

Theravance Biopharma, Inc.  
Form 10-Q  
June 24, 2014  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**Form 10-Q**

---

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2014

OR

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-36033

---

## **THERAVANCE BIOPHARMA, INC.**

(Exact Name of Registrant as Specified in its Charter)

---

**Cayman Islands**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**38-3572512**  
(I.R.S. Employer  
Identification No.)

**PO Box 309**  
**Ugland House, South Church Street**  
**George Town, Grand Cayman, Cayman Islands**  
(Address of Principal Executive Offices)

**KY1-1104**  
(Zip Code)

**(650) 808-6000**

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of June 6, 2014, the number of outstanding shares of the registrant's common stock was 32,260,105.



Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**TABLE OF CONTENTS**

	<b>Page No.</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	3
<u>Item 1. Financial Statements</u>	3
<u>Condensed Combined Balance Sheets as of March 31, 2014 and December 31, 2013</u>	3
<u>Condensed Combined Statements of Operations and Comprehensive Loss for the three months ended March 31, 2014 and 2013</u>	4
<u>Condensed Combined Statements of Cash Flows for the three months ended March 31, 2014 and 2013</u>	5
<u>Notes to Condensed Combined Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	25
<u>Item 4. Controls and Procedures</u>	25
<b><u>PART II. OTHER INFORMATION</u></b>	26
<u>Item 1. Legal Proceedings</u>	26
<u>Item 1A. Risk Factors</u>	26
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	46
<u>Item 3. Defaults Upon Senior Securities</u>	46
<u>Item 4. Mine Safety Disclosures</u>	46
<u>Item 5. Other Information</u>	46
<u>Item 6. Exhibits</u>	46
<u>Signatures</u>	47
<u>Exhibit Index</u>	48

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****THERAVANCE BIOPHARMA, INC.****CONDENSED COMBINED BALANCE SHEETS****(In thousands)**

	<b>March 31, 2014 (Unaudited)</b>	<b>December 31, 2013 *</b>
<b>Assets</b>		
Current assets:		
Accounts receivable, net of allowances of \$209 (unaudited) and \$89	\$ 3	\$ 199
Receivables from collaborative arrangements	90	934
Prepaid and other current assets	4,493	2,567
Inventories	11,014	10,406
Total current assets	15,600	14,106
Restricted cash	833	833
Property and equipment, net	9,734	10,238
Total assets	\$ 26,167	\$ 25,177
<b>Liabilities and parent company deficit</b>		
Current liabilities:		
Accounts payable	\$ 4,984	\$ 6,940
Accrued personnel-related expenses	13,417	9,870
Accrued clinical and development expenses	9,890	9,714
Other accrued liabilities	2,521	2,122
Deferred revenue	7,732	8,207
Total current liabilities	38,544	36,853
Deferred rent	4,891	4,774
Deferred revenue	648	585
Commitments and contingencies (Notes 4 and 6)		
Parent company deficit	(17,916)	(17,035)
Total liabilities and parent company deficit	\$ 26,167	\$ 25,177

\* The condensed combined balance sheet at December 31, 2013 has been derived from audited combined financial statements.

*See accompanying notes to condensed combined financial statements.*



Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**CONDENSED COMBINED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

**(Unaudited)**

(In thousands)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
Revenue:		
Product sales	\$ 945	\$
Revenue from collaborative arrangements		22
<b>Total revenue</b>	<b>945</b>	<b>22</b>
Costs and expenses:		
Cost of goods sold	188	
Research and development	41,723	25,408
Selling, general and administrative	19,052	6,788
<b>Total costs and expenses</b>	<b>60,963</b>	<b>32,196</b>
<b>Net loss and comprehensive loss</b>	<b>\$ (60,018)</b>	<b>\$ (32,174)</b>

*See accompanying notes to condensed combined financial statements.*

Table of Contents**THERAVANCE BIOPHARMA, INC.****CONDENSED COMBINED STATEMENTS OF CASH FLOWS****(Unaudited)**

(In thousands)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Operating activities</b>		
Net loss	\$ (60,018)	\$ (32,174)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	732	703
Stock-based compensation	12,701	5,516
Changes in operating assets and liabilities:		
Accounts receivable	196	
Receivables from collaborative arrangements	844	(1,022)
Prepaid and other current assets	(1,811)	(1,255)
Inventories	(617)	(2,481)
Accounts payable	(1,094)	(150)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	4,563	(3,694)
Deferred rent expense	117	(202)
Deferred revenue	(412)	6,268
Net cash used in operating activities	(44,799)	(28,491)
<b>Investing activities</b>		
Purchases of property and equipment	(1,620)	(740)
Payments received on notes receivable		100
Net cash used in investing activities	(1,620)	(640)
<b>Financing activities</b>		
Transfers from parent company	46,419	29,131
Net cash provided by financing activities	46,419	29,131
<b>Net increase (decrease) in cash and cash equivalents</b>		
<b>Cash and cash equivalents at beginning of period</b>		
<b>Cash and cash equivalents at end of period</b>	\$	\$

*See accompanying notes to condensed combined financial statements.*



Table of Contents

**THERAVANCE BIOPHARMA, INC.**

**Notes to the Condensed Combined Financial Statements**

**Unaudited**

**1. Description of Operations and Summary of Significant Accounting Policies**

*Description of Operations*

In April 2013, Theravance, Inc. ( "Theravance" ) announced its intent to spin off its drug discovery and development business which is focused on discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need ( "Drug Discovery and Development Business" ) from its development and commercial responsibilities under the 2002 collaboration agreement and the 2004 strategic alliance agreement, each with Glaxo Group Limited (which we refer to, together with its affiliates, as "GSK" ) and associated potential royalty revenues from RELVAR® ELLIPTA®/BREQ® ELLIPTA® (fluticasone furoate/vilanterol: FF/VI), ANORO ELLIPTA® (umeclidinium bromide/vilanterol: UMEC/VI) and vilanterol monotherapy. On June 1, 2014 Theravance transferred its research and development ( "R&D" ) operations to Theravance Biopharma, Inc., and on June 2, 2014 Theravance made a pro rata dividend distribution to its stockholders of record on May 15, 2014 of one ordinary share of Theravance Biopharma, Inc. for every three and one half shares of Theravance common stock outstanding on the record date (the "Spin-Off" ) resulting in a dividend of 32,260,105 ordinary shares of Theravance Biopharma distributed to Theravance's stockholders.

The Spin-Off was effected pursuant to a Separation and Distribution Agreement between Theravance and Theravance Biopharma, Inc. (the "Separation and Distribution Agreement" ), which provides, among other things, for the principal corporate transactions required to effect the Spin-Off and certain other agreements governing Theravance's relationship with Theravance Biopharma, Inc. after the Spin-Off. These agreements are discussed further in Note 7.

Theravance Biopharma, Inc. ( "Theravance Biopharma" , the "Company" , or "we" and other similar pronouns) is a biopharmaceutical company with a pipeline of internally discovered product candidates, strategic collaborations with pharmaceutical companies and an approved product. Theravance Biopharma is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including bacterial infections, central nervous system ( "CNS" )/pain, respiratory disease, and gastrointestinal ( "GI" ) motility dysfunction. We also have an economic interest in future payments that may be made by GSK under agreements with Theravance relating to certain drug programs, including UMEC/VI/FF and the MABA program, as monotherapy with GSK961081 ( "081" ) and as a combination ( "081/FF" ).

*Basis of Presentation*

The condensed combined financial information as of March 31, 2014, and for the three months ended March 31, 2013 and 2014 are unaudited but include all adjustments (consisting only of normal recurring adjustments), which we consider necessary for a fair presentation of the financial position at such date and of the operating results and cash flows for those periods, and have been prepared in accordance with U.S.

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

generally accepted accounting principles ( GAAP ) for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The accompanying unaudited condensed combined financial statements should be read in conjunction with the audited combined financial statements and notes thereto included in the information statement filed as an exhibit to the Company s Registration Statement on Form 10 filed with the Securities and Exchange Commission ( SEC ) on May 7, 2014.

