

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

June 3, 2014

Via E-mail

Anish Bhatnagar Chief Executive Officer Capnia, Inc. 2445 Faber Place, Suite 250 Palo Alto, CA 94303

Re: Capnia, Inc.

Draft Registration Statement on Form S-1

Submitted May 8, 2014

CIK No. 1484565

Dear Mr. Bhatnagar:

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.

Artwork

- 1. You may include text in your artwork only to the extent necessary to explain briefly the visuals in the presentation. Additionally, it is not appropriate to highlight key product features and performance claims in your artwork without balancing the presentation to highlight key product limitations and/or competitive disadvantages. Please revise your graphics accordingly.
- 2. We refer to your disclosure on page 10 indicating that you have not generated any revenues from commercial product sales. To the extent that you seek to highlight your "CoSenseTM" product in the gatefold to the prospectus, please balance your presentation by explaining briefly that you have not generated revenues from this product.

Overview, page 1

3. Please balance your disclosure within the opening paragraph concerning your products under development by also highlighting your disclosure on page 10 that you have not generated commercial sales to date. With respect to your Serenz technology, please tell us why you believe it is appropriate to highlight the positive results from clinical trials without also highlighting: (1) negative results from these trials, as discussed on page 88 and (2) the challenges you face in achieving regulatory approval and commercialization, as discussed on page 89.

CoSense, page 1

- 4. Your disclosure on page 1 indicates that the ETCO measurement provides "a direct measurement" of bilirubin production; however, your disclosure on page 76 and elsewhere indicates that CoSense measures carbon monoxide and "estimates" bilirubin production. Please revise or advise.
- 5. We note your disclosures on pages 16 and 74 concerning transcutaneous monitors. Please explain to us why you believe that these transcutaneous monitors would not enable physicians to practice in accordance with the AAP guidelines when evaluating jaundiced neonates.
- 6. Please tell us the basis of your belief that CoSense has an advantage relative to competitive products with respect to its "accuracy over a range of operating environments."

Our Breath Analysis Technology Platform, page 2

7. Please revise to clarify, if true, that CoSense also utilizes the same Breath Analysis Technology Platform.

Serenz, page 3

- 8. Please tell us how the clinical trials described on pages 87-89 support your disclosure that Serenz has shown "a rapid and almost immediate onset of effect."
- 9. Please balance your Summary discussion of Serenz by also highlighting (i) your disclosure on page 18 indicating that the mechanism of action for Serenz has not been determined or validated (ii) your disclosure on page 53 that following this offering you will need additional funds to fund Phase III clinical trials and (iii) your disclosure on pages 17, 22 and 89 indicating that GlaxoSmithKline has expressed an intention to terminate your development and commercialization relationship based on its belief that Serenz would be classified as a drug-device combination and that termination of this relationship may negatively impact perceptions of Serenz' potential.

Risks Associated With Our Business, page 3

10. Please revise your Summary to highlight the risks that you describe: (i) on page 10 concerning the significant losses you have incurred since inception, your anticipated losses for the foreseeable future and the size of your accumulated deficit to date, and (ii) on page 14 concerning the "going concern" qualification provided by your auditors for the fiscal year ended December 31, 2013.

Healthcare reform measures..., page 39

11. Please revise here and elsewhere as appropriate to indicate whether the 2.3% tax will apply to sales of your CoSense product.

Risk Factors, page 45

12. We reference the discussion on page 45 of the material adjustments to various accounts that resulted in a restatement to your financial statements and led you to conclude there were material weaknesses. Please explain to us the nature of these adjustments. We see you reference Management's Discussion and Analysis for disclosure of your remediation plan and the actions that you have executed during 2014 related to the material weaknesses. Please tell us where this disclosure is included in your filing.

Cautionary Statement..., page 50

13. You may not disclaim responsibility for the accuracy and completeness of your disclosure nor may you qualify your disclosure by reference to "law." Accordingly, please revise to remove this disclaimer.

