



DIVISION OF
CORPORATION FINANCE

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

Mail Stop 4720

March 4, 2016

Walter Klempe
Chief Executive Officer
Moleculin Biotech, Inc.
2575 West Bellfort, Suite 333
Houston, Texas 77054

**Re: Moleculin Biotech, Inc.
Registration Statement on Form S-1
Filed February 1, 2016
Amendment No. 1 to Registration Statement on Form S-1
Filed February 16, 2016
File No. 333-209323**

Dear Mr. Klempe:

We have reviewed your registration statement and amendment 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.

Registration Statement on Form S-1

Company Information and Moleculin Merger, page 5

1. Please tell us how you will account for the operating loans to Moleculin in the amount of \$300,000 to \$310,000 that will be forgiven at the completion of the IPO. Cite the relevant accounting literature to support your accounting.

Risk Factors, page 11

"We have completed and will in the future complete related party transactions..." page 12

2. Please describe for us the related party transactions you did not conduct on an arm's length basis how you accounted for them.

“The intellectual property rights we have licensed from MD Anderson...” page 18

3. Please restore your deleted statement about your knowledge of any funding agreements that would impinge on the IP rights you have licensed from MD Anderson and specify the extent of your due diligence to confirm this fact.

Use of Proceeds, page 25

4. Please indicate the extent to which you contemplate using offering proceeds to pay down existing debt or to satisfy obligations, such as your installment payments to MD Anderson for past due fees, discussed on page F-18.

Management’s Discussion and Analysis of Financial Condition..., page 37

Critical Accounting Policies and Significant Judgments and Estimates, page 38

5. In your response to comment 17, you state that you estimate the fair value of your common stock using the most recent selling price available. Please tell us the date, the number of shares sold for cash, your relationship to the purchaser(s), and the stock price to support your debt conversion price of \$0.1299 during August and September 2015 and \$0.20 during October and December 2015. Furthermore, to the extent your stock was sold to a related party, please tell us how you determined that such transaction was conducted at an arm’s length.
6. Please explain the difference between the most recent common stock valuation of \$0.20 on December 30, 2015 and the midpoint of your current estimated IPO price of \$5.50.

Research and Development Expense, page 39

7. Tell us why you believe patent prosecution fees are appropriately classified as research and development expense.

Business, page 43

Our Drug Candidates, page 44

Annamycin, page 44

8. We refer to our prior comment 19. Please revise your prospectus to disclose:
 - the reason given by Callisto in its public filings for terminating further development of Annamycin as a treatment for adult acute leukemia was that the clinical data did not support further clinical evaluation;

- the clinical data which you intend to use to apply for a new IND and on which you are basing your assessment of Annamycin's therapeutic potential are the data generated by Callisto in its earlier clinical trials, completed in 2007; and
 - the basis of your decision to move forward with the development of Annamycin notwithstanding Callisto's prior evaluation of this product candidate.
9. In addition, we note your disclosure that Annamycin "demonstrated efficacy" in the prior Phase I study and "demonstrated a similar efficacy profile" in the subsequent Phase I/II study. However, the focus of the studies to which you refer was dose tolerance and patient safety, not product efficacy. As you acknowledge in your response to comment 19, the trials were "not designed to reach statistical significance" and therefore would not satisfy the FDA's standards for proof of efficacy. In fact, the study you cite concludes only that Annamycin "has encouraging anti-leukemic activity," which is not sufficient to support a claim of efficacy. Accordingly, please remove from your prospectus any statements or suggestion that Annamycin was effective or demonstrated efficacy in prior clinical trials, as the concept of "efficacy" is well-defined by the FDA and generally understood in the pharmaceutical industry to refer to measurable proof of a product's effectiveness sufficient to support regulatory approval.

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.

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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 Keira Nakada at (202) 551-3659 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, Daniel Greenspan at (202) 551-3623 or me at (202) 551-3675 with any other questions.

Sincerely,

/s/ Mary Beth Breslin for

Suzanne Hayes
Assistant Director
Office of Healthcare and Insurance

cc: Cavas S. Pavri, Esq.