

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

Mail Stop 4546

August 11, 2016

Paul Bavier General Counsel & Secretary Biodel Inc. 100 Saw Mill Road Danbury, CT 06810

Re: Biodel Inc.

**Preliminary Proxy Statement on Schedule 14A** 

Filed July 13, 2016 File No. 001-33451

Dear Mr. Bavier:

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 these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments.

#### Letter to Stockholders

1. In the letter addressed to your stockholders from your chief executive officer, please note that you suspended operations at the end of 2015 and have no plans to resume them, that you intend for the issuance of shares described in Proposal No. 1 to result in your absorbing Albireo's operations in place of your own, and that failure to compete the exchange could result in, among other things, your liquidation.

Questions and Answers about the Transaction
"Q: Will holders of the shares... be able to trade those shares?," page 5

2. We note your statement that the shares of Biodel common stock will be issued to Albireo shareholders in transactions exempt from registration under the Securities Act of 1933 in reliance on Section 4(a)(2) and Regulation D. Please provide an analysis supporting the availability of these exemptions.

# "Q: Do persons involved in the Transaction have interests that may conflict...?," page 5

3. Please quantify the benefits that Biodel directors and named executive officers will receive as a result of the vesting and settlement of stock options, restricted stock and restricted stock units, the change in control severance plan benefits, retention plan awards, amount of additional compensation to be received under new employment terms, and any other amounts payable in connection with the transaction.

#### Risk Factors

#### Risks Related to Biodel

"Biodel's business to date has been significantly dependent on the success of its product pipeline ...," page 22

4. Please amend this risk factor to state whether you intend to resume development of BIOD-531, including Study 3-157 or Study 3-250, following the share exchange.

# The Transaction

# Background of the Transaction, page 101

- 5. To provide shareholders with an understanding of how, when and why the terms of the proposed transaction evolved, please substantially revise your disclosure in this section to describe in sufficient detail when and how the various contacts between Biodel and Albireo were initiated, the identities of the parties present at the meetings, and the material terms and issues that were discussed during meetings and via telephone. By means of non-exclusive example:
  - Describe the terms discussed at the meeting on December 4, 2015, in the letter of interest submitted December 15, 2015 and in the revised term sheets exchanged on March 16, 2016,
  - Explain the "views on valuation" discussed on December 22, 2015, and
  - Describe the "general parameters" of a potential transaction discussed on January 12, 2016 and those submitted in response to a request for bid letters on February 10, 2016.
- 6. We note your disclosure throughout this section that you considered and discussed with a number of companies a potential merger or other business combination transaction. Please expand your disclosure to describe the alternative transactions and explain why they were not pursued. For instance:
  - Describe the terms of the transaction discussed with Company A and why the transaction was not pursued after the phone call on December 23, 2015. Provide similar disclosure of the transaction discussed with Company C and why it was not pursued after the meeting held on February 10, 2016;

- Describe the terms of the reverse merger discussed with Company D on March 2, 2016 and in the term sheet sent on March 17, 2016; and
- Explain the basis for the recommendation that Company E not be pursued as a finalist merger candidate as noted on page 106.
- 7. Please describe approximately when and how discussions between you and Company A were initiated. Also describe the nature and substance of the presentation that was received from Company A on September 21, 2015.
- 8. We note your disclosure on page 106 that you sent a revised term sheet and exclusivity agreement to Company D on March 15, 2016. Please provide additional detail around the board's conclusion to enter into an exclusivity agreement with Company D despite pending negotiations with Albireo.
- 9. Please briefly describe the process by which you selected semifinalist candidates and the criteria for grouping them as either "tier one" or "tier two" candidates. Also clarify the significance of grouping the companies into each tier, and explain the factors used to "further refine" the list of tier one and tier two candidates on February 16, 2016.
- 10. Please describe the reason(s) for selecting Company D, Company E and Albireo as finalist candidates in February 2016.
- 11. Please state the date that Company D informed you that it was withdrawing as a possible business combination candidate and the reason(s) it gave, if any, for its decision to withdraw.
- 12. Please revise to briefly describe the nature of the changes in the exchange agreement that was signed on May 24, 2016 and the amendment dated July 13, 2016 as noted on page 111.

#### Opinion of the Biodel Financial Advisor, page 115

13. We note your statement on page 115 that your financial advisor provided its opinion for the sole benefit and use of your board of directors. We also note the statement on page 118 that the opinion was "intended for the benefit and use of the board of directors" and "may not be used for any other purpose" without Ladenburg's prior written consent. We note a similar statement on page 3 of Ladenburg's opinion, which is attached as Annex B. Because these limitations are inconsistent with the disclosures relating to the opinion, such limitations should be deleted. Alternatively, please disclose the basis that shareholders cannot rely upon the opinion to support any claims against Ladenburg Thalmann arising under applicable law. Please describe any applicable legal authority regarding the availability of such a potential defense. In the absence of applicable legal authority, please disclose that the availability of such a defense will be resolved by a court of competent jurisdiction. In addition, please disclose that resolution of the question

of the availability of such a defense will have no effect on the rights and responsibilities of the board of directors under applicable law. Further, please disclose that the availability of such a legal defense to Ladenburg would have no effect on the rights and responsibilities of either Ladenburg or the board of directors under the U.S. federal securities law.

