



DIVISION OF  
CORPORATION FINANCE

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

Mail Stop 4720

March 6, 2016

Harlan W. Waksal, M.D.  
President and Chief Executive Officer  
Kadmon Holdings, LLC  
450 East 29th Street  
New York, NY 10016

**Re: Kadmon Holdings, LLC  
Draft Registration Statement on Form S-1  
Submitted February 8, 2016  
CIK No. 0001557142**

Dear Dr. Waksal:

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.

Overview, page 1

1. A prospectus summary should not include a lengthy description of your business and business strategy. Instead, the summary should highlight those aspects of your offering that are the most significant, excluding detail that detracts from the most significant points and not repeating identical disclosure from other sections of your document. In this regard we note that your disclosure on pages 1 through 5 appears identical to your disclosure on pages 103 through 107. Please revise accordingly.
2. The prospectus summary should provide a balanced presentation of your business. We note, however, that your summary focuses exclusively on your pre-commercial research and development efforts and lacks disclosure concerning your current commercial operations. Please substantially revise the summary to provide prominent disclosure of

your current commercial operations. Your discussion should highlight your dependency on revenues derived from marketing branded and generic drugs (pages 13 and 29) and address material trends negatively impacting those revenues (pages 29, 55 and 91).

3. We note your reference in the first paragraph to a “multi-disciplinary research and clinical development group” that has brought more than 15 drugs to market; however, your business section does not appear to discuss any drugs that you have commercialized. Please revise or provide us support for the disclosure and its prominence in the summary.
4. Please revise to clarify the meaning of scientific and technical terms. For example, and without limitation, please provide a brief explanation of the following terms:
  - blood-brain barrier;
  - leptomeninges;
  - epidermal growth factor receptor;
  - Src;
  - proto-oncogene tyrosine-protein kinase;
  - autosomal dominant PKD;
  - statistically significant;
  - trientine hydrochloride;
  - penicillamine; and
  - cytokines
5. We refer to your disclosure in the first sentence of the second bullet point on page 1. Please revise to clarify whether you are stating that the preclinical product is designed to penetrate the blood-brain barrier unlike other TKIs or whether you are stating that your product does in fact penetrate the blood-brain barrier unlike other TKIs. If it is the latter, then please provide us support for the assertion.
6. We note your reference to “potent” activity on page 1 and elsewhere in your prospectus. Please revise your disclosure to explain the meaning of this term in the context of your industry.

Our Strategy, page 3

7. Please disclose your basis for stating that your formulation is suitable for young children.

Our Clinical Stage Pipeline, page 4

8. Please revise your clinical stage pipeline table to differentiate whether a clinical study is planned or whether FDA has approved an IND application. For example, we note the development stage marker is the same for KD025 (IPF and cGVHS) and (scleroderma and SLE) even though the development stages are approved Phase 2, and current Phase 2 planning, respectively. Please also add a Phase III column to the table.

Risks Related to Our Business, page 6

9. Please expand the disclosure in the first bullet point to highlight the risk disclosure on page 13 concerning your anticipation that expenses will increase substantially in the future.
10. We refer to your risk factors on page 14 concerning your indebtedness and your ability to service that indebtedness. Please revise your summary to highlight these risks associated with your debt. Additionally, please highlight that your auditor has expressed substantial doubt about your ability to continue as a going concern.

Implications of Being an Emerging Growth Company, page 7

11. 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.

Clinical development is a lengthy and expensive process with a potentially uncertain outcome, page 16.

12. Please reconcile your disclosure on page 16 that KD034 is in clinical trials with the tables on pages 4 and 106 and your disclosure on 124 which indicate that you are not in clinical trials.

Use of Proceeds, page 67

13. We refer to your disclosure on page 63 indicating that you expect to use the net proceeds of this offering to repay indebtedness under your existing credit facilities. Accordingly, revise the use of proceeds section to identify the debt that you will repay and the applicable repayment amount. Please refer to Instruction 4 of Item 504 of Regulation S-K. With reference to your disclosure on page 174, also tell us and, if applicable, disclose whether offering proceeds will be used to repay the \$3 million to Dr. Waksal in 2016.
14. We refer to your disclosure in the first bullet point concerning “certain Phase II clinical studies” for KD025. We also note your summary disclosure on page 5 highlighting the importance KD025 development to your business prospects. Accordingly, if you intend to use offering proceeds for specific KD025 indications or studies, please revise to identify these studies or indications and the approximate amount of any proceeds.

