

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

DIVISION OF CORPORATION FINANCE

February 20, 2013

<u>Via E-Mail</u> Mr. Gil Efron Chief Financial Officer Kamada Ltd. 7 Sapir Street Kiryat Weizmann Science Park P.O. Box 4081 Ness Ziona 74140 Israel

> Re: Kamada Ltd. Draft Registration Statement on Form F-1 Submitted January 23, 2013 CIK No. 0001567529

Dear Mr. Efron:

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.

- 1. Please note that where we provide examples or references to portions of your draft registration statement to illustrate what we mean by our comments, they are examples and not exhaustive lists. If our comments are applicable to portions of the draft registration statement that we have not cited as examples, please make the appropriate changes elsewhere in the document in accordance with our comments.
- 2. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 3. Please confirm that the graphics included in your draft registration statement are the only graphics you will use in your prospectus. If you will use any additional graphic, visual or

> photographic information in the printed prospectus, please provide us a proof of each such item for our review prior to its use. Please note that we may have comments regarding this material.

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.

Cover Page

5. We note that you state on the cover page that you "will list [your] ordinary shares on the Nasdaq Global Market..." However, on page 39 you state that you have applied to list your shares, and on page 46 you state that you expect to apply to list your shares. Please clarify the status of your Nasdaq application in these sections and elsewhere, as appropriate.

Table of Contents, page i

6. Please move the statement regarding the dealer prospectus delivery obligation to the outside back cover page of the prospectus, as required by Item 502(b) of Regulation S-K.

Prospectus Summary, page 1

- 7. Please delete the language in the preface to the prospectus summary that indicates that the summary is not complete. While the summary, by definition, will not contain all of the information included in the prospectus, it should nevertheless be a complete summary.
- 8. In your summary and throughout the draft registration statement where you disclose that you have generated an operating profit for the nine months ended September 30, 2012, please specify the amount of profit.

Risk Factors

"We may not be able to commercialize our product candidates..." page 16

9. To the extent you have experienced any of the risks identified in this risk factor, such as delays in obtaining your clinical materials, third-party contractors' noncompliance with regulatory requirements, suspension or termination of clinical research due to regulatory noncompliance, or fraudulent activity by clinical researchers, please revise your disclosure to describe or provide examples of the relevant incidents where material.

"Our products involve biological intermediaries..." page 19

10. Please revise the last paragraph to expand your description or provide examples of past situations that have caused you to write off the value of products or incur unexpected costs as a result of contaminated product.

"Our ability to continue manufacturing and distributing..." page 19

11. To the extent you have received citations for deficiencies or deviations from procedures, or were required to report material deviations from procedures, please revise your disclosure to describe or provide examples of these incidents.

"Our Distribution segment is dependent on a few suppliers..." page 24 Marketing and Distribution, page 91

12. You state that you have distribution agreements with each of Bioproducts Laboratories Ltd. and Biotest A.G., sales of whose products represented 39% and 42%, respectively, of your revenues for the nine-months ended September 30, 2012. Please describe the material terms of each of these agreements and file them as exhibits to your registration statement.

"Product liability claims or product recalls involving our products..." page 26

13. To the extent you have received or are aware of product liability claims or product recalls involving your products or products you sell, please revise your disclosure to describe these incidents.

"Our success depends in part on our ability to obtain and maintain protection..." page 30

14. If you are aware of any counterfeit versions of your products or other unauthorized use of your intellectual property, please expand your disclosure to identify the unauthorized use and the circumstances relating thereto.

"We may be subject to claims that we infringe..." page 32

15. If you have received any notice from any third party regarding infringement of its intellectual property, please expand your disclosure to identify the notice and the circumstances relating thereto.

"We are subject to extensive environmental, health and safety, and other laws..." page 36

16. If you have received any notice or claim of a violation of any of these laws or regulations, please expand your disclosure to identify the notice or claim and the circumstances relating thereto.

"Future sales of our ordinary shares..." page 38

17. Please file a form of the lock-up agreement as an exhibit to your registration statement.

"We are an 'emerging growth company' with reduced reporting requirements..." page 41

18. Please correct or delete the cross-reference in the second paragraph to your discussion elsewhere in the registration statement of your status as an emerging growth company, as no such heading appears under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

"The tax benefits that are available to us require us to continue..." page 42

19. Please discuss how transferring production of Glassia to Baxter will affect your ability to comply with the "Approved Enterprise" and "Privileged Enterprise" conditions.

Use of Proceeds, page 47

- 20. If you have no specific plans for the proceeds to be received, please discuss the principle reasons for your offering.
- 21. If you intend to prioritize among the possible uses of proceeds, such that some uses are more important than others, please describe this ordering. In addition, please provide a brief description of any expansion plans for your distribution capabilities or your manufacturing infrastructure.

Selected Consolidated Financial Data, page 51

22. Please provide the exchange rate information required by Part I, Item 3.A.3 of Form 20F.

Management's Discussion and Analysis of Financial Condition and Results of Operations Key Components of Our Results of Operations Revenues, page 58

23. Please clarify your statement regarding your expectation of sales of Glassia to Baxter will grow over the longer term when you have disclosed elsewhere that Baxter plans on manufacturing Glassia at which point you will begin receiving royalties.