The accompanying unaudited condensed combined financial statements have been prepared using Theravance s historical cost basis of the assets and liabilities of the various activities that comprise the Drug Discovery and Development Business of Theravance and reflect the combined results of operations, financial condition and cash flows of Theravance Biopharma as a wholly-owned subsidiary of Theravance in conformity with U.S. GAAP. The various assets, liabilities, revenues and expenses associated with Theravance have been allocated to the historical condensed combined financial statements of Theravance Biopharma in a manner expected to be consistent with the Separation and Distribution Agreement. Changes in parent company deficit represent Theravance s net investment in Theravance Biopharma, after giving effect to Theravance Biopharma s net loss, parent company expense allocations, and net cash transfers to and from Theravance.

For purposes of preparing the unaudited condensed combined financial statements, the Drug Discovery and Development Business was derived from Theravance s historical consolidated financial statements, allocations of revenues, R&D expenses, and non-operating income and expenses to Theravance Biopharma were made on a specific identification basis. For purposes of allocating general and administrative expenses from Theravance s historical consolidated financial statements, costs directly related to the Drug Discovery and Development Business were allocated to Theravance Biopharma on a specific identification basis or based on the substance of the underlying effort. Theravance Biopharma s general and administrative expenses also include allocations of Theravance s general corporate overhead expenses, including finance, legal, human resources, information technology and other

Table of Contents

administrative functions. These allocations of general corporate overhead expenses were primarily based on the substance of the underlying effort or an estimated number of full-time employees that worked with the Drug Discovery and Development Business. The condensed combined balance sheets of Theravance Biopharma include assets and liabilities that were allocated to Theravance Biopharma principally on a specific identification basis.

Management believes that the condensed combined statements of operations and comprehensive loss include a reasonable allocation of costs incurred by Theravance which benefited Theravance Biopharma. However, such expenses may not be indicative of the actual level of expense that would have been incurred by Theravance Biopharma if it had operated as an independent, publicly traded company or of the costs expected to be incurred in the future. As such, the financial information herein may not necessarily reflect the financial position, results of operations, and cash flows of Theravance Biopharma in the future or what it would have been had Theravance Biopharma been an independent, publicly traded company during the periods presented.

***Inventories***

Inventories consist of raw materials, work-in-process and finished goods related to the production of VIBATIV® (telavancin). Raw materials include VIBATIV® active pharmaceutical ingredient ( API ) and other raw materials. Work-in-process and finished goods include third party manufacturing costs and labor and indirect costs we incur in the production process. Included in inventories are raw materials and work-in-process that may be used as clinical products, which are charged to R&D expense when consumed. In addition, under certain commercialization agreements, we may sell VIBATIV® packaged in unlabeled vials that are recorded in work-in-process. Inventories are stated at the lower of cost or market value. We determine the cost of inventory using the average-cost method for validation batches. We analyze our inventory levels quarterly and write down any inventory that is expected to become obsolete, that has a cost basis in excess of its expected net realizable value or for inventory quantities in excess of expected requirements.

***Revenue Recognition***

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the nature of the fee charged for products or services delivered and the collectability of those fees. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria are met.

***Product Revenues***

We sell VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers order VIBATIV® through these distributors. Commencing in the first quarter of 2014, we record revenue on the sale of VIBATIV® on a sell-through basis, once the distributors sell the product to healthcare providers.

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payer mix in target markets, industry benchmarks and experience to date. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV® by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV® experienced by Theravance's former collaborative partner, Astellas, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

*Sales Discounts:* We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. We account for cash discounts by reducing accounts receivable by the full amount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

Table of Contents

Chargebacks and Government Rebates: For VIBATIV® sales in the U.S., we estimate reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service (PHS) as well as government-managed Medicaid programs. Our reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such health care providers. Our accrual for Medicaid is based upon statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the consolidated balance sheet. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

Distribution Fees and Product Returns: We have written contracts with our distributors that include terms for distribution-related fees. We record distribution-related fees based on a percentage of the product sales price. We offer our distributors a right to return product purchased directly from us, which is principally based upon the product's expiration date. Additionally, we have granted more expansive return rights to our distributors following our product launch of VIBATIV®. We will generally accept product returns during the six months prior to and twelve months after the product expiration date on product that had been sold to our distributors. Product returned is generally not resalable given the nature of our products and method of administration. We have developed estimates for VIBATIV® product returns based upon historical VIBATIV® sales from Theravance's former collaborative partner, Astellas. We record distribution fees and product returns as an allowance against accounts receivable.

Allowance for Doubtful Accounts: We maintain a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of March 31, 2014 and December 31, 2013, there was no allowance for doubtful accounts as we have not had any write-offs historically.

*Collaborative Arrangements and Multiple-Element Arrangements*

Revenue from nonrefundable, up-front license or technology access payments under license and collaborative arrangements that are not dependent on any future performance by us is recognized when such amounts are earned. If we have continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of continuing performance obligation.

We account for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Subtopic 605-25, Multiple Element Arrangements. For new or materially amended multiple element arrangements, we identify the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. We allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence (VSOE) of selling price, if it exists, or third-party evidence (TPE) of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, we use the best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

For multiple-element arrangements entered into prior to January 1, 2011, we determined the delivered items under our collaborative arrangements did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, we

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

recognized revenue from non-refundable, upfront fees and development contingent payments in the same manner as the final deliverable, which is ratably over the expected term of our performance of R&D services under the agreements. These upfront or contingent payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a current or non-current liability on the consolidated balance sheets and recognized over the estimated period of performance. We periodically review the estimated performance periods of our contracts based on the progress of our programs.

Table of Contents

Where a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue or as an accrued liability and recognized as a reduction of R&D expenses ratably over the term of our estimated performance period under the agreement. We determine the estimated performance periods, and they are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated performance period and, therefore revenue recognized, would occur on a prospective basis in the period that the change was made.

Under certain collaborative arrangements, we have been reimbursed for a portion of our R&D expenses. These reimbursements have been reflected as a reduction of R&D expense in our consolidated statements of operations, as we do not consider performing research and development services to be a part of our ongoing and central operations. Therefore, the reimbursement of research and developmental services and any amounts allocated to our research and development services are recorded as a reduction of R&D expense.

Amounts deferred under a collaborative arrangement in which the performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue and accrued liability in the period that termination occurred, provided that there are no remaining performance obligations.

We account for contingent payments in accordance with FASB Subtopic ASC 605-28 Revenue Recognition Milestone Method. We recognize revenue from milestone payments when (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) we do not have ongoing performance obligations related to the achievement of the milestone. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

Table of Contents**2. Collaborative Arrangements*****Revenue from Collaborative Arrangements***

We recognized revenue from collaborative arrangements as follows:

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>	
	<b>2014</b>	<b>2013</b>
Merck	\$	\$ 5
R-Pharm CJSC		17
Total revenue from collaborative arrangements	\$	\$ 22

***Clinigen Group******Commercialization Agreement***

In March 2013, Theravance entered into a commercialization agreement (the *Clinigen Commercialization Agreement*) with Clinigen Group plc (Clinigen) to commercialize VIBATIV® for the treatment of hospital acquired nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. Under the agreement, Theravance granted Clinigen exclusive commercialization rights in the European Union and certain other European countries (including Switzerland and Norway). Theravance received a \$5.0 million (unaudited) upfront payment in March 2013. This agreement was assigned to us in the Spin-Off, and we will now be eligible to receive tiered royalty payments on net sales of VIBATIV®, ranging from 20% to 30%. We are responsible, either directly or through our vendors or contractors, for supplying at Clinigen's expense both API and finished drug product for Clinigen's commercialization activities. The agreement has a term of at least 15 years, with an option to extend exercisable by Clinigen. However, Clinigen may terminate the agreement at any time after it has initiated commercialization upon 12 months' advance notice.

