

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

October 31, 2013

Via E-mail
Derek Chalmers, Ph.D., D.Sc.
President and Chief Executive Officer
Cara Therapeutics, Inc.
1 Parrot Drive
Shelton, Connecticut 06484

Re: Cara Therapeutics, Inc.

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Draft Registration Statement on Form S-1 Submitted October 4, 2013

CIK No. 0001346830

Dear Dr. Chalmers:

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.

#### General

- 1. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
- 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.

# <u>Prospectus Summary</u> General

- 3. We note that your registration statement includes several references to data attributed to IMS Health, Inc. Please briefly describe who IMS Health is. In addition, please disclose what your relationship is to IMS Health and whether the information attributed to IMS Health was compiled on your behalf.
- 4. Please revise your disclosure here and as necessary throughout the prospectus to explain the phrase "peripheral mechanism of action." Please also explain how "peripherally-active" products are distinguishable from "centrally-active" products and why this is important to the development of CR845. Your discussion should specifically explain how "peripherally-active" kappa opioids, like CR845, avoid both the psychiatric side-effects of "centrally-active" prior kappa opioids and the CNS side effects of mu opioids.
- 5. Please define or explain your use of the following terms or phrases at their first use in the prospectus:
  - "short bolus;"
  - "anti-emetic;"
  - "NSAIDs;"
  - "oral bioavailability;"
  - "pharmacokinetic predictability;"
  - "somnolence;" and
  - "transient prolactin elevations;"
- 6. Please explain the purpose of "rescue medication" as used in your clinical trials.

#### Our Product Candidates, page 2

- 7. In the "Status" column of your table, please indicate that I.V. CR845 has completed Phase 2 clinical testing.
- 8. Please define the term "statistically significant."
- 9. Please briefly summarize the results of the Phase 1 clinical trial you have completed for Oral CR845.

### Risk Factors

"If we fail to supply CR845 to our collaboration partners...," page 13

10. We note your risk factor disclosure that you currently have a single supplier for I.V. CR845 and that failure to provide adequate supply of CR845 product to your co-collaborators could result in a breach of your agreements and potential loss of revenue for the Company. Please identify the single supplier to which you are referring as required under Item 101(h)(4)((v) of Regulation S-K. Please also describe the terms of your current contractual arrangements with this supplier.

# "The FDA may determine that I.V. CR845 or any of our other product candidates have undesirable side effects...," page 16

11. Please revise your risk factor disclosure to identify the specific "poorly tolerated side effects" associated with kappa opioid agonists.

# "If the manufacturers upon whom we rely fail to produce our product candidates...," page 25

12. We note your disclosure that you have developed a formulation of Oral CR845 based on a third party's proprietary technology but have not yet negotiated terms related to use of such technology for commercial manufacturing. Please revise your disclosure to describe the technology used, indicate how you obtained the rights to use the third party's proprietary technology for the development of Oral CR845 and identify the party from whom you obtained such technology.

# "We will incur increased costs as a result of operating as a public company," page 38

13. Please include in this risk factor, to the extent practicable, an estimate of the annual costs associated with your reporting obligations.

# Special Note Regarding Forward-Looking Statements, page 47

14. We note your statement that "there can be no assurances as to the accuracy or completeness" of information obtained from industry and general publications, studies and surveys. We also note your statement that results and estimates derived from internal research "have not been verified by any independent source." Please revise your disclosure to remove these statements as it is not appropriate to directly or indirectly disclaim liability for information in the registration statement.

# Use of Proceeds, page 48

15. Please separate the amount of net proceeds you intend to use to conduct the Phase 1 clinical trial of Oral CR845 and the amount you intend to use for the Phase 2a clinical trial.

# Capitalization, page 50

16. It appears the total capitalization amount presented within the capitalization table represents in substance total liabilities, convertible preferred stock and stockholders' equity rather than total capitalization. Please revise or advise us.

# Selected Financial Data, page 54

17. Please present pro forma earnings per share data in this section consistent with your disclosure on page F-4.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates

Share-Based Compensation, page 67

- 18. In order for us to fully understand the equity fair market valuations reflected in your financial statements, please include an itemized chronological schedule covering all equity instruments issued since January 1, 2012 through the date of your response. Separately represent to us that you will update this schedule for any appropriate issuances after the date of your response through the date you complete your offering. Please provide the following information separately for each equity instrument issuance:
  - The date of the transaction;
  - The number of shares/options issued/granted;
  - The exercise price or per share amount paid;
  - Your fair market value per share estimate and how the estimate was made;
  - The identity of the recipient, indicating if the recipient was a related party;
  - Nature and terms of concurrent transactions; and
  - The amount of any compensation or interest expense element.

When you have determined the IPO price range, include a reconciliation that progressively bridges your fair market value determinations to the estimated IPO price range. Please reconcile and explain the differences between the mid-point of your

estimated offering price range and the fair values included in your analysis.

#### **Business**

#### Our Product Candidates, page 73

- 19. Please revise your disclosure to explain how use of CR845 will avoid drug-drug interactions.
- 20. Please revise the discussion of the results of your clinical trials to identify what the corresponding p values refer to.
- 21. Please revise your tables at pages 79 and 83 to explain what the abbreviation "ANOVA" refers to.

# I.V. CR845, page 73

22. Please revise your disclosure to indicate whether total pain relief score, or TOTPAR, is an FDA-recognized endpoint for acute pain clinical trials.

#### Principal Stockholders, page 119

23. Please amend this disclosure to include the individual(s) who has voting and/or investment power over the common shares held by Healthcare Private Equity Limited Partnership.

# Exhibit Index, page II-7

24. Please indicate in this index which of your exhibits will be the subject of your application for confidential treatment.

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 Ibolya Ignat at (202) 551-3656 or Andrew Mew at (202) 551-3377 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, 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: Babak Yaghmaie
Stephanie Levy
Darren DeStefano
Cooley LLP
1114 Avenue of the Americas
New York, New York 10036