Results of Operations

Nine Months Ended September 30, 2012 Compared to Nine Months Ended September 30, 2011 Revenues, page 61

- 24. Please revise your disclosure here and in your comparison of annual results, as appropriate, to address the following comments:
 - Describe and quantify the milestone payments recognized in 2011 that were not recognized in 2012.
 - Separately quantify and discuss changes in product revenues in terms of changes in price versus changes in volume. See Item 303(a)(3)(iii) of Regulation S-K.
 - In discussing volume and price increases or decreases, please explain the underlying reason(s) for the changes. For example, although you disclose in your annual comparison that the increase in your distribution segment revenues is mainly attributable to an increase in sales of IGIV products, you do not appear to discuss why there is an increase. Please note that this bullet also applies to your explanations of changes in cost and expense line items.

Research and Development Expense, page 62

- 25. Regarding your development pipeline activities, please revise your disclosure to include the following for each of your research and development projects:
 - The costs incurred during each period presented and to date;
 - The nature of efforts and steps necessary to complete the project;
 - The risks and uncertainties associated with completing development;
 - The extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project; and
 - Where a future milestone such as completion of a development phase, date of filing with a regulatory agency, or approval from a regulatory agency can be reliably determined, disclosure should be made.

If you do not maintain any research and development costs by project, disclose that fact and explain why management does not maintain and evaluate research and development costs by project. Provide other quantitative or qualitative disclosure that indicates the amount of the company's resources being used on the project.

<u>Liquidity and Capital Resources</u> Cash Flows from Operating Activities, page 67

26. Please revise your disclosure to discuss the underlying causes of your operating cash flows. In this regard, your current disclosure appears to merely reiterate the significant line-items in the operating activities section of your cash flow statements prepared under the indirect method.

Contractual Obligations and Commitments, page 68

27. Please revise your disclosure of long-term debt obligations to include interest on your convertible debenture obligation for the years presented at the current rate. Revise footnote (1) to discuss the variable nature of this interest and include an analysis of sensitivity to changes in the interest rate.

Business, page 74

28. We note your disclosure on page 75 and elsewhere as to the number of potential cases of AATD treated, the number of patients suffering from AATD and the number of patients diagnosed with AATD. Please tell us how you derived your estimates of the size of the potential market for AATD.

Our Competitive Strengths, page 75

29. We note your disclosure of the percentage of revenues derived from sales in the United States and Europe, as well as Latin America and Asia. If practicable, please provide the percentage of revenues derived separately from each of the United States, Europe, Latin America and Asia for the periods given.

Our Product Portfolio Proprietary Products Segment—Snake Bite Antiserum, page 81

30. If your business is substantially dependent on your agreement with the Israeli Ministry of Health, please describe the material terms of this agreement and file it as an exhibit to your registration statement.

Strategic Partnerships—Baxter (Glassia), page 86

31. Regarding your strategic partnership with Baxter, please disaggregate the \$45 million payments to be received separately for distribution rights and milestones set forth in distribution and licensing agreements. In addition, disaggregate the total milestones payments into meaningful categories such as development, regulatory, and/or commercial milestones. Please also disclose the nature of the underlying events which trigger the milestone payments.

Distribution Agreement, page 86

- 32. Please specify the minimum amount you are entitled to receive from Baxter each year for purchases of Glassia.
- 33. You state that after 2015, Baxter has no obligation to purchase a minimum amount of Glassia. However, Baxter's failure to purchase a specified minimum of Glassia over a

certain period of time provides you with the right to terminate the agreement. Clarify the "certain period of time" this relates to as the current disclosure is vague.

Technology License Agreement, page 87

34. Please specify the minimum royalty amount and the royalty percentage you are entitled to receive from Baxter.

Strategic Partnerships-Chiesi (Inhaled AAT for AATD product), page 87

- 35. Regarding your strategic agreement with Chiesi, please disaggregate the \$60 million contingent payments to be received separately for regulatory and sales milestones and quantify the upfront payment received. Tell us how you are accounting for the upfront payment.
- 36. In addition, please expand your discussion of the material terms of your agreement to specify the minimum amount of Inhaled AAT that Chiesi is required to purchase each year.

Strategic Partnerships—PARI, page 88

37. Please expand your discussion of the material terms of your agreement with PARI to specify the royalty rates payable by the parties.

Customers, page 92

- 38. You state that Kupat Holim Clalit accounted for 25% of your total revenues, which suggests that your business is substantially dependent on this relationship. If you have an agreement with Kupat Holim Clalit, please describe its material terms and file it as an exhibit to your registration statement.
- 39. You state that that your distributors in Brazil, Thailand, and India are major customers. To the extent you have agreements with these customers on which your business is substantially dependent, please describe the material terms of t agreements and file them as exhibits to your registration statement.

Intellectual Property—Patents, page 100

40. You state that of your five families of patents and patent applications, your two patents protecting your manufacturing process are material. You state further that your patents are expected to expire between 2018 and 2027. Please revise your disclosure to provide the specific expiration dates and jurisdiction of your material patents for your manufacturing process, as well as any other patents that you consider to be material to your business.