Under the Clinigen Commercialization Agreement, the significant deliverables were determined to be the license, committee participation and manufacturing supply. Theravance determined that the license represents a separate unit of accounting as the license, which includes rights to Theravance's underlying technologies for VIBATIV®, has standalone value because the rights conveyed permit Clinigen to perform all efforts necessary to use Theravance's technologies to bring the compound through commercialization and based the best estimate of selling price for the license based on potential future cash flows under the arrangement over the estimated commercialization period. Theravance determined that the committee participation represents a separate unit of accounting as Clinigen could negotiate for and/or acquire these services from other third parties and based the best estimate of selling price of the committee participation based on the nature and timing of the services to be performed. Theravance determined the best estimate of selling price for the manufacturing supply based on a fully burdened cost to purchase and transfer the underlying API and finished goods from Theravance's third party contract manufacturer. The license, committee representation and supply obligations under the Clinigen Commercialization Agreement are now our obligations.



## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

The \$5.0 million upfront payment received by Theravance was allocated to two units of accounting based on the relative selling price method as follows: \$4.9 million to the license and \$0.1 million to the committee participation. Theravance did not recognize any revenue from the license and committee participation as the technical transfer activities were not completed as of March 31, 2014 and the associated units of accounting were not delivered. The amount of the upfront payment allocated to the committee participation was deferred and will be recognized as revenue over the estimated performance period. Amounts received under a future separate supply agreement for API and finished goods, which will be manufactured by our third party contract manufacturers, will be recognized as revenue to the extent of future API and finished goods inventory sales.

Table of Contents**Reimbursement of R&D Costs**

Under certain collaborative arrangements, we are entitled to reimbursement of certain R&D costs. Our policy is to account for the reimbursement payments by our collaboration partners as reductions to R&D expense.

The following table summarizes the reductions to R&D expenses related to the reimbursement payments:

(In thousands)	Three Months Ended March 31,		
	2014	2013	
Merck	\$	\$	1,429
Alfa Wassermann società per azioni		72	208
R-Pharm CJSC		18	326
Total reduction to R&D expense	\$	90	\$ 1,963

**3. Inventories**

Inventories were as follows:

(In thousands)	March 31,	December 31,
	2014	2013
Raw materials	\$ 3,997	\$ 5,138
Work-in-process	2,225	360
Finished goods	4,792	4,908
Total inventories	\$ 11,014	\$ 10,406

**4. Share-Based Compensation**

As of March 31, 2014, we had not issued any share-based awards to our employees. We have adopted an equity incentive plan that provides for the grant of equity-based awards, including restricted shares, restricted share units, options, share appreciation rights and other equity-based awards, to our directors, officers and other employees and advisors. Shortly after the spin-off, we granted share options to our directors pursuant to our outside director automatic grant program and to our employees joining Theravance Biopharma.

Our employees have in the past received Theravance share-based compensation awards, and therefore, the following disclosures pertain to share-based compensation that has been allocated to Theravance Biopharma related to Theravance stock-based equity awards. Accordingly, the amounts presented are not necessarily indicative of future performance and do not necessarily reflect the results that we would have experienced as an independent, publicly-traded company for the periods presented.

*Performance-Contingent Restricted Stock Awards*

Over the past three years, the Compensation Committee of Theravance's Board of Directors (the Compensation Committee) has approved grants of performance-contingent RSAs to senior management and a non-executive officer. Generally, these awards have dual triggers of vesting based upon the achievement of certain performance goals by a pre-specified date, as well as a requirement for continued employment. When the performance goals are deemed achieved for these types of awards, time-based vesting and, as a result, recognition of stock-based compensation expense commence. Included in these performance-contingent RSAs is the grant of 1,290,000 special long-term retention and incentive performance-contingent RSAs to senior management in 2011. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and require continued employment.

Table of Contents

As of March 31, 2014, Theravance determined that the achievement of the requisite performance conditions for vesting of the first tranche of awards was probable and, as a result, \$6.8 million of stock-based compensation expense was recognized by us in the first quarter of 2014. The total stock-based compensation expense of \$7.0 million for the first tranche was recognized through May 2014.

In May 2014, the Compensation Committee approved the modification of the remaining tranches related to this grant contingent upon the Spin-Off. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the equity awards. The remaining tranches of the equity awards remain subject to performance and service conditions. The maximum remaining potential stock-based compensation expense associated with these awards after the modification is \$24.5 million, of which \$10.7 million will be recognized by either Theravance or us, based on which company employs the individuals who hold these awards during the twelve-month service period commencing in June 2014.

***Stock-Based Compensation Expense***

The allocation of stock-based compensation expense included in the condensed combined statements of operations and comprehensive loss was as follows:

(In thousands)	Three Months Ended March 31,	
	2014	2013
Research and development	\$ 4,721	\$ 3,688
Selling, general and administrative	7,980	1,828
Total stock-based compensation expense	\$ 12,701	\$ 5,516

Total stock-based compensation expense capitalized to inventory was not material for the three months ended March 31, 2014 and 2013.

***Valuation Assumptions***

The range of weighted-average assumptions Theravance used to estimate the fair value of stock options granted was as follows:

	Three Months Ended March 31,	
	2014	2013
<b><i>Employee stock options</i></b>		
Risk-free interest rate	1.8-2.0%	1.0%-1.1%
Expected term (in years)	6	6
Volatility	60%	58%
Dividend yield	%	%
Weighted-average estimated fair value of stock options granted	\$ 21.29	\$ 12.32

**5. Income Taxes**

We account for income taxes on a separate tax return basis although our operations have historically been included in the tax returns filed by Theravance. Due to ongoing operating losses and the inability to recognize any income tax benefit, there is no provision for income taxes for any periods presented.

**6. Commitments and Contingencies**

*Special Long-Term Retention and Incentive Cash Awards Program*

In 2011, Theravance granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment.

As of March 31, 2014, Theravance's management determined that the achievement of the requisite performance conditions for the first tranche of awards was probable and, as a result, \$9.1 million of cash bonus expense was recognized by us in the first quarter of 2014. In May 2014, the total cash bonus of \$9.5 million for the first tranche was paid.

Table of Contents

In May 2014, the Compensation Committee approved the modification of the remaining tranches related to this grant contingent upon the Spin-Off. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the cash awards. The remaining tranches of the cash awards were forfeited. The maximum remaining potential cash bonus expense associated with these cash bonus awards after the modification is \$11.2 million, the majority of which will be recognized by us over a twelve-month service period commencing in June 2014.

**7. Subsequent Events**

The Spin-Off was effected pursuant to a Separation and Distribution Agreement dated June 1, 2014, which provides, among other things, for the principal corporate transactions required to effect the Spin-Off and certain other agreements governing Theravance's relationship with us after the Spin-Off. These agreements are discussed below.

*Separation and Distribution Agreement*

In connection with the Spin-Off, on June 1, 2014, Theravance and Theravance Biopharma entered into the Separation and Distribution Agreement. The Separation and Distribution Agreement identifies the assets transferred, liabilities assumed and contracts assigned to us as part of the Spin-Off, and describes when and how these transfers, assumptions and assignments will occur. In particular, all of the assets and liabilities associated or primarily used in connection with the drug discovery and development business operations were transferred to us, including:

- VIBATIV® (telavancin), a bactericidal, once daily injectable antibiotic;
- Our small molecule product candidate pipeline currently focused on bacterial infections, CNS/pain, respiratory disease, and GI motility dysfunction; and
- A portion of the equity interests in Theravance Respiratory Company, LLC, which will entitle us to receive 85% of the economic interest in any future payments made by GSK under the various GSK agreements relating to UMEC/VI/FF and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (ICS), and any other product or combination of products that may be discovered and developed in the future under the GSK agreements (other than RELVAR®/ELLIPTA®, BREO®/ELLIPTA®, ANORO ELLIPTA® and VI monotherapy).