- 14. On page 118, you disclose that Albireo's implied equity value and implied total enterprise value were calculated using, in part, \$6 million of value ascribed to your public listing. Elsewhere, you note that your enterprise value was negotiated by you and Albireo to be \$6 million. Please state here that the \$6 million value figure you cite was negotiated between the parties and assigns no value to any of your product candidates or other assets.
- 15. In your discussion of the Selected Initial Public Offering Transactions Analysis, the Selected Publicly Traded Companies Analysis and the Selected Precedent Transactions, please state if there were any transactions and/or companies, as applicable, that fit your selection criteria but were excluded from these analyses and if so please explain the reason(s) for the exclusions.
- 16. Please include the enterprise values for each of the transactions and companies included in the fairness opinion analyses referred to in the comment above.

#### Financial Projections and Liquidation Analysis, page 124

17. Please supplementally provide us with copies of any materials prepared by Ladenburg Thalmann in connection with its fairness opinion, including, among other things, any "board books," drafts of the fairness opinion provided to the board of directors, and any summaries of presentations made to the board of directors. We may have further comments on your disclosure once we have had the opportunity to review these materials.

#### Biodel Named Executive Officer Golden Parachute Compensation, page 127

18. We note that you have not included a separate resolution subject to the advisory vote of shareholders regarding the Regulation S-K Item 402(t) disclosure on pages 127 – 128. Please include such a resolution or advise why you have not done so.

Matters Being Submitted to a Vote of Biodel Stockholders

Biodel Proposal No. 2: Approval of the Amendment to the Amended and Restated Certificate of
Incorporation of Biodel Effecting the Reverse Stock Split, page 159

19. Please disclose the number of shares of common stock currently authorized and outstanding before the reverse split, as well as the number to be authorized and outstanding both after the reverse split and after the issuance of Biodel shares to Albireo

- shareholders. Clarify whether the reverse split is necessary to have sufficient authorized shares of common stock to complete the exchange.
- 20. Please state whether or not you have any plans, arrangements, understandings, etc. after the exchange is completed to issue any of the authorized but unissued common shares that will result from the reverse stock split.

#### **Biodel Business**

Suspended Research and Development and Clinical Programs, page 174

21. Please indicate whether, after completion of the share exchange, you have any intention of resuming development of the GEM program or any of your other pipeline product candidates. In this regard, please also disclose the status of your IND application for your GEM product candidate.

# Albireo Business Elobixibat, page 197

- 22. Please include in your disclosure a brief discussion of the importance and use of statistical significance in clinical trial analytics. Please also provide an explanation of "p-values" explain the significance of the p-values observed in the Phase 2 trials and clarify the relationship between statistical significance and p-values of less than 0.001 and 0.002.
- 23. Here and elsewhere in your document where you note that a serious adverse event was observed in a clinical trial, such as the three events observed in the Phase 2b clinical trial in the U.S. for elobixibat as noted on page 199 and the Echo 1 and 2 trials described on pages 200 201, please revise to describe the events observed.

Albireo Management's Discussion and Analysis of Financial Condition and Results of Operations

Results of Operations – Research and Development Expenses, page 246

24. Please provide tabular disclosure of R&D expenses incurred disaggregated by preclinical and clinical stage product for the periods ended 2015 and 2014 and for the 3 months ended March 31, 2016.

**Index to Biodel Financial Statements** 

Notes to Consolidated Financial Statements

Note 1 – Summary of significant accounting policies and basis of presentation-Revenue Recognition, page F-29

25. In regards to the out-license agreements entered into with EA Pharma and Ferring International during 2012 (and for which milestone revenue was recognized during 2015)

and 2014) please provide the appropriate disclosures in accordance with ASC subparagraphs 605-28-50-2(b) through 50-2(d)

# Note 2 – Fair value of financial instruments, page F-34

26. You disclose that the 2015 and 2014 Convertible Notes and the Loan Facility are being carried at cost less unamortized discount. Please disclose the fair values of these debt instruments pursuant to ASC 825-10-50-10.

<u>Unaudited Pro Forma Condensed Combined Financial Statements</u>
<u>Unaudited Pro Forma Combined Statement of Operations for the Three Months Ended March 31, 2016 and the Year Ended December 31, 2015, page F-87</u>

27. Please provide historical basic and diluted EPS per the requirements in Rule 11-02(b)(7) of Regulation S-X.

# 1. Basis of Presentation-Preliminary purchase consideration allocation, page F-90

28. In regards to the \$6.4 million bargain purchase gain to be recognized in conjunction with the proposed business combination, please provide the disclosure required by ASC 805-30-50-1(f)(2).

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.

You may contact Jacob Luxenburg at (202) 551-2339 or Angela Connell at (202) 551-3426 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, Mary Beth Breslin at (202) 551-3625 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: Miguel J. Vega, Esq. Cooley LLP