

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

August 29, 2013

Via E-mail
Rick E. Winningham
Chief Executive Officer
Theravance Biopharma, Inc.
Ugland House, South Church Street
George Town, Grand Cayman
Cayman Islands KY1-1104

Re: Theravance Biopharma, Inc.

Registration Statement on Form 10-12B Filed August 1, 2013

File No. 001-36033

Dear Mr. Winningham:

We have reviewed your filing and have the following comments. In our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter within 10 business days 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, please tell us why in your response.

After reviewing the information you provide in response to these comments, we may have additional comments.

#### General

1. Please revise your filing to update all financial information and related disclosures though June 30, 2013. Please see Item 3-12 of Regulation S-X.

Exhibit 99.1 Summary Programs, page 3

2. Here, and in your disclosure on page 61, please state the basis of your assertion that your triple-component product candidate may advance directly from Phase 1 clinical studies to Phase 3 clinical studies. Clarify whether there have been discussions with the FDA regarding this possibility and if so, disclose the advice or guidance the FDA communicated as to how this could occur.

# Selected Risks of our Business and Industry, page 5

- 3. Please revise the above-referenced caption to also refer to risks associated with your spin-off, as well as of your business and industry. Furthermore, you should expand this discussion to include the risks and challenges you list on page 43, as well as the other significant risks currently facing your investors, which include but are not necessarily limited to the following:
  - The directors and executive officers of both you and Theravance will hold a
    controlling equity interest in both companies, thereby creating potential conflicts of
    interest;
  - The limitations imposed on you by the Tax Sharing and Indemnification Agreement with Theravance, which may prevent you from pursuing transactions that could maximize the value of your business;
  - The possibility that you may not be able to identify an alternative commercialization partner for VIBATIV and the costs involved in reintroducing it to the U.S. market yourselves;
  - Your reliance on single-source manufacturers and suppliers and how, in your view, such reliance has damaged your commercial prospects in the past, as when commercialization of VIBATIV was halted:
  - The possibility that your collaboration partners may not satisfy their obligations under your agreements, or that they may terminate their partnerships with you, as Astellas Pharma Inc. did in January 2012; and
  - The adverse effect on developing and commercializing your product candidates that would result if you were unable to enter into future collaborations.

## Summary of the Spin-off, page 6

4. Under the sub-caption "U.S. federal income tax consequences", please clarify, if true, that receipt of a favorable IRS ruling as to the tax free nature of the spin-off is not a condition to the consummation of the transaction.

# Risk Factors Risks Related to the Spin-Off

5. Please include a risk factor disclosing that the separation will take effect without a shareholder vote, that your stockholders will have no opportunity to impact this action and that their sole recourse will be to divest themselves of your common stock in advance of the ex-dividend date.

"We may be required to satisfy certain indemnification obligations to Theravance . . ., page 17"

6. Please describe the indemnification obligations that you could be required to assume under the Separation and Distribution Agreement including indebtedness, obligations or liabilities retained by Theravance and explain the circumstances under which that could occur. Also, please remove the words "we may agree to indemnify" as this suggests the registrant may choose not to assume liabilities, obligations or indebtedness under the terms of the agreement.

"The tax liability to Theravance as a result of the spin-off could be substantial.", page 18

7. Please provide your estimate of the excess of the fair value of the assets to be transferred to the registrant and the net operating loss carryforwards available to offset the resulting tax liability.

"Theravance Biopharma's ability to repurchase its shares will be limited following its distribution," page 20

8. Please explain how your inability to repurchase in excess of 20% of outstanding shares could disadvantage the registrant or create adverse effects for shareholders.

"Theravance Biopharma may be treated as a U.S. corporation for U.S. federal income tax purposes," page 20

9. Clarify, if true, that the receipt of a an IRS ruling regarding the registrant's status as a U.S. corporation for federal income tax purposes is not a condition to consummation of the spin-off and that the registrant does not intend to seek such a ruling.

### Risks Relating to the Company

"We anticipate that we will incur losses for the foreseeable future . . .," page 21

10. Please include in this risk factor the amount of your accumulated deficit after the spin-off.

"If we cannot identify a suitable commercialization partner for VIBATIV in the U.S. we will need to develop the capability to market, sell and distribute the product," page 24

11. Please explain here, as well as in your disclosure on page 83, why Astellas Pharma Inc. exercised its right to terminate the collaboration agreement relating to VIBATIV.