In addition, in connection with the Spin-Off, we were capitalized with \$393.0 million in cash. Except as expressly set forth in the Separation and Distribution Agreement or any ancillary agreement, all assets were transferred to us on an as is, where is basis. Under the terms of the Separation and Distribution Agreement, we will indemnify Theravance, and Theravance will indemnify us from and after the Spin-Off with respect to all debts, liabilities and obligations transferred to Theravance in connection with the Spin-Off (including failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the Spin-Off) and any breach by us of the Separation and

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

Distribution Agreement, the Transition Services Agreement, the Employee Matters Agreement and the Tax Matters Agreement.

### *Transition Services Agreement*

On June 2, 2014, we also entered into a Transition Services Agreement with Theravance pursuant to which Theravance and we will provide each other with a variety of administrative services, including financial, tax, accounting, information technology, legal and human resources services, for a period of time of up to two years following the Spin-Off. We expect that most of these services will be provided within the first six to twelve months following the Spin-Off. In connection with the services performed under the Transition Services Agreement, each party shall pay a monthly fee to the performing party.

### *Tax Matters Agreement*

On June 2, 2014, we also entered into a Tax Matters Agreement with Theravance that governs Theravance's and our respective rights, responsibilities and obligations after the Spin-Off with respect to taxes. Under the Tax Matters Agreement, all tax liabilities (including tax refunds and credits) (i) attributable to Theravance's drug discovery and development business for any and all periods or portions thereof ending prior to or on, the distribution date, (ii) resulting or arising from the contribution of Theravance's drug discovery and development business to us, the distribution of our ordinary shares and the other separation transactions and (iii) otherwise attributable to Theravance, will be borne solely by Theravance. As a result, we should generally expect to be liable only for tax liabilities attributable to, or incurred with respect to, the drug discovery and development business after the distribution date.

Table of Contents

***Employee Matters Agreement***

On June 1, 2014, we also entered into an Employee Matters Agreement with Theravance, which governs the employee benefit obligations of Theravance and us as they relate to current and former employees. The Employee Matters Agreement allocates liabilities and responsibilities relating to employee benefit matters, including 401(k) plan matters that are subject to ERISA in connection with the separation, as well as other employee benefit programs. The Employee Matters Agreement also provides the mechanics for the adjustment on the distribution date of equity awards (including stock options, restricted stock, and restricted stock units) granted under Theravance's equity compensation programs.

***Theravance Respiratory Company, LLC Limited Liability Company Agreement***

Prior to the Spin-Off, Theravance assigned to Theravance Respiratory Company, LLC ( TRC ), a Delaware limited liability company formed by Theravance, its strategic alliance agreement with GSK and all of its rights and obligations under its collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO ELLIPTA® and vilanterol monotherapy. Our equity interest in TRC entitles us to an 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC. The drug programs assigned to TRC include UMEC/VI/FF and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (ICS), and any other product or combination of products that may be discovered and developed in the future under these GSK agreements. Our economic interest will not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO ELLIPTA® or vilanterol monotherapy.

On May 31, 2014, we entered into the TRC LLC Agreement with Theravance that governs the operation of TRC. Under the TRC LLC Agreement, Theravance will be the manager of TRC, and the business and affairs of TRC shall be managed exclusively by the manager, including (i) day to day management of the drug programs in accordance with the existing GSK agreements, (ii) preparing an annual operating plan for TRC and (iii) taking all actions necessary to ensure that the formation, structure and operation of TRC complies with applicable law and partner agreements.



Table of Contents

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

This Report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements in this Report, other than statements of historical facts, including statements regarding the Spin-Off, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations and objectives could be forward-looking statements. The words anticipates, believes, could, designed, estimates, expects, intends, may, plans, projects, pursuing, will, would and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, those discussed in Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Report. Our forward-looking statements in this Report are based on current expectations and we do not assume any obligation to update any forward-looking statements.

**Management Overview**

We are a biopharmaceutical company with one approved product that was discovered and developed internally, a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. We are focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including bacterial infections, central nervous system (CNS)/pain, respiratory disease, and gastrointestinal (GI) motility dysfunction. By leveraging our proprietary insight of multivalency to drug discovery, we are pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need. We also have an economic interest in future payments that may be made by Glaxo Group Limited (which we refer to, together with its affiliates, as GSK) under agreements with Theravance, Inc. relating to certain drug programs, including UMEC/VI/FF and the MABA program, as monotherapy with GSK961081 (081) and as a combination (081/FF).

Our strategy focuses on the discovery, development and commercialization of medicines with superior efficacy, convenience, tolerability and/or safety using our proprietary insight in chemistry, biology and multivalency, where applicable. Multivalency refers to the simultaneous attachment of a single molecule to multiple binding sites on one or more biological targets. When compared to monovalency, whereby a molecule attaches to only one binding site, multivalency can significantly increase a compound's potency, duration of action and/or selectivity. Multivalent compounds generally consist of several individual small molecules, at least one of which is biologically active when bound to its target, joined by linking components. In addition, we believe we can enhance the probability of successfully developing and commercializing medicines by identifying at least two structurally different product candidates, whenever practicable, in each therapeutic program.

We believe that in some instances strategic collaborations and licensing activities will help us succeed at implementing our research, development and commercialization strategy for our product and product candidates. Through such strategic collaborations or licensing activities, we believe that we can enhance our ability to develop and expand our pipeline as well as commercialize products once approved.

Prior to June 2, 2104, we had never operated as a separate, stand-alone entity. In addition, there have been a number of events over the past several years that have had a significant impact on our operations. As a result of these factors, our historical financial results are not likely to be indicative of our future financial performance.

**The Separation of Theravance Biopharma from Theravance**

In April 2013, Theravance, Inc. ( Theravance ) announced its intent to spin off its drug discovery and development business which is focused on discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need ( Drug Discovery and Development Business ) from its development and commercial responsibilities under the 2002 collaboration agreement and the 2004 strategic alliance agreement, each with Glaxo Group Limited (which we refer to, together with its affiliates, as GSK ) and associated potential royalty revenues from RELVAR® ELLIPTA®/BREQ® ELLIPTA® (fluticasone furoate/vilanterol: FF/VI), ANORO ELLIPTA® (umeclidinium bromide/vilanterol: UMEC/VI) and vilanterol monotherapy. On June 1, 2014 Theravance transferred its research and development ( R&D ) operations to us, and on June 2, 2014 Theravance made a pro rata dividend distribution to its stockholders of record on May 15, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Theravance common stock outstanding on the record date (the Spin-Off ).

Table of Contents

The Spin-Off was effected pursuant to a Separation and Distribution Agreement between Theravance and us (the Separation and Distribution Agreement), which provides, among other things, for the principal corporate transactions required to effect the Spin-Off and certain other agreements governing Theravance's relationship with us after the Spin-Off.

**Basis of Presentation**

The combined financial statements have been prepared using Theravance's historical cost basis of the assets, liabilities, revenues, and expenses of the various activities that comprise the Drug Discovery and Development Business as a component of Theravance and reflect the results of operations, financial condition and cash flows of the Drug Discovery and Development Business as a component of Theravance. The statements of operations include expense allocations for general corporate overhead functions historically shared with Theravance, including finance, legal, human resources, information technology and other administrative functions, which include the costs of salaries, benefits and other related costs, as well as consulting and other professional services. Where appropriate, these allocations were made on a specific identification basis. Otherwise, the expenses related to services provided to the Drug Discovery and Development Business by Theravance were allocated to Theravance Biopharma based on the relative percentages, as compared to Theravance's other businesses, of headcount or square footage usage.

The costs historically allocated to us by Theravance for the services it has shared with us may not be indicative of the costs we will incur for these services following the Spin-Off. Certain anticipated incremental costs and other adjustments that give effect to the Spin-Off are not reflected in our historical combined financial statements.

