

SECURITIES AND EXCHANGE COMMISSION

FORM UPLOAD

SEC-originated letters to filers

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CEMPRA, INC.

CIK: **1461993** | IRS No.: **262644445** | State of Incorpor.: **DE** | Fiscal Year End: **1231**

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DIVISION OF
CORPORATION FINANCE

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

November 7, 2011

Via E-Mail

Prabhavathi Fernandes, Ph.D.
President and Chief Executive Officer
Cempra Holdings, LLC (to be converted to Cempra, Inc.)
6340 Quadrangle Drive, Suite 100
Chapel Hill, North Carolina 27517-8149

**Re: Cempra Holdings, LLC
Registration Statement on Form S-1
Filed October 12, 2011
File No. 333-177261**

Dear Dr. Fernandes:

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.

FORM S-1

General

1. 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 we may have comments regarding these materials.
2. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not complete lists. If our comments are applicable to portions of the filing that we have not cited as examples, please make the appropriate changes in accordance with our comments.
3. Please update the discussion in your prospectus to the most recent date practicable.

4. Please note that our comments on your request for confidential treatment will be provided under separate cover. Please be advised that we will not be in a position to consider a request for acceleration of effectiveness of the registration statement until we resolve all issues concerning the confidential treatment request.
5. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments. As you are likely aware, you must file this amendment prior to circulating the prospectus.
6. 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 \$20 and 10% if you price above \$20.

Table of Contents Page

7. We note your statements concerning the lack of any guarantee for the accuracy of third party data, that you have not verified the information contained in the third party sources you have used, and the accuracy of the results and estimates of your research has not been verified by independent sources. One may infer from these statements that you do not take responsibility for information from third parties you include in the prospectus. Please remove this language, or expand the disclosure to clearly state that you are liable for the information in your prospectus.

Our Company, page 1

8. Please expand the discussion to clarify what portion of the \$19.6 billion antibiotics market is attributed to each of the specific type of products and services you intend to provide. If you do not intend to serve the global market, the discussion of your anticipated market should be revised accordingly. In addition, since you intend to meet unmet medical needs, please explain how you determined the size of the potential market in the absence of comparable sales data.
9. Please reconcile your reference to unmet needs with the comparison you have made between your proposed products and the existing drugs levofloxacin and linezolid.
10. Please disclose whether and when you filed applications with the FDA for your proposed products.
11. The prospectus summary section should provide a balanced presentation of the information presented in the body of the filing. As currently written, your summary focuses only on the positive attributes of the company. Please balance the current discussion with a discussion of the challenges and risks you face, at least as prominent and detailed as your current discussion of your positive attributes, including a discussion of:

- The lack of revenues from your development stage operations;
- The challenges you face to obtain FDA approval of your products;
- The fact your independent auditors express substantial doubt about your ability to continue as a going concern;
- Your dependence on third parties, including contract research organizations, suppliers and manufacturers; and
- The fact you licensed your CEM-101 product candidate and other possible candidates from Optimer Pharmaceuticals and these licenses can be terminated on short notice if you are unable to make substantial up-front, milestone, and royalty payments.

CEM-101 (Solithromycin): a Novel IV and Oral Macrolide for CABP, page 1

12. We note your reference to the number of prescriptions for azithromycin written for respiratory tract infections, however you are developing CEM-101 for CABP. Please revise the discussion to provide the number of azithromycin prescriptions written for CABP.

13. Please revise the discussion to clarify the meaning and significance of:

- a “pivotal trial program;”
- non-inferiority from an efficacy perspective; and
- end of Phase 2 meeting.

Taksta: An Oral Therapy for S aureus, including MRSA, in ABSSSI, page 3

14. Please define the term “loading dose.”

15. Please clarify how Taksta is unique compared to the fusidic acid already in use outside the United States. In addition, since fusidic acid is already available, please discuss whether the product is patentable and has been patented by others.

Risk Factors

“If we fail to obtain additional financing....” page 13

16. To the extent possible, please quantify the cost of your currently anticipated research and development activities through completion of Phase 3 for CEM-101 and Taksta.

“We rely on third parties to conduct our clinical trials....” page 14

17. Please identify the third party contract research organizations you are reliant upon in this risk factor. In addition, please file your agreements with these organizations as exhibits to the registration statement and describe their material terms in the Business section of the prospectus. Alternatively, please provide us with an analysis that supports your conclusion

that the agreements are not required to be filed pursuant to Item 601(b)(10) of Regulation S-K.

“Our dependence upon third parties for the manufacture and supply....” page 15

18. Please identify the API provided by Wockhardt and whether this API is readily available from other suppliers. If you have entered into a supply agreement with Wockhardt, please file the agreement as an exhibit and describe the material terms of the agreement in the Business section. Alternatively, please provide us with an analysis that supports your conclusion that the agreement is not required to be filed pursuant to Item 601(b)(10) of Regulation S-K.

