to produce bulk drug substance and drug products required for your clinical trials of MG01CI. Please expand your disclosure to provide more information regarding your relationship with this manufacturer. For example, please discuss the following:

- Please identify the manufacturer;
- Please discuss each parties’ obligations, including the existence of any minimum purchase orders or financial obligations beyond flat payments for products manufactured, such as royalties; and

- Please discuss any term and termination provisions related to this manufacturing arrangement.

If your arrangement with the third-party manufacturer has been memorialized in a written agreement, please file the agreement as an exhibit to your registration statement, or provide us with a legal analysis as to why this agreement is not material pursuant to Item 8 of Form F-1 and Item 601(b)(10) of Regulation S-K.

Management, page 50

55. Please add a risk factor that addresses the risk to your business and financial condition of the provisions in your amended and restated articles of incorporation that limit the liability of your directors, and require you to indemnify your directors and officers under Israeli law.

Employment Agreements with Executive Officers; Consulting and Directorship Services Provided by Directors, page 62

56. On page 62, you state “Please see ‘Risk factors—Risks Relating to Our Business and Industry.’ for a further description of the enforceability of non-competition clauses.” There does not appear to be any information in the Risk Factors section regarding the enforceability of non-competition clauses. Please revise your filing to either remove the cross-reference, or add disclosure regarding this subject to the Risk Factors section.

Principal Shareholders, page 65

57. Please disclose the identity of the individual(s) with voting and dispositive power over the shares held by beneficial owner Hasasit Medical Research Services & Development Ltd.
58. Please disclose the number of your U.S. holders and percentage of shares held by them. For guidance, please see Item 7.A.2 of Form 20-F.

Taxation, page 75

Israeli Tax Considerations, page 75

59. An investor is entitled to rely on the Israeli tax information contained in the registration statement. Accordingly, delete your disclaimers that the “discussion of Israeli income tax and capital gain tax considerations is for general information only” and “is not tax advice” as they imply that an investor may not so rely on the information.
60. We note your statements on pages 79-80 that, although you do not expect to be a PFIC in 2013, 2014 or in a subsequent year, “because this determination is made annually after

the close of each taxable year, because [you] hold and expect to continue to hold following this offering a substantial amount of cash and cash equivalents, and because the calculation of [your] assets may be based in part on the value of [your] ordinary shares, which may fluctuate after this offering and may fluctuate considerably given that market prices of technology companies historically often have been volatile, it is difficult to predict whether [you] will be a PFIC in any taxable year.” Accordingly, provide a risk factor that briefly discusses the risks to your U.S. holders should you be classified as a PFIC. Include in this discussion the fact that, should you be classified as a PFIC, you do not intend to furnish the information necessary for U.S. holders to make qualified electing fund elections that would provide some relief from the PFIC rules.

#### Financial Statements

##### Notes to Financial Statements

##### Note 6: Convertible Notes, page F-15

61. Please clarify your accounting of the adjustable conversion feature embedded in your convertible notes:

- Whether and how the beneficial conversion feature was recognized at the issuance;
- Whether the “additional redemption amount” is different from the fair value of the conversion feature; and,
- Whether the conversion feature was remeasured at each reporting date.

Cite the accounting literature to support your accounting.

##### Note 9: Shareholders’ Equity, page F-17

62. Please provide us an analysis that supports your recording of a compensation expense in the amount of \$1,466,000 in the year ended December 31, 2011 and a dividend in the amount of \$180,000 for the year ended December 31, 2011.

##### Note 10: Related Party Balances and Transactions, page F-22

63. Please clarify your footnote disclosure “a” to explain what you mean by “independent,” since the contractor being a shareholder and a director appears to preclude this contractor from being independent.

##### Item 8. Exhibits and Financial Statement Schedules, page II-1

64. Please file a Form of Convertible Note as an exhibit to your registration statement.

65. You have filed the Consulting Agreement between the Company and Adler Consulting LLC as Exhibit 10.1 to your registration statement. However, this agreement is not described in your prospectus. In an appropriate place in your prospectus, please disclose the material terms of this agreement, including the subject of the consulting agreement,

the obligations of each party, any financial provisions, and the term and termination provisions.

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
- 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.

Dr. Yaron Daniely  
Alcobia Ltd.  
February 10, 2013  
Page 14

You may contact Keira Nakada at (202) 551-3659 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Rose Zukin at (202) 551-3239, Jennifer Riegel at (202) 551-3575, or me at (202) 551-3710 with any other questions.

Sincerely,

/s/ Jennifer Riegel for

Jeffrey P. Riedler  
Assistant Director

cc: Edwin L. Miller, Jr.  
ZAG/S&W LLP  
1633 Broadway Ave.  
New York, NY 10019