**Program Highlights**

*Economic Interests in GSK Respiratory Programs Partnered with Theravance*

Prior to the Spin-Off, Theravance assigned to Theravance Respiratory Company, LLC (TRC), a Delaware limited liability company formed by Theravance, its strategic alliance agreement with GSK and all of its rights and obligations under its collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO ELLIPTA® and vilanterol monotherapy. Our equity interest in TRC entitles us to an 85% economic interest in any future payments made by GSK under the strategic alliance agreement and under the portion of the collaboration agreement assigned to TRC. The drug programs assigned to TRC include UMEC/VI/FF and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (ICS), and any other product or combination of products that may be discovered and developed in the future under these GSK agreements. Our economic interest will not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO ELLIPTA® or vilanterol monotherapy.

On May 31, 2014, we entered into the TRC LLC Agreement with Theravance that governs the operation of TRC. Under the TRC LLC Agreement, Theravance is the manager of TRC, and the business and affairs of TRC are managed exclusively by the manager, including (i) day to day management of the drug programs in accordance with the existing GSK agreements, (ii) preparing an annual operating plan for TRC and (iii) taking all actions necessary to ensure that the formation, structure and operation of TRC complies with applicable law and partner agreements. On June 1, 2014, we assigned our interests in TRC to Theravance Biopharma R&D, Inc., our wholly-owned subsidiary.

*UMEC/VI/FF*

The UMEC/VI/FF program seeks to provide the activity of two bronchodilators (UMEC and VI) plus an inhaled corticosteroid (FF) in a single delivery device. In this program, the LABA and LAMA molecules that comprise GSK's ANORO ELLIPTA® will be co-formulated in a single blister strip, and the inhaled corticosteroid, FF, will be administered from an adjacent blister strip both of which would be administered together in GSK's ELLIPTA® inhaler. The royalty rates applicable to worldwide net sales of UMEC/VI/FF under the collaboration agreement are upward-tiering from 6.5% to 10%.

*Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)*

GSK961081 ( 081) is an investigational, single-molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activities. 081 has completed a Phase 2b study, a Phase 1 study in combination with the ICS, fluticasone propionate ( FP ), and a number of Phase 3 enabling non-clinical studies. 081 is now being progressed as a combination with FF delivered once-daily in the ELLIPTA® inhaler which requires additional work on non-clinical studies, manufacturing and a Phase 1 bioequivalence study. As a result, it is unlikely that a Phase 3 study with 081 will commence in 2014. Preclinical Phase 3-enabling studies with the combination 081/FF are ongoing to explore its potential as a once-daily medicine delivered in the ELLIPTA® inhaler.

Table of Contents

In 2005, GSK licensed Theravance's bifunctional muscarinic antagonist-beta2 agonist (MABA) program under the strategic alliance agreement, which agreement will be assigned to TRC, and in October 2011, Theravance and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the Additional MABAs). GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to TRC, at which point TRC may develop and commercialize such Additional MABAs alone or with a third party. We have entered into an extension agreement with GSK in which we have agreed to be subject to certain restrictive covenants similar to those applicable to Theravance under the collaboration and strategic alliance agreements with GSK. One of those covenants provides that for so long as a MABA product candidate remains in active development under the strategic alliance agreement, we will not, whether alone or with a third party, conduct a clinical study with respect to a MABA compound (or a product containing a MABA compound). However, if we license a non-MABA compound to a third party that chooses to combine such compound with a MABA compound, that third party would not be similarly restricted provided that we do not direct the third party's development or commercialization efforts or share any GSK confidential information.

If a single-agent MABA medicine containing 081 is successfully developed and commercialized, TRC is entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. If a MABA medicine containing 081 is commercialized only as a combination product, such as 081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, TRC is entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS combination, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing 081 is successfully developed and commercialized in multiple regions of the world, TRC could earn total contingent payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, TRC could earn total contingent payments of up to \$129.0 million.

***Bacterial Infections Programs***

*VIBATIV® (telavancin)*

VIBATIV® (telavancin) is a bactericidal, once-daily injectable antibiotic discovered by Theravance in a research program dedicated to finding new antibiotics for serious infections due to *Staphylococcus aureus* and other Gram-positive bacteria, including methicillin-resistant (MRSA) strains. VIBATIV® is approved in the U.S. and Canada for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria. VIBATIV® is also approved in the U.S. for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable.

In May 2012, Theravance entered into a Technology Transfer and Supply Agreement with Hospira Worldwide, Inc. (Hospira) for VIBATIV® drug product supply. In June 2013, the U.S. Food and Drug Administration (FDA) approved Hospira as a VIBATIV® drug product manufacturer. This agreement with Hospira has been assigned to us. On August 14, 2013 Theravance announced the reintroduction of VIBATIV® to the U.S. market with the commencement of shipments into the wholesaler channel. While we have contracted a small sales force and are expanding our medical affairs presence, other commercialization alternatives for the U.S. market are being evaluated.

In September 2011, the European Commission granted marketing authorization for VIBATIV® for the treatment of adults with nosocomial pneumonia (NP), including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not

suitable. However, in May 2012, the European Commission suspended this marketing authorization because the previous single source drug product supplier did not meet the current Good Manufacturing Practice ( cGMP ) requirements for the manufacture of VIBATIV®. In March 2014, the European Commission lifted the suspension. We anticipate that commercialization in the European Union will commence upon availability of product and satisfaction of all pre-launch requirements.

*Central Nervous System/Pain Programs*

*Oral Peripheral Mu Opioid Receptor Antagonist TD-1211*

TD-1211 is an investigational once-daily, orally administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed with a goal of alleviating gastrointestinal side effects of opioid therapy without affecting analgesia. In July 2012, Theravance announced positive topline results from the Phase 2b Study 0084, the key study in the Phase 2b program evaluating TD-1211 as potential treatment for chronic, non-cancer pain patients with opioid-induced constipation. The Phase 2b program consisted of three studies (0074, 0076 and 0084) designed to evaluate doses and dosing regimens for Phase 3. We are currently evaluating our Phase 3 strategy due to potentially evolving FDA requirements for this class of drug.

Table of Contents

*Monoamine Reuptake Inhibitor TD-9855*

We are developing TD-9855, an investigational norepinephrine and serotonin reuptake inhibitor discovered by Theravance, for the treatment of chronic pain conditions. In April 2014, Theravance announced positive results from a Phase 2 study of TD-9855 in patients with fibromyalgia. Recently, TD-9855 did not meet the primary efficacy endpoints in the Phase 2 study in adult patients with Attention-Deficit/Hyperactivity Disorder.

***Respiratory Program***

*Long-Acting Muscarinic Antagonist (LAMA) TD-4208*

We are developing TD-4208, a once-daily inhaled nebulized muscarinic antagonist discovered by Theravance, for the treatment of a subset of COPD patients whom we believe are underserved by current hand-held products. We believe that such a medicine could serve as a foundation for several combination nebulized products as well as potential metered dose inhaler ( MDI ) or dry powder inhaler ( DPI ) products. In September 2013, Theravance reported positive top-line data from a Phase 2b study to evaluate the bronchodilatory effect, pharmacokinetics, safety and tolerability of multiple doses of TD-4208. In this study, TD-4208 met the primary efficacy endpoint for all six doses studied and demonstrated a statistically significant change versus placebo from baseline in forced expiratory volume in one second ( FEV1 ). All doses of TD-4208 were generally well tolerated in the study with rates of adverse events comparable to placebo. In April 2014, Theravance initiated a dose ranging Phase 2b study with TD-4208 as a nebulized aqueous solution in patients with moderate to severe COPD.

Pursuant to our extension agreement with GSK, for so long as there is at least one collaboration product being developed or commercialized under the collaboration agreement in which we have an economic interest pursuant to our interest in TRC, we will not carry out clinical development for the treatment and/or prophylaxis of respiratory diseases with any LABA, including any LABA in combination with TD-4208, subject to limited exceptions. However, if we license TD-4208 to a third party that chooses to combine TD-4208 with a LABA compound, that third party would not be similarly restricted provided that we do not direct the third party's development or commercialization efforts or share any GSK confidential information.