“We may be required to suspend or discontinue clinical trials....” page 12

19. We note that two of the factors you cite that may delay the commencement and rate of completion of clinical trials are “unforeseen safety issues or adverse side effects.” If you have identified any safety issues or material adverse effects, please revise your disclosure to include an additional risk factor(s) to address the safety issues or material adverse effects you have encountered to date in preclinical studies and clinical trials.

“If we use hazardous and biological materials....” Page 23

20. Please expand the disclosure to state whether you currently maintain liability insurance with respect to your use of hazardous materials. If so, briefly describe the potential liabilities that are and are not covered and, if material, the cost of such coverage. If you do not have coverage for the use of hazardous materials, please revise the risk factor discussion to include the lack of coverage for potential contamination expenses.

“If we are sued for infringing intellectual property rights....” Page 25

21. To the extent you have experienced problems in the past or are aware of any claims regarding infringement of intellectual property rights, please expand the discussion to describe these problems or claims.

“To raise additional funds to support our business operations....” page 21

22. We note the reference to the August 2011 notes. Please expand the discussion to clarify the impact of the corporate conversion upon the restrictions you describe.

“We will incur significant increased costs as a result of operating as a public company...” page 29

23. We note your assertion that you cannot predict or estimate the amount or timing of additional costs. Please delete this statement and include your best estimate of these expenses during your first year as a public company, and on an annual basis thereafter.

Use of Proceeds, page 27

24. Please expand the discussion to separately estimate the amount of proceeds you will use to fund:
- Clinical and non-clinical research and development costs for CEM-101 including Phase 2 IV-to-oral stepdown trial and one Phase 3 oral trial;
 - Clinical and non-clinical research and development costs for Taksta, including one Phase 3 trial; and
 - For working capital and general corporate purposes.
25. Please clarify whether you anticipate the amount allocated for the Phase 2 IV-to-oral trial and the Phase 3 oral trial for CEM-101 and the Phase 3 trial for Taksta is sufficient to complete these respective trials.

Critical Accounting Policies
Stock-based Compensation, page 46

26. We may have additional comments on your accounting for stock compensation and related disclosure once you have disclosed an estimated offering price. At that time, please provide quantitative and qualitative disclosures explaining the difference between the estimated offering price and the fair value at each grant date.
27. Disclose the significant assumptions used in determining the fair value of the common stock at December 8, 2010 and March 31, 2011 explaining the change from \$.22 to \$.45 to \$.53. Explain how the completion of Phase II for Taksta in the fourth quarter of 2010 was considered. Also, disclose when the decision to proceed with an initial public offering was made and any clinical milestones that affected the decision.

Business – General, page 58

28. In view of your limited number of employees, please expand your business section to explain the process you employed to develop your products, describing the means by which research has been conducted, studies designed and performed, regulatory filings prepared and clinical results analyzed.
29. Please expand the discussion relative to your various trials to indicate when the specific trial referred to in discussion was completed.

Taksta, page 59

30. We note your statement that fusidic acid is an antibiotic that has been approved and sold in Europe and other countries for decades. Please expand the discussion to clarify whether fusidic acid has been sold for the treatment of ABSSSI and, if so, by whom.

CEM-101 Market Opportunity, page 61

31. We note your reference to possible limitations or side effects of currently available treatments. Please expand the discussion to describe the resistance issues, limitations and side effects, if any, experienced to date with CEM-101.
32. We note your reference to the initial market acceptance for Ketek. Please clarify whether the market experienced for Ketek is the size of the market you anticipate for CEM-101.

Taksta has an established safety profile, page 69

33. We note the statement that the oral administration of fusidic acid has “demonstrated a safety profile consistent with other non-US approved product labeling.” Please expand the discussion to address whether the profile is consistent with US approved product labeling.

Taksta has a lower incidence of resistance due to our proprietary loading dose regimen, page 69

34. Please expand the discussion to provide additional information concerning the resistance reported during oral treatment outside the United States, including the studies conducted and the nature of the resistance. In addition, please provide additional information relative to your loading dose regimen and how it differs from conventional dosage methods.

Table 8, page 72

35. Please expand the discussion to explain the difference, if any, between the Taksta tablets and the Fucidin tablets.
36. Please explain what you mean by the statement “a steady state level that is well over 10 times the MIC90 of staphylococci and streptococci...”

Pre-clinical data, page 72

37. Please explain what you mean by the phrase “...susceptibility to Taksta and comparators by both microdilution according to...”

Planned Clinical Trials, page 73

38. Please expand the discussion to indicate when the end of Phase 2 meeting occurred.
39. Please expand the discussion to provide an estimate of the time that may be required to complete the various trials and studies required for FDA approval.

Our Commercialization Strategy, page 74

40. We note the statement that “the CEM-101 opportunity will be maximized by having both a hospital-based sales force and a primary care sales force. We believe we could build a sales force to sell directly to the hospital market.” Please expand the discussion to clarify the extent to which you currently have a primary care sales force or an existing partnership with a larger pharmaceutical company to sell your products.