Market, Industry and Other Data, page 52

14. Please revise to disclose which market research you commissioned and who you commissioned to perform it. Please also file their consent as an exhibit to the registration statement. Refer to Rule 436(a).

Use of Proceeds, page 53

15. Please revise page 53 to disclose the approximate amount of proceeds to be used for each of the purposes identified in the third and fifth paragraphs. Please also revise your Summary disclosure on pages 5-6 to highlight briefly the amounts to be used for each of these purposes.

Capitalization, page 55

16. Please revise to remove cash and cash equivalents from the table on page 55 since this is not a component of your capitalization for purposes of this disclosure

17. Please explain to us the terms and provisions of the conversion of the convertible promissory notes and convertible preferred stock and whether this is automatic prior to the closing of the offering or if there are certain conditions that must be met for the conversion.

Management's Discussion and Analysis

Common Stock Valuation Methodologies, page 66

18. Please revise to disclose the estimate of the fair value of your stock based on the methodologies discussed on pages 65 and 66.

Results of Operations, page 67

19. Please revise to include a discussion of your revenue for fiscal 2013.

Liquidity and Capital Resources, page 68

20. We note you expect significant expenditures in the future. Please revise to disclose your estimated working capital needs and capital expenditures over the next year and discuss plans to fund your liquidity requirements.

Contractual Obligations..., page 69

21. Please tell us why the note obligations referenced on pages F-21 are not included in the table. Please also add a footnote that discusses the additional debt issued since the conclusion of the fiscal year ended December 31, 2013.

Convertible Promissory Notes, page 70

22. Please revise MD&A and your financial statements to disclose how you accounted for the 25% and 30% conversion discounts discussed on pages 70 and 71.

JOBS Act accounting election, page 71

23. Please reconcile your disclosure on page 71 that you will adopt the extended transition period with your disclosure on page 43 that you have irrevocably elected not to avail yourself of the exemption.

Business, page 72

24. When discussing the results and findings for your clinical trials, please replace or supplement terms such as "high" accuracy, "low" imprecision, "close correlation," "statistically significant improvements," "signs of efficacy" and other similarly vague statements with quantified disclosure that supports each assessment.

<u>Limitations of Current Diagnostic Methods, page 74</u>

- 25. Please revise to explain the basis for your statements here, on pages 82-83, and elsewhere concerning the inaccuracy of the diagnostic tools currently available in the marketplace.
- 26. Please tell us why you do not include discussion of gas chromatography in this section. In this regard, we note your disclosure on page 78 of the trial comparing the relative performance of gas chromatography and CoSense.

Clinical Trials, page 78

- 27. Please revise to clarify your basis for concluding that the Stanford University study indicates that CoSense "provides accurate readouts." Please also tell us how the information in Figure 4 validates the ability of CoSense to detect the presence of hemolysis. To the extent that the information in Figure 4 does not address the performance of your product, please revise to include this information in a more appropriate section of your Business discussion.
- 28. Please revise to clarify how the clinical trial conducted at The Children's Hospital of Zhejiang shows that "ETCO measurement with CoSense can accurately determine the presence of hemolysis." In this regard, your disclosure on page 74 states that blood tests, such as the Coombs test, are inaccurate. Accordingly, it is unclear how this trial could demonstrate the accuracy of your product given your disclosure that the study shows that CoSense "can provide information to the physician currently provided by invasive blood tests" which you state elsewhere are inaccurate.
- 29. We refer to Figure 5 on page 79. Please revise the table to clarify, if true, that "ETCOc" represents the performance of your CoSense product. Please also revise your disclosure to explain each of the measurements presented in the table. Please also disclose whether the results of this trial indicate that other three diagnostic tests presented in the first column are more or less accurate than CoSense as compared to results achieved from Coombs testing.
- 30. With respect to the clinical trial involving children with sickle cell anemia, please tell us your basis for concluding that the ETCO levels were "reliably measured." In this regard, please tell us, and revise as appropriate, to explain how the reliability of your product was measured in the trial.