"If we lose key management or scientific personnel . . .," page 32

12. Please include in this risk factor the name(s) and title(s) of the individual(s) whose departure you believe could create a material adverse effect.

Risks Related to Legal and Regulatory Uncertainty
"If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate . . .," page 33

13. Please include in this risk factor past or present challenges to your intellectual property, if any, and disclose the current status of ongoing challenges and the resolution of past challenges.

#### The Spin-Off

Formation of Theravance Respiratory Company LLC, page 44

- 14. Please discuss the business purposes and related material consequences for the registrant, Theravance and their respective shareholders resulting from the creation of the LLC and having it to hold certain of the GSK-partnered products. Explain how management decided which products it would and would not contribute to the LLC.
- 15. Please tell us why Theravance, Inc. will contribute the rights to ANORO<sup>TM</sup> ELLIPTA<sup>TM</sup> to Theravance Respiratory Company LLC and then retain 100% of the interest in those rights. Tell us why Theravance, Inc. simply did not retain those rights and not contribute them to TRC similar to its treatment of the rights to RELVAR<sup>TM</sup> ELLIPTA<sup>TM</sup>/BREO<sup>TM</sup> ELLIPTA<sup>TM</sup>.

# Formation of Holding Company Prior to the Spin-Off, page 45

- 16. Please explain the business reasons and related material consequences for shareholders of the registrant of choosing your particular corporate structure. Explain why management chose to incorporate a holding company in the Cayman Islands and wholly-owned subsidiaries in the Cayman Islands and Delaware.
- 17. In this section you disclose your intention to form a U.S. operating subsidiary. In two separate risk factors on page 32 you indicate that the U.S. subsidiary is already operating out of San Francisco, California. This inconsistency appears in various places throughout the filing. Please revise your disclosures to consistently indicate that you will either form the U.S. subsidiary after the spin-off or that it is already formed.

# Program Highlights, page 62

18. You should file your agreements with GSK, R-Pharm CJSC, Hikma Pharmaceuticals LLC, Merck and Alfa Wasserman as exhibits to the registration statement, as they will be material to your operations after the spin-off. You should also disclose all material terms of the GSK, R-Pharm, Hikma and Alfa Wasserman agreements in your registration statement, including material rights and obligations of both parties, payment provisions, duration and termination provisions, to the extent that you have not done so already. Please amend your registration statement accordingly or, alternatively, provide us with an analysis as to why you believe these agreements are not material.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Fair Value of Stock-Based Compensation Awards, page 81

19. Please tell us whether you plan to grant equity awards of Theravance Biopharma prior to or in conjunction with the spin-off transaction. To the extent you plan to issue such awards, please revise your disclosure to so indicate and explain how you plan to value and account for those awards.

Results of Operations
Costs and Expenses
Research and Development Expenses, page 83

20. In the third paragraph following the table on page 84 you indicate that you do not disclose research and development expenses by program because you do not track all of the individual components at that level. Please revise your disclosure to disclose by program the costs you track at that level and reconcile the total to the appropriate line item presented in the table, for instance your external costs. If you do not track any costs at the program level, please tell us how you were able to allocate research and development expenses between those attributable to Theravance, Inc. versus those attributable to Theravance Biopharma, Inc.

# Liquidity and Capital Resources, page 85

- 21. We note your statement that at the closing of the spin-off, Theravance will provide you with cash and cash equivalents of approximately \$300 million. As Theravance's most recent quarterly report on Form 10-Q reflected cash and cash equivalents totaling nearly \$200 million, please indicate both here and wherever appropriate in your Our Business discussion how Theravance intends to generate the remaining \$100 million. Please also state the amount of cash and cash equivalents Theravance will retain on its balance sheet, if any. You should also include a summary of this information in the Summary.
- 22. Please disclose details about your anticipated commercialization of the FDA approved product VIBATIV, to include but not be limited to:
  - When you expect to begin commercialization in the U.S.;
  - An estimate of the cost needed to begin commercialization;
  - An estimate of the time it will take to remove the suspension on the European Union marketing authorization; and
  - When you expect manufacturing and/or commercialization to restart in the European Union now that the Company has a commercialization agreement with Clinigen Group plc.