***GI Motility Dysfunction Program***

*Velusetrag*

Velusetrag is an oral, investigational medicine discovered by Theravance and developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT4 receptor. In October 2012, Theravance entered into a development and collaboration arrangement with Alfa Wassermann società per azioni (S.p.A.) ( Alfa Wassermann ) for velusetrag, under which the parties agreed to collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis (a medical condition consisting of a paresis (partial paralysis) of the stomach, resulting in food remaining in the stomach for a longer time than normal). In January 2013, Theravance and Alfa Wassermann announced the initiation of a Phase 2 proof-of-concept study to

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

evaluate the efficacy and safety of velusetrag for the treatment of patients with diabetic or idiopathic gastroparesis. This agreement with Alfa Wassermann has been assigned to us and such agreement provides for a term of 15 years from first commercialization or, if later, until certain patents expire. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while we retain full rights to velusetrag in the U.S., Canada, Japan and certain other countries. In April 2014, Theravance announced positive top-line results from a Phase 2 study that evaluated gastric emptying, safety and tolerability of multiple doses of velusetrag, and based on these results, Theravance and Alfa Wassermann have agreed to advance velusetrag into a Phase 2b study later this year. Pursuant to our agreement with Alfa Wassermann, the first Phase 2 study was, and the bulk of the Phase 2b study will be, funded by Alfa Wassermann. If Alfa Wassermann exercises its license option at the completion of the Phase 2 program, then we will be entitled to receive a \$10.0 million option fee. If velusetrag is successfully developed and commercialized, we will be entitled to receive potential future contingent payments totaling up to \$53.5 million, and royalties on net sales by Alfa Wassermann ranging from the low teens to 20%.

### *TD-8954*

TD-8954, like velusetrag, is a highly selective agonist with high intrinsic activity at the human 5-HT<sub>4</sub> receptor. We are investigating the development potential of TD-8954 for acute use in the hospital setting for patients who require rapid restoration of upper and lower GI motility. We believe that TD-8954 may help hospitalized patients with enteral feeding intolerance, or EFI, and potentially other GI disorders. A Phase 2a study evaluating the safety, tolerability and pharmacodynamics of a single dose of TD-8954 administered intravenously compared to metoclopramide in critically ill patients with EFI is ongoing.



Table of Contents

**Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our combined financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on Theravance's historical experiences and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

***Revenue Recognition***

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the nature of the fee charged for products or services delivered and the collectability of those fees. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria are met.

***Product Revenues***

We sell VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers order VIBATIV® through these distributors. Commencing in the first quarter of 2014, we record revenue on the sale of VIBATIV® on a sell-through basis, once the distributors sell the product to healthcare providers.

Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflect such reductions in revenue as either an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions are based on management's estimates that consider payer mix in target markets, industry benchmarks and experience to date. We monitor inventory levels in the distribution channel, as well as sales of VIBATIV® by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of our agreements with customers, historical product returns of VIBATIV® experienced by Theravance's former collaborative partner, Astellas, rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions. We update our estimates and assumptions each quarter and if actual future results vary from our estimates, we may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

***Sales Discounts:*** We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We expect our customers to comply with the prompt payment terms to earn the cash discount. We account for cash discounts by reducing accounts receivable

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

by the full amount and recognizing the discount as a reduction of revenue in the same period the related revenue is recognized.

*Chargebacks and Government Rebates:* For VIBATIV® sales in the U.S., we estimate reductions to product sales for qualifying federal and state government programs including discounted pricing offered to Public Health Service ( PHS ) as well as government-managed Medicaid programs. Our reduction for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such health care providers. Our accrual for Medicaid is based upon statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers, and our expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to us are recorded in other accrued liabilities on the consolidated balance sheet. For qualified programs that can purchase our products through distributors at a lower contractual government price, the distributors charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as an allowance against accounts receivable.

*Distribution Fees and Product Returns:* We have written contracts with our distributors that include terms for distribution-related fees. We record distribution-related fees based on a percentage of the product sales price. We offer our distributors a right to return product purchased directly from us, which is principally based upon the product's expiration date. Additionally, we have granted more expansive return rights to our distributors following our product launch of VIBATIV®. We will generally accept

Table of Contents

product returns during the six months prior to and twelve months after the product expiration date on product that had been sold to our distributors. Product returned is generally not resalable given the nature of our products and method of administration. We have developed estimates for VIBATIV® product returns based upon historical VIBATIV® sales from Theravance's former collaborative partner, Astellas. We record distribution fees and product returns as an allowance against accounts receivable.

Allowance for Doubtful Accounts: We maintain a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of March 31, 2014, there was no allowance for doubtful accounts as we have not had any write-offs historically.

*Collaborative Arrangements and Multiple Element Arrangements*

Revenue from nonrefundable, up-front license or technology access payments under license and collaborative arrangements that are not dependent on any future performance by us is recognized when such amounts are earned. If we have continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of continuing performance obligation.

We account for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) Subtopic 605-25, Multiple Element Arrangements. For new or materially amended multiple element arrangements, we identify the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. We allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence ( VSOE ) of selling price, if it exists, or third-party evidence ( TPE ) of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, we use the best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

For multiple-element arrangements entered into prior to January 1, 2011, we determined the delivered items under our collaborative arrangements did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, we recognized revenue from non-refundable, upfront fees and development contingent payments in the same manner as the final deliverable, which is ratably over the expected term of our performance of R&D services under the agreements. These upfront or contingent payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a short-term or long-term liability on the consolidated balance sheets and recognized over the estimated period of performance. We periodically review the estimated performance periods of our contracts based on the progress of our programs.

Where a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative arrangement, they are recorded as deferred revenue and recognized as revenue or as an accrued liability and recognized as a reduction of R&D expenses ratably over the term of our estimated performance period under the agreement. We determine the estimated performance periods, and they are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated performance period and, therefore revenue recognized, would occur on a prospective basis in the period that the change was made.

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

Under certain collaborative arrangements, we have been reimbursed for a portion of our R&D expenses. These reimbursements have been reflected as a reduction of R&D expense in our consolidated statements of operations, as we do not consider performing research and development services to be a part of our ongoing and central operations. Therefore, the reimbursement of research and developmental services and any amounts allocated to our research and development services are recorded as a reduction of R&D expense.

Amounts deferred under a collaborative arrangement in which the performance obligations are terminated will result in an immediate recognition of any remaining deferred revenue and accrued liability in the period that termination occurred, provided that there are no remaining performance obligations.

We account for contingent payments in accordance with FASB Subtopic ASC 605-28 Revenue Recognition Milestone Method. We recognize revenue from milestone payments when (i) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement and (ii) we do not have ongoing performance obligations related to the

Table of Contents

achievement of the milestone. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment (a) is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item or items as a result of a specific outcome resulting from our performance to achieve the milestone, (b) relates solely to past performance, and (c) is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement.

***Inventories***

Inventories consist of raw materials, work-in-process and finished goods related to the production of VIBATIV® (telavancin). Raw materials include VIBATIV® active pharmaceutical ingredient (API) and other raw materials. Work-in-process and finished goods include third party manufacturing costs and labor and indirect costs we incur in the production process. Included in inventories are raw materials and work-in-process that may be used as clinical products, which are charged to R&D expense when consumed. In addition, under certain commercialization agreements, we may sell VIBATIV® packaged in unlabeled vials that are recorded in work-in-process. Inventories are stated at the lower of cost or market value. We determine the cost of inventory using the average-cost method for validation batches. We analyze our inventory levels quarterly and write down any inventory that is expected to become obsolete, that has a cost basis in excess of its expected net realizable value or for inventory quantities in excess of expected requirements.