Pricing and Reimbursement, page 81

31. Please revise to explain briefly any positive or negative impacts resulting from reimbursement in the form of Diagnosis-Related Group payment as opposed to reimbursement from payors directly.

Clinical Trials of Serenz in Allergic Rhinitis, page 87

32. Please expand your disclosure to explain the basis for your belief that the magnitude of the effect of your product is larger than that of many other antihistamines, and in the range of that seen with intranasal corticosteroids. In this regard, please quantify and explain the Total Nasal Symptom Scores achieved by your product in each of the six studies for each nasal category and indicate how these scores compare relative to specific antihistamines and corticosteroids that you reference in this section, as well as the "topical decongestants" that you reference on page 73.

Clinical Trials of Serenz Using as-Needed Dosing, page 87

- 33. We refer to Figures 9 and 10. Please revise your disclosure to explain each of the measurements presented in the tables.
- 34. Please disclose the number of patients tested in each of the six trials. Please also disclose how the four to six hour relief described in the final paragraph on page 87 compares relative to competitive products in the marketplace.
- 35. We note that the final two trials you describe at the bottom of page 88 do not appear to involve "as-needed dosing." Accordingly, please revise to add a new heading that more accurately describe what was measured in these two trials.

Our Partnership for Serenz, page 89

- 36. Please revise to disclose, if known, whether FDA staff has provided feedback to GlaxoSmithKline indicating that the product would be classified as a drug-device combination.
- 37. Please revise to explain the material termination provisions of the development and commercialization agreement. To the extent that the agreement is not terminated prior to effectiveness of the registration statement, please file the agreement as a material contract pursuant to Regulation S-K, Item 601(b)(10).

Intellectual Property, page 90

38. Please revise to describe all of the material service agreements that you reference on page 34 and file them as exhibits.

Our Breath Analysis Technology..., page 90

39. Please revise the final sentence on page 90 to disclose the royalty provisions.

Federal Food, Drug, and Cosmetic Act, page 91

40. With respect to CoSense, please revise to identify the applicable device classification and disclose whether CoSense went through the 510(k) premarket notification process or the *de novo* 510(k) review process.

Management, page 92

41. Please revise to disclose the business experience and identify all employers as required by Regulation S-K, Item 401(e). In this regard, and without limitation, it is not clear who employed Mr. Wondka from April 2011 to May 2013 or what Mr. Nabhan's business experience was during 2013 and early 2014.

2013 Summary compensation table, page 110

- 42. Please reconcile your disclosure on page 111 that Mr. Mario had a base salary of 125,000 during 2013 with your disclosure in the table which indicates that he did not receive a salary.
- 43. We refer to footnote 4. Please tell us your basis for not including the fees received during 2013 in the compensation table.

Financial Statements

Note 2. Revenue Recognition, page F-13

44. Please revise to explain whether you have any additional obligations related to the license agreement with GSK. We note on page F-9 that in April 2014 GSK gave notice of their intention to terminate the agreement and return the license rights back to you. Please clarify how this termination impacts the revenue recognized in fiscal 2013 related to the license agreement, including whether any amounts will need to be repaid and whether the accounts receivable from GSK at December 31, 2013 will be collected.

Note 9. Stock Option Compensation, page F-26

45. Please tell us the estimated initial public offering price range. To the extent that there is a significant difference between the estimated grant-date fair value of your common stock during the past twelve months and the estimated IPO price, please discuss for us each significant factor contributing to the difference.

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 Jeanne Bennett at (202) 551-3606 or Brian Cascio, Accounting Branch Chief, at (202) 551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Joseph McCann at (202) 551-6262 or Daniel Morris, Special Counsel, at (202) 551-3314 with any other questions.

Sincerely,

/s/ Daniel Morris for

Amanda Ravitz Assistant Director

cc: <u>Via E-mail</u>

Elton Satusky, Esq. - Wilson Sonsini Goodrich & Rosati