Intellectual Property, page 75

41. We note your discussion on page 77 pertaining to your plan to obtain regulatory exclusivity for your dosing protocols and formulations for fusidic acid, please expand the discussion to clarify whether you are currently aware of any applications from competitors pertaining to fusidic acid.

Collaborations and Commercial Agreements, page 78

42. Please expand the discussion in the first paragraph of this section to quantify the term “additional limited milestone payments” in the event more than four products are developed.
43. Please expand the discussion in this section or the intellectual property section with respect to each patent underlying the respective licenses to indicate:
 - When the patent was filed; and
 - Whether the licensor or you are responsible for the costs of the legal defense of the patent.

Manufacturing, page 79

44. Please expand the discussion to describe the material term and termination provisions of the Ercros agreement.
45. We note the statement that you “believe Ercros is one of only two currently known manufacturers that can produce fusidic acid compliant with the purity required for human use.” Please identify the other known manufacturer and reconcile the statement with your

statement “we have yet to identify a viable second source of fusidic acid but continue to research alternatives.”

Employees, page 86

46. We note you have ten employees, including your executive staff, engaged in research and development activities. Please expand your disclosure to describe any consulting agreements, independent contractor arrangements or other means by which you engage personnel to carry out the development of your proposed products. To the extent any of such arrangements are material to your business, please revise the discussion to provide a description of the material terms of each agreement, including, but not limited to, payment provisions, obligations, rights, term and termination provisions. In addition, please file these agreements as exhibits or provide us with a detailed analysis supporting your determination that the agreements are not required to be filed pursuant to Item 601(b)(10)(ii)(B) of Regulation S-K.

Executive Compensation, page 93

47. Please revise your discussion of annual bonuses in your Compensation Discussion and Analysis section to provide a detailed description of the individual and corporate goals that were established by the compensation committee for each named executive officer, the extent to which such goals were achieved and the relationship between the level of achievement and the bonus awards that were ultimately granted. In addition, you should explain why the board and/or the compensation committee chose to make non-equity awards to your CEO and CFO that were less than the target of 25% of their base salaries.
48. Please revise your discussion of periodic stock option awards in your Compensation Discussion and Analysis section to explain the board’s basis for the specific option awards paid to your CEO and CFO in 2010.

Summary Compensation Table, page 95

49. We note Dr. Still resigned in March 2010. Please clarify whether the amounts reflected under the salary column are the payments made for the first three months of 2010 or annualized amounts. We may have additional comments.
50. In addition to the NEOs currently listed in the Summary Compensation Table, we note that you had three key employees serving in their positions during 2010. If any of these employees were in charge of a principal business unit, division or function, or otherwise performed a policy-making function for the company, you may be required to include them in the Summary Compensation Table. Please refer to Item 402(a)(3) of Regulation S-K and advise us whether Dr. Oldach, Dr. Periera or Dr. Scot should be considered NEOs. Furthermore, please tell us whether the company employed a Chief Scientific or Medical Officer after the resignation of Dr. Still in March 2010. We may have additional comments.

Transactions With Related Persons, page 103

51. Please provide a discussion of the policies and procedures utilized by your audit committee to review and approve related party transactions and the policies and procedures your audit committee will use to review and approve such transactions subsequent to the consummation of the proposed offering.

Principal Stockholders, page 106

52. Please expand the discussion to identify the natural person with voting or investment power over the securities held by:

- Intersouth Partners VI, L.P. and its affiliates;
- Blackboard BioVentures Inc.; and
- Devon Park Bioventures, L.P.

Financial Statements

Report of Independent Registered Public Accounting Firm, page F-2

53. Please provide a report from your independent registered public accounting firm that shows the city and state where it was issued. Also, this report refers to information in Note 11, dated October 12, 2011, which we were unable to locate. Please explain this reference.

Valuation Assumptions for Stock Option Plans, page F-11

54. Tell us why the volatility assumption changed so much from 2008 to 2009. Include the period of time over which you measured volatility. Also provide us the names of the peer public companies you used and the volatilities of each.

Exhibits

55. We note that exhibits 2.1, 3.1 and 3.2 are “form of” exhibits. Please tell us when you anticipate filing the actual documents currently reflected as “forms of.”

Signatures

56. We note the registrant is Cempra Holdings, LLC which entity will be converted into Cempra, Inc. The registration statement, however, has not been signed by Cempra Holdings, LLC and has been signed only by Cempra, Inc., an entity not currently in existence. Please advise or revise. We may have additional comments.

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.

You may contact Franklyn Wyman, Staff Accountant, at (202) 551-3660 or Lisa Vanjoske, Assistant Chief Accountant, at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact John Krug, Senior Counsel, at (202) 551-3862, Dan Greenspan, Branch Chief, at (202) 551-3623, or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey Riedler
Assistant Director

Dr. Prabhavathi Fernandes
Cempra Holdings, LLC
November 7, 2011
Page 11

cc: Alexander M. Donaldson, Esq.
Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, North Carolina 27607