**Results of Operations*****Revenues***

Total revenue, as compared to the prior year period, was as follows:

(In thousands)	Three Months Ended March 31,				Change	
	2014		2013			
Product sales	\$	945	\$	\$	945	%
Revenue from collaborative arrangements				22	(22)	(100)
Total revenue	\$	945	\$	22	923	NM

*NM Not meaningful*

Total revenue increased in the first quarter of 2014 from the comparable period in 2013 primarily due to product sales resulting from the recognition of revenue from VIBATIV®, which includes amounts that were previously deferred. Commencing in the first quarter of 2014, we record revenue on the sale of VIBATIV® on a sell-through basis, once the distributors sell the product to healthcare providers.

***Cost of goods sold***

Cost of goods sold, as compared to the prior year period, was as follows:

(In thousands)	Three Months Ended March 31,				Change	
	2014		2013			
Cost of goods sold	\$	188	\$	\$	188	%

Cost of goods sold in the first quarter of 2014 resulted from recognizing revenue from product sales of VIBATIV®.

***Research and Development Expenses***

Our R&D expenses consist primarily of employee-related costs, external costs, and various allocable expenses. We budget total R&D expenses on an internal department level basis, we do not have program level reporting capabilities. We manage and report our R&D activities across the following four cost categories:

- 1) Employee-related costs, which include salaries, wages and benefits;
- 2) External costs, which include clinical trial related expenses, other contract research fees, consulting fees, and contract manufacturing fees;
- 3) Stock-based compensation, which includes expenses associated with our stock option and other award plans; and
- 4) Facilities and other, which include laboratory and office supplies, depreciation and other allocated expenses, which include general and administrative support functions, insurance and general supplies.

Table of Contents

The following table summarizes our research and development expenses incurred during the periods presented:

(In thousands)	Three Months Ended March 31,			Change
	2014	2013		
Employee-related	\$ 19,299	\$ 9,102	\$ 10,197	112%
External costs	11,814	7,001	4,813	69
Stock-based compensation	4,721	3,688	1,033	28
Facilities, depreciation and other allocated	5,889	5,617	272	5
Total R&D expenses	\$ 41,723	\$ 25,408	\$ 16,315	64%

R&D expenses increased 64% to \$41.7 million in the first quarter of 2014 from the comparable period in 2013 primarily due to higher employee-related costs of \$10.2 million, external-related costs of \$4.8 million and stock-based compensation expense of \$1.0 million. Employee-related costs and stock-based compensation expense increased primarily due to the achievement of performance conditions for the first tranche of awards under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011, which resulted in additional cash bonus and stock-based compensation expense during the first quarter of 2014. The key clinical trials we were conducting in the first quarter of 2014 were our Phase 2 clinical study in our MARIN program with TD-9855 for fibromyalgia, a Phase 2b study in our LAMA program with TD-4208 and Phase 1 studies in earlier stage programs. In the comparable period in 2013 our key clinical trials primarily consisted of our Phase 2 clinical studies in our MARIN program with TD-9855 for ADHD and fibromyalgia, a Phase 2b study in our LAMA program with TD-4208 and Phase 1 studies in earlier stage programs.

Under certain of our collaborative arrangements we received partial reimbursement of external costs and employee-related costs, which have been reflected as a reduction of R&D expenses of \$0.1 million and \$2.0 million for the three months ended March 31, 2014 and 2013

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses, as compared to the prior year period, were as follows:

(In thousands)	Three Months Ended March 31,			Change
	2014	2013		
Selling, general and administrative expenses	\$ 19,052	\$ 6,788	\$ 12,264	181%

Selling, general and administrative expenses increased 181% to \$19.1 million in the first quarter of 2014, from the comparable period in 2013 primarily due to higher stock-based compensation expense, external costs from VIBATIV® commercialization activities, an increase in external legal and accounting fees in connection with the Spin-Off and higher employee-related costs. Stock-based compensation expense and employee-related costs increased primarily due to the achievement of performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011, which resulted in additional stock-based compensation of \$6.1 million and cash bonus expense of \$1.3 million during the first quarter of 2014. Selling, general and administrative expenses include stock-based compensation expense of \$8.0 million and \$1.8 million for the three months ended March 31, 2014 and 2013.

**Liquidity and Capital Resources**

At the closing of the Spin-Off, Theravance provided us cash and cash equivalents and marketable securities of \$393.0 million. In addition, Theravance is obligated to fund all current liabilities, with the exception of deferred rent, deferred revenue, accrued vacation and accrued discretionary cash bonus that were incurred by us through the Spin-Off date in accordance with the Separation and Distribution Agreement between us. For ease of administration and in connection with the assignment of certain rights and obligations under the Separation and Distribution Agreement, certain current liabilities, which were transferred to us on the Spin-Off date, are to be paid by us. As such, Theravance will provide additional funding to us to reimburse us for these liabilities that were incurred before the Spin-Off and transferred to us on the Spin-Off date. Such payment by Theravance is expected to be made in late June 2014 or early July 2014.

We expect our cash, cash equivalents and marketable securities will fund our operations for at least the next twelve months based on current operating plans and financial forecasts.



Table of Contents

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product and product candidates into and through clinical studies, which are very expensive. For example, in April 2014 we initiated a second Phase 2b study with TD-4208, our LAMA compound, for which we began incurring start-up costs in the first quarter of 2014, and we announced positive results from a Phase 2 study of TD-9855 in our MARIN program for fibromyalgia. Also, in July 2012, Theravance announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we are seeking to partner these programs, we may choose to progress one or more of these programs into later-stage clinical studies by ourselves or progress telavancin, our approved antibiotic, into a Phase 3 study for a new indication by ourselves, which could increase our anticipated operating expenses substantially. We currently employ or have contracted with a small number of sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV®. Furthermore, if we cannot or choose not to identify a commercialization partner for VIBATIV® in the U.S., we will not be able to leverage a commercialization partner's capabilities and infrastructure and we will incur all of the costs and expenses associated with the commercialization of VIBATIV® in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expansion of medical affairs presence, manufacturing and third party vendor logistics and consultant support.

In 2011, Theravance granted special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and continued employment. As of March 31, 2014, Theravance's management determined that the achievement of the requisite performance conditions was probable and, as a result, \$9.1 million of cash bonus expense was recognized by us in the first quarter of 2014. In May 2014, the total cash bonus expense of \$9.5 million for the first tranche was paid.

In May 2014, the Compensation Committee of the Board of Directors of Theravance (the Compensation Committee) approved the modification of the remaining tranches related to this grant contingent upon the Spin-Off. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the cash awards. The remaining tranches of the cash awards were forfeited. The maximum remaining potential cash bonus expense associated with these cash bonus awards after the modification is \$11.2 million, the majority of which will be recognized by us over a twelve-month service period commencing in June 2014.

If our current operating plans or financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements. Furthermore, if in our view favorable financing opportunities arise, we may seek additional funding at any time. However, future financing may not be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as presently conducted.

**Cash Flows**

(In thousands)	Three Months Ended				
	March 31,		March 31,		Change
	2014	2013	2014	2013	
Net cash used in operating activities	\$	44,799	\$	28,491	\$ 16,308
Net cash used in investing activities		1,620		640	980
Net cash provided by financing activities		46,419		29,131	17,288

*Cash Flows from Operating Activities*

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

Cash used in operating activities is primarily driven by net loss, excluding the effect of non-cash charges or differences in the timing of cash flows and earnings recognition.

Net cash used in operating activities in the three months ended March 31, 2014 was \$44.8 million, which was primarily due to:

- \$47.4 million used in operating expenses, after adjusting for non-cash related items of \$13.6 million consisting primarily of stock-based compensation expense of \$12.7 million, depreciation and amortization expenses of \$0.7 million, and rent expense of \$0.2 million;
- \$1.8 million used to increase prepaid expenses and other current assets; and
- \$4.6 million provided by the net increase in accrued liabilities primarily due to increases in accrued personnel-related expenses, accrued clinical and development expense, and other accrued liabilities.