Employees, page 101

41. Please disclose the number of employees for each of the past three years. See Part I, Item 6.D. of Form 20-F.

Property, page 102

42. Please file your lease agreements with respect to your production plant in Beit Kama and your principal offices and research and development laboratory in Ness Ziona as exhibits to your registration statement.

Management, page 103

43. Please provide the names and addresses of the company's auditors together with their membership in a professional body as required by Part I, Item 1.C. of Form 20-F.

Directors, page 104 Voting Agreement, page 126

44. Please identify the directors nominated by Gov pursuant to the loan agreement, as required by Part I, Item 6.A.5 of Form 20-F. In addition, please expand your disclosure on page 126 to describe the material terms of the loan agreement still in effect, including any amounts outstanding to the extent required by Part I, Item 7.B.2 of Form 20-F, and file the loan agreement as an exhibit to your registration statement.

Compensation of Executive Officers, page 116

45. Please update your compensation disclosure for the year ended December 31, 2012.

Employment Agreements with Executive Officers, page 120

46. Please expand your disclosure to describe the material terms of your employment agreements with each of your executive officers and file those agreements as exhibits to your registration statement.

Principal Shareholders, page 123

47. Please revise the table to list Damar Chemicals, Inc. and Gov Financial Holdings Ltd. as owners of 5% or more of your ordinary shares, identifying the individual(s) who possess(es) voting and/or investment power over the ordinary shares held by each entity.

- 48. Please identify, to the extent the information is available to you, the individual(s) who possess(es) voting and/or investment power over the ordinary shares held by Excellence group and Meitav group.
- 49. Please provide the information regarding changes in the percentage ownership of your principal shareholders required by Part I, Item 7.A.1(b) of Form 20-F.

<u>Certain Relationships and Related Party Transactions</u> <u>Tuteur S.A.C.I.F.I.A, page 125</u>

50. Please revise your description of your Tuteur agreement to specify the minimum purchase amount.

Issuance of Securities

51. Please file the form of warrant issued to the Investors as an exhibit to your registration statement.

Expenses Relating to this Offering, page 149

52. Please revise the table to include your estimated expenses for your transfer agents' fees and any premiums paid to insure directors or officers for liabilities to the extent required by Part I, Item 9.F. of Form 20-F and the Instruction to Item 9.F.

Notes to Consolidated Financial Statements Note 2: Significant Accounting Policies m. Intangible assets, page F-19

53. In the first paragraph you indicate that internally generated intangible assets, excluding capitalized development costs, are recognized in profit or loss when incurred. In your research and development costs policy on page F-20 you indicate that research expenditures are recognized in profit or loss when incurred. Please revise your policy disclosure to describe your accounting for development costs. Please clarify under what conditions you would capitalize development costs and whether you have capitalized such costs.

Note 15: Non-current Liabilities b. Convertible debentures, page F-38

54. You disclose that you account for the equity component of these debentures separately from the liability component. Please provide us your analysis supporting your accounting and reference for us the authoritative literature you rely upon. In your response, please specifically tell us why the debentures in their entirety are not financial liabilities under subparagraph b of the definition in paragraph 11 of IAS 32 considering

that your debentures appear to have at least two different conversion rates. Also in your response, please tell us why the conversion feature is not an embedded derivative under paragraph 11 of IAS 39.

Note 19: Contingent Liabilities and Commitments, page F-50

- 55. In subparagraph k on page F-54 you disclose your agreement with Baxter. Please tell us how you account for each component of this agreement and reference for us the authoritative literature you rely upon to support your accounting. In this regard, it appears that the fees you received relate to the Distribution Agreement and the License Agreement, but it is unclear what consideration you conveyed under the Raw Materials Supply Agreement. In your response, please clarify whether the rate you pay for fraction IV supply is at fair value and whether there is any value inherent in the Raw Materials Supply Agreement.
- 56. In the last paragraph on page 90 you disclose that Baxter receives no payment for the supply of fraction IV to be used for the manufacture of Glassia by Baxter that it will sell in its territory. In the first paragraph on page F-55 you indicate that Baxter will supply you raw material free of charge that you will use to manufacture product to be sold to Baxter for distribution under the Distribution Agreement. Please revise your disclosure to remove the apparent inconsistency between these statements. In the former instance, please explain by Baxter would need to ship product to you if they will manufacture Glassia. In addition, separately explain to us whether and, if so, how the agreement by Baxter to supply fraction IV to you at no cost is considered in your accounting for the Raw Materials Supply Agreement as stipulated in the previous comment.

Note 26: Operating Segments, page F-67

57. Please provide the disclosures required by paragraph 32 of IFRS 8 or tell us why this disclosure is not required.

Recent sales of unregistered securities, page II-3

58. Please update this section and elsewhere, as necessary, to include the recent option issuances described in note 29 to the financial statements.

General

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 Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Amy Reischauer at (202) 551-3793, 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

cc: <u>Via E-Mail</u> Andrew D. Thorpe Morrison & Foerster LLP 425 Market Street San Francisco, CA 94105