Management's Discussion and Analysis of Financial Condition and Results of Operations  
Components of Statement of Operations  
Research and Development expenses, page 83

15. While you do not allocate personnel-related costs, including stock-based compensation, costs associated with broad technology platform improvements and other indirect costs to specific product candidates, please provide as much quantitative and qualitative disclosure as possible about the amount of costs, both internal and external, incurred during each period presented on each of your major research and development projects. To the extent that you cannot attribute costs to each project, please explain why management does not maintain and evaluate those costs by project.

Critical Accounting Policies and Significant Judgments and Estimates  
Unit-based compensation expense, page 87

16. We may have additional comments on your accounting for equity issuances including equity 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 membership units leading up to the IPO and the estimated offering price.

Liquidity and Capital Resources  
Operating activities, Page 95

17. Please expand your discussion to address material changes in the underlying drivers such as where the actual usages and sources of cash existed in your discussion of operating cash flows during the years presented. In doing so, please ensure that you are not merely describing items identified on the face of the statement of cash flows.

Business, page 103

18. Please disclose the location and date of regulatory approval for your clinical trials. For example, please disclose if a clinical trial is conducted in the United States pursuant to an IND.

Key Differentiating Attributes of KD025, page 108

19. We refer to your disclosure concerning the November 25, 2014 publication. Please identify the author(s) of the report and file their consent to the summary you provide on page 108.
20. Please provide a brief description of the Psoriasis Area and Severity Index (PASI).

KD025 Clinical Program, page 108

21. Please revise the last sentence on page 108 to disclose when the trial became fully enrolled. In addition, disclose the primary endpoint of your study.

Planned Phase 2 Clinical Study of KD025 in Moderate to Severe Psoriasis, page 109

22. Please revise your disclosure to explain, if known, why the FDA has advised you of the need to evaluate the potential of KD025 to induce carcinogenicity in two species.

Completed Clinical Studies of KD025, page 110

23. In your table on page 111 or elsewhere, as applicable, please disclose the primary endpoint of each trial and whether such endpoints were achieved. We also note the footnotes to the table. Please revise the narrative disclosures on pages 110 or 112 to discuss adverse events, including grade levels.

KD026, page 120

24. We refer to your last bullet point on page 3. Please revise here and elsewhere, as applicable, to discuss whether you intend KD026 to be used as monotherapy or combination therapy for Type 2 diabetes. Discuss the process, and if applicable, challenges associated with developing and commercializing a combination therapy.

Symphony Evolution, Inc., page 128

25. Please revise your disclosure to include the nature and scope of intellectual property transferred, aggregate commercial milestones and royalty term. Also, indicate the date when the last patent expires for this license and the other material licenses addressed in your disclosures.

Nano Terra, Inc. (KD025, KD026), page 128

26. Please file the joint venture agreement as an exhibit or explain why it is not a material contract.
27. Please expand your disclosure to discuss the nature and scope of intellectual property transferred. In this regard, we note that the disclosure on page 177 references a drug development platform and three unidentified clinical stage products. With respect to the payment obligations you assumed from Nano Terra, please clarify whether these obligations are limited to the royalty percentages discussed in the final paragraph on page 128.

Valeant Pharmaceuticals North America, LLC, page 129

28. Please disclose the amount of the milestone payment that you reference in this section. Also, revise to clarify whether the agreement has been automatically extended until February 2017.

Chiromics, LLC, page 129

29. Please revise your disclosure to further describe the compound libraries transferred pursuant to the agreement. In addition, please disclose the amounts paid to date. Also, clarify whether you have any remaining financial obligations under the contract.

AbbVie Inc., page 130

30. Please revise to identify each of the agreements within the series and discuss in greater detail the rights and duties of the parties.”

Our Intellectual Property, page 131

31. We refer to the second sentence under the heading. Please revise to identify which of your product candidates are covered by patents and patent applications that you own or license. For each of the four clinically advanced product candidates identified in your summary, please discuss the duration of patent coverage and the types of applicable patent protections in the portfolio (*i.e.*, composition of matter, use, process, etc.).

Competition, page 132

32. Please revise this section to discuss the competitive conditions applicable to your branded and generics business.

Director Compensation, page 158

33. We refer to the disclosure on page 178 concerning Dr. Samuel D. Waksal’s board service. Please revise to disclose his fiscal 2015 compensation.

2015 Summary Compensation Table, page 161

34. We refer to footnote 3. Please tell us whether you will be able to calculate these figures or provide estimated values in the table footnote prior to effectiveness of the registration statement.

Employment Agreements, page 164

35. Please expand your disclosure to discuss the material terms of each of your employment agreements. In addition, please file the employment agreement for Mr. Poukalov as an exhibit to the registration statement.