# Our Relationship with Theravance, Inc. after the Spin-Off, page 90 General, page 90

23. Please include the anticipated duration of each of the agreements and their termination provisions.

# Unaudited Pro Forma Financial Statements, page 94

- 24. Please tell us why you do not provide a pro forma statement of operations and reference for us the authoritative literature you rely upon to support your position. In your response, at a minimum please address the following items:
  - Please tell us how you handled senior management compensation in your historical financial statements and why no apparent pro forma adjustment is warranted given that your management will serve both you and Theravance, Inc. after the spin-off.
  - Please tell us why no apparent pro forma adjustment is warranted for the change in Theravance, Inc. equity awards. In this regards, it appears that the Theravance, Inc. stock options and restricted stock awards that will be held by employees of Theravance Biopharma after the split will be changed to include provisions that unvested awards will immediately vest in certain circumstances upon a change of control of Theravance Biopharma. In addition, the six-year performance RSAs will be converted to time based vesting as disclosed on page 57. It appears that these modifications of the original awards will result in remeasurements of the awards.
  - Please tell us why no apparent pro forma adjustment is warranted for the 98% interest in Theravance Respiratory Company LLC other than the ANORO<sup>TM</sup> ELLIPTA<sup>TM</sup> product.
  - Please tell us why no apparent pro forma adjustment is warranted for any cost or compensation associated with services received or provided under the Transition Services Agreement.

### Combined Financial Statements, pages F-3 – F-6

- 25. Please tell us why it is appropriate to present financial statements of the Drug Discovery and Development Business of Theravance, Inc. (i.e., carve-out financial statements) and reference for us the authoritative literature you relied upon to support your position. Explain why it is not appropriate to include the historical information of Theravance, Inc. and present pro forma financial information that removes the assets and liabilities retained by Theravance, Inc. for that latest balance sheet and removes the revenues and expenses retained by Theravance, Inc. for the latest fiscal year and interim period. In your response, please tell us your consideration of the following facts and how they impacted your assessment to present carve-out financial statements:
  - The business retained by Theravance, Inc. appears to be similar to that of your continuing business. At a minimum, it appears that you both continue to pursue drug development in general and each of you pursues, although not exclusively in your case, respiratory therapies. Explain to us how these businesses are different.

- Your senior management team will also manage Theravance, Inc. after the spin-off transaction.
- Both you and Theravance, Inc. retain an interest in Theravance Respiratory Company LLC.
- You will operate out of facilities that are currently those of Theravance, Inc. Please tell us whether Theravance, Inc. will continue to use those facilities after the spin-off.
- 26. Presuming you can substantiate presenting carve-out financial statements of the Drug Discovery and Development Business of Theravance, Inc., please address the following comments:
  - Please tell us why it is appropriate to present your carve-out financial statements as being those of Theravance Biopharma, Inc. when you disclose on page 45 that you were not incorporated until July 2013. Explain why you do not characterize these financial statements as being those of the Drug Discovery and Development Business.
  - Please tell us why it is appropriate to characterize these financial statements as combined
    financial statements when it does not appear that the Drug Discovery and Development
    Business was historically performed in separate legal entities. Explain why you do not
    characterize your balance sheets as statements of assets and liabilities of the Drug
    Discovery and Development Business and your statements of operations as statements of
    revenues and expenses of the Drug Discovery and Development Business.
  - Please confirm that Theravance Biopharma, Inc. has no material assets, liabilities and/or
    operations at the present time and does not expect to have any prior to the spin-off and
    revise your disclosure throughout the filing to clarify. Otherwise, please tell us why it is
    appropriate to not present separate audited financial statements of this legal entity in your
    filing.

Notes to the Combined Financial Statements
Note 2. Summary of Significant Accounting Policies
Bonus Accruals, page F-11

27. Please expand your disclosures to explain the requisite performance conditions that you determined were not probable resulting in not recognizing compensation expense.

# Note 6. Income Taxes, page F-25

28. You disclose in the last paragraph on page F-25 carrying over to page F-26 that the deferred tax assets presented are hypothetical amounts and will not equal the deferred tax assets of Theravance Biopharma after the spin-off transaction. Please tell us your consideration for presenting in your pro forma financial information estimates of your deferred tax assets after the spin-off.

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 all 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 Christine Allen Torney at (202) 551-3652 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jeffrey P. Riedler

Jeffrey P. Riedler Assistant Director

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

Bradford J. Shafer, Esq. SVP and General Counsel, Theravance, Inc. David T. Young, Esq. Gunderson Dettmer LLP