



DIVISION OF  
CORPORATION FINANCE

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

August 21, 2013

Via E-Mail

Robert K. Merrell  
Vice President, Finance  
Lipocine Inc.  
675 Arapleen Drive, Suite 202  
Salt Lake City, Utah 84108

**Re: Lipocine Inc.  
Form 8-K  
Filed July 25, 2103  
File No. 333-178230**

Dear Mr. Merrell:

We have reviewed your filing 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 within ten business days by amending your filing, by providing the requested information, or by advising us when you will provide the requested response. 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 filing and the information you provide in response to these comments, we may have additional comments.

General

1. Please amend your Form 8-K to include all the information that would be required if Lipocine Operating had filed a Form 10-Q for the quarterly period ended June 30, 2013. This includes updating the interim financial statements in Exhibit 99.1 and the pro forma financial information in Exhibit 99.3.

Item 2.01

Business—Industry, page 4

2. We note your statement that “although there are some adverse effects associated with the use of testosterone replacement, the benefits generally far outweigh the risks in patients being treated for hypogonadism.” It is our understanding, however, that there is a dearth of large-scale, long-term studies assessing the risks and benefits of testosterone replacement therapy. Accordingly, please remove this statement.

Product Candidates, page 6

3. Please revise your disclosure to explain briefly what you mean by “bringing the absorption process under formulation control and making the product robust to physiological variables.”
4. To the extent practicable, please minimize the use of highly technical terminology in this section and elsewhere in your filing that may be unfamiliar to lay investors. If the use of such terms is necessary, please give the meaning and significance of such terms in plain language that may be understood by a person not acquainted with this industry or scientific field. For example, an explanation of the terms “undecanoate,” “ester prodrug,” “eugonadal” and “dose titration” should accompany their first usage in the filing.
5. Please revise your disclosure to explain briefly what you mean by “the lower bound of the 95% confidence interval.”
6. Please revise your disclosure to explain briefly what you mean by “the Phase II study results for all groups revealed that  $C_{ave}$  and  $C_{max}$  were highly correlated and there was a high probability of titrating to acceptable  $C_{max}$  levels by maintaining  $C_{ave}$  levels below about 600 ng/dL.”
7. In your discussion of the completed Phase II study for LPCN 1021, please clarify that the results of your trial for the 225 mg twice-a-day dose is not a guarantee that any future Phase III trials will similarly meet the primary and secondary endpoints required by the FDA for approval of a TRT product and cannot, in the absence of a successful pivotal Phase III trial, serve as the basis for FDA marketing approval of LPCN 1021.
8. Please also provide information in your table on page 7 for the results of the 225 mg group on days 22 and 29 for patients in Group V.
9. We note that the study duration for your Phase II trial ranged from 15 days to 29 days, depending on the group of patients involved. We also note that your proposed Phase III trial will be substantially longer, with patients receiving treatment for up to thirteen weeks. Please make clear whether this longer treatment period is part of the FDA’s criteria for approval of a TRT and whether it is possible that the company may have difficulty replicating the results observed in the Phase II trial for the 225 mg twice-a-day dose as a result of a significantly longer treatment period.

LPCN 1111: A Next Generation Oral Product Candidate for TRT, page 8

10. Please revise your disclosure to state whether you submitted an IND for the Phase I study of LPCN 1111 in post-menopausal women or explain why no IND was required.

Hydroxyprogesterone caproate, or HPC/Preterm Birth, or PTB, Market Overview, page 9

11. We note your statement that LPCN 1107 may be eligible for orphan drug designation if it is deemed to be a major contribution to patient care. Please expand this discussion to clarify that there are additional criteria that must be met to obtain an orphan drug designation and briefly describe those requirements or cross-reference to the appropriate discussion elsewhere in your filing.

Risk Factors

12. Please include a risk factor that addresses the risks associated with the fact that none of your directors are independent, as defined in the NASDAQ Stock Market rules.

“We are an emerging growth company...” page 36

13. We note your statement here that you plan to avail yourself of the exemption under Section 107(b) of the JOBS Act from new or revised accounting standards. This conflicts with your statement on page 51 that you have irrevocably elected not to avail yourselves of this exemption. Please revise our disclosure to reconcile this discrepancy. In addition:
- If you have elected to opt out of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b), include a statement that the election is irrevocable; or
  - If you have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2), provide a risk factor explaining that this election allows you to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Please state in your risk factor that, as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates. Include a similar statement in your critical accounting policy disclosures.

“We may incur substantial costs a result of litigation ...” page 39

14. Please identify the subject matter of the company’s pending patent applications that are the subject of the interference requests made to the U.S. Patent Office in September and October 2012.

Management’s Discussion and Analysis of Financial Condition and Results of Operations Overview of Our Business, page 43

15. We note that you reacquired the rights to LPCN 1021 from Abbott in March 2012 in exchange for up to a 1.5% royalty rate on net sales. Please describe all of the material

terms of your agreement with Abbott governing such reacquisition, including each party's obligations, financial provisions other than the 1.5% royalty obligation, the duration of the agreement and any termination provisions. In addition, please file this agreement as an exhibit to your filing, or provide us with a legal analysis as to why this agreement need not be filed pursuant to Item 601(b)(10) of Regulation S-K.

Critical Accounting Policies and Significant Judgments and Estimates, page 52

16. We note your statement that you enter into arrangements with collaboration partners. Please revise your disclosure to clarify whether you have any active collaboration agreements in place. Please also include a description of the material terms of any such agreements, including each party's obligations, any financial provisions, the duration of the agreements and any termination provisions. In addition, please file a copy of each agreement as an exhibit to your filing, or provide us with a legal analysis as to why any such agreement need not be filed pursuant to Item 601(b)(10) of Regulation S-K.

Related Person Transactions, page 61

17. Please expand your description of your assignment and services agreement with Spriaso LLC to describe the duration of the agreement and any termination provisions. In addition, please file this agreement as an exhibit to your filing or provide us with a legal analysis as to why this agreement need not be filed pursuant to Item 601(b)(10) of Regulation S-K.

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 Exchange Act of 1934 and all applicable Exchange 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.

In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

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You may contact Donald Abbott at (202) 551-3608 or Joel Parker at (202) 551-3651 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: Via E-Mail  
John T. McKenna  
Cooley LLP  
3175 Hanover Street  
Palo Alto, CA 94304-1130