Related Party Agreements in Effect Prior to this Offering, page 174

36. Please revise this section to identify each related party and to disclose the amount of each transaction. For example, we note that on page 175 you disclose several closings with “certain investors and other parties at various purchase prices.”
37. We refer to your disclosure of an “equity instrument” issued by Dr. Samuel Waksal to a third party organization. Please revise to clarify the related party nature of this transaction. With a view to disclosure, please tell us whether the reduction in the liability is related solely to a reduced valuation for your Class A units.

Relationship with NT Life Sciences, LLC, page 177

38. We refer to the first sentence under the heading. Please revise to put the Series B Convertible Preferred Stock investment in perspective. In this regard, it is not clear whether you have a material ownership position in Nano Terra.

Dr. Samuel D. Waksal’s Former Roles at Kadmon, page 178

39. With a view to potential disclosure, please tell us the extent of Dr. Waksal’s economic interest in Kadmon I, LLC.

Registration Rights Agreements, page 194

40. Please describe briefly the “customary piggyback registration rights” referenced in this section.

Consolidated Financial Statements

Consolidated Balance Sheets, page F-3

41. Please tell us whether you plan to provide pro forma presentation on the face of your financial statements that will give effect to the conversion of your outstanding membership units into shares of common stock prior to the closing of this offering. If not, explain why.

Notes to the Consolidated Financial Statements

2. Summary of Significant Accounting Policies

- 42. Please disclose your accounting policy for loan modifications, debt restructurings and extinguishments. Address troubled debt restructurings as applicable.
- 43. We note references to derivative securities and derivative liabilities in your submission. Please revise your disclosure to include your accounting policy for each type of derivative instrument.

Revenue Recognition, page F-10

- 44. Disclose your accounting policy applicable to amendments to your collaboration agreements and reference for us the related accounting literature.

Unit-based Compensation Expense, page F-11

- 45. Please revise your accounting policy to explain your accounting policy for exchanges, replacements and modifications of employee stock options disclosed on pages F-46 and F-47.

Recent Accounting Pronouncements, page F-17

- 46. Please revise to indicate when you expect to adopt recent accounting pronouncements, such as ASU 2015-15 and ASU 2015-17 and explain their expected impact on your financial statements. If such pronouncements have already been adopted, disclose the adoption date and explain the effect of the adoption on your financial statements.

4. Commercial Partnership, page F-22

- 47. Please disclose the name of the counterparties to your commercial agreements. Describe the elements and deliverables you identified in your revenue arrangements and clarify your process in considering whether the elements are separate units of accounting. Explain how you allocated the arrangement consideration to the various elements of the agreements. Describe the revenue attribution model you follow for each element, for example for the gain recognized in 2013 on divestiture of marketing rights. Reference the authoritative accounting literature by paragraph to substantiate your accounting.

5. Debt, page F-24

- 48. You disclose several debt agreements in your note. These agreements are convertible, have registration rights and/or have warrants or other features such as the PIK interest feature of the Senior Convertible Term Loan and the Second-Lien Convert. For your debt agreements with convertible and/or other elements and features, please tell us how



you allocated the loan proceeds between the debt component and the other elements. Reference for us the applicable accounting literature used to support your accounting. Specify if any elements are considered to be derivative instruments and clarify in the disclosures.

13. Commitments, page F-52

49. On page 50, you disclose that on some of the products you have licensed, you owe significant development and commercial milestone payments as well as royalties. Please clarify whether you currently owe these milestones or whether you are referring to payments that will be made in the future. If you currently owe these payments, please describe and quantify them for us and tell us how they are reflected in your financial statements.

14. Contingencies, page F-53

50. As it relates to the Rosenfield litigation, you disclose that the Company believes it has a strong defense and that it is reasonably possible, but not probable, that you will have an unfavorable outcome in this matter. When there is at least a reasonable possibility of loss, ASC 450-20-50-4 requires disclosure of an estimate of the possible loss or range of loss or a statement that such estimate cannot be made. Please revise your disclosure to comply with the guidance or advise us.

Exhibit Index

51. Please file a form of your warrants.
52. Please file the August 28, 2015 Intercreditor Agreement.
53. Please file the limited liability company agreement.
54. Please submit all exhibits as soon as practicable. We may have further comments upon examination of these exhibits.

Harlan W. Waksal, M.D.  
Kadmon Holdings, LLC  
March 6, 2016  
Page 10

You may contact Ibolya Ignat at (202) 551-3636 or Sharon Blume at (202) 551-3474 if you have questions regarding comments on the financial statements and related matters. Please contact Tara Keating Brooks at (202) 551-8336 or Joseph McCann at (202) 551-6262 with any other questions.

Sincerely,

/s/ Joseph McCann for

Suzanne Hayes  
Assistant Director  
Office of Healthcare and Insurance

cc: Christopher C. Paci, Esq. - DLA Piper LLP (US)