Table of Contents

Net cash used in operating activities in the three months ended March 31, 2013 was \$28.5 million, which was primarily due to:

- \$26.2 million used in operating expenses, after adjusting for non-cash related items of \$6.0 million consisting primarily of stock-based compensation expense of \$5.5 million and depreciation and amortization expenses of \$0.7 million, partially offset by a reduction of rent expense of \$0.2 million;
- \$6.1 million received in upfront fees from collaboration partners Clinigen and R-Pharm;
- \$3.7 million used to reduce accrued personnel related expenses and other accrued liabilities primarily due to the pay out of the 2012 bonus plan;
- \$2.5 million used to increase work-in-process inventory; and
- \$1.0 million used to increase collaboration receivable related to reimbursement of R&D services.

*Cash Flows from Investing Activities*

Net cash used in investing activities in the three months ended March 31, 2014 was \$1.6 million, which was primarily due to purchases of property and equipment.

Net cash used in investing activities in the three months ended March 31, 2013 was \$0.6 million, which was primarily due to purchases of property and equipment of \$0.7 million, partially offset by payments received on notes receivable of \$0.1 million.

*Cash Flows from Financing Activities*

Net cash provided by financing activities in the three months ended March 31, 2014 and 2013 was \$46.4 million and \$29.1 million, respectively, which was due to transfers from Theravance.

**Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet financial arrangements and have not established any structured finance or special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets.

*Commitments and Contingencies*

In 2011, Theravance granted special long-term retention and incentive RSAs to members of senior management and special long-term retention and incentive cash bonus awards to certain employees. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year time frame from 2011 through December 31, 2016 and continued employment. As of March 31, 2014, Theravance's management determined that the achievement of the requisite performance conditions for the first tranche of awards was probable and, as a result, \$6.8 million of stock-based compensation expense and \$9.1 million of cash bonus expense was recognized by us in the first quarter of 2014 related to this grant. The total stock-based compensation expense of \$7.0 million for the first tranche was recognized through May 2014. In May 2014, the total cash bonus of \$9.5 million for the first tranche was paid.

In May 2014, the Compensation Committee approved the modification of the remaining tranches related to this grant contingent upon the Spin-Off. The modification acknowledged the Spin-Off and permitted recognition of achievement of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the equity and cash awards. The remaining tranches of the equity awards remain subject to performance and service conditions. The remaining tranches of the cash awards were forfeited. The maximum remaining potential stock-based compensation expense associated with these equity awards after the modification is \$24.5 million, of which \$10.7 million will be recognized by either Theravance or us, based on which company employs the individuals who hold these equity awards during the twelve-month service period commencing in June 2014. The maximum remaining potential cash bonus expense associated with these cash bonus awards after the modification is \$11.2 million, the majority of which will be recognized by us over a twelve-month service period commencing in June 2014.

Table of Contents

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities.

*Interest Rate Sensitivity*

We expect to invest the cash and cash equivalents contributed to us by Theravance in an investment portfolio of investment grade, highly liquid debt securities, which are designed to limit the amount of credit exposure to any one issue, issuer or type of instrument. We do not plan to use derivative financial instruments for speculative or trading purposes. We expect to carry our investments in debt securities at fair value, estimated as the amount at which an asset or liability could be bought or sold in a current transaction between willing parties. We expect to diversify our credit risk and invest in debt securities with high credit quality. We will continue to monitor our credit risks and evaluate the potential need for impairment charges related to credit risks in future periods.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

We conducted an evaluation as of March 31, 2014, under the supervision and with the participation of our management, including our Chief Executive Officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) (i) is recorded, processed, summarized and reported within required time periods and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Limitations on the Effectiveness of Controls*

Our management, including our Chief Executive Officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Theravance Biopharma have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

*Changes in Internal Control over Financial Reporting*

No change in our internal control over financial reporting occurred during the quarter ended March 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

We are not currently a party to any material litigation or other material legal proceedings.

**ITEM 1A. RISK FACTORS**

**RISKS RELATING TO THE RECENT SPIN-OFF**

*We and our shareholders may not realize the potential benefits from the spin-off.*

On June 2, 2014 the spin-off of the Company from Theravance, Inc. ( Theravance ) was completed via a pro rata dividend distribution to Theravance stockholders of record of one of our ordinary shares for every three and one half shares of Theravance common stock outstanding on the May 15, 2014 record date. We and our shareholders may not realize the potential benefits that we expect from our spin-off from Theravance. By separating from Theravance, there is a risk that our company may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Theravance. In addition, we will incur significant costs, including those described below, which may exceed our estimates, and we will incur some negative effects from our separation from Theravance, including the loss of potential royalty revenue derived from certain of Theravance s late-stage partnered respiratory assets (the Royalty Business ).

*Our historical financial information may not reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented and is not necessarily indicative of our future financial position, future results of operations or future cash flows.*

Our historical financial information does not necessarily reflect what our financial position, results of operations or cash flows would have been as a stand-alone company during the periods presented and is not necessarily indicative of our future financial position, future results of operations or future cash flows. This is primarily a result of the following factors:

- Prior to the spin-off, our business was operated by Theravance as part of its broader corporate organization rather than as a stand-alone company, and our business was able to leverage Theravance s financial resources and creditworthiness;

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

- Certain general administrative functions are performed by Theravance for the combined entity. Our historical combined financial statements reflect allocations of costs for services shared with Theravance. These allocations may differ from the costs we will incur for these services as an independent company;
- Our cost of capital will likely be higher than Theravance's cost of capital prior to the spin-off; and
- We are now responsible for the additional costs associated with being an independent, public company, including costs related to corporate governance and listed and registered securities.

Our accounting and other management systems and resources may not be adequately prepared to meet the financial reporting and other requirements to which we became subject following the spin-off. If we are unable to achieve and maintain effective internal controls, our business, financial position and results of operations could be adversely affected.

As a result of the spin-off, we are subject to the reporting and other obligations under the Exchange Act, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which will require annual management assessments of the effectiveness of our internal control over financial reporting. When and if we are a large accelerated filer or an accelerated filer and are no longer an emerging growth company, each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. These reporting and other obligations will place significant demands on our management and administrative and operational resources, including accounting resources.

To comply with these requirements, we anticipate that we may need to upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional legal, accounting and/or finance staff. If we are unable to upgrade our financial and management controls, reporting systems, information technology and procedures in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired. In addition, if we are unable to conclude that our internal control over financial reporting is effective (or if the auditors are unable to express an opinion on the effectiveness of our internal controls), we could lose investor confidence in the accuracy and completeness of our financial reports.



Table of Contents

Our management will be responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Any failure to achieve and maintain effective internal controls could have an adverse effect on our business, financial position and results of operations.

***We have no history operating as an independent company upon which you can evaluate us.***

We do not have an operating history as a stand-alone entity. While our drug discovery and development business has constituted a substantial part of the historic operations of Theravance, we did not operate as a stand-alone company without the Royalty Business until the spin-off. As a new independent company, our ability to satisfy our obligations and achieve profitability will be primarily dependent upon the future performance of our drug discovery and development business, and we will not be able to rely upon the revenues, capital resources and cash flows of the Royalty Business remaining with Theravance. In addition, we will need certain transition services from Theravance to be able to operate our business and we will be required to deliver a significant number of services to Theravance during a transition period.

***Concerns about our prospects as a stand-alone company and employee compensation and benefits after the spin-off or otherwise, could affect our ability to retain employees.***

The spin-off represents a significant organizational change and our employees may have concerns about our prospects as a stand-alone company, including our ability to successfully operate the new entity over the long-term, and our ability maintain our independence after the spin-off. If we are not successful in assuring our employees of our prospects as an independent company, our employees may seek other employment, which could materially adversely affect our business.

Substantially all of our employees hold stock options, restricted stock and/or restricted stock units for shares of Theravance common stock and will continue to vest in such Theravance equity interests based on service to us. We believe that the continued vesting of Theravance equity awards will help us retain our employees as a stand-alone company. However, we can no longer grant our employees equity awards for Theravance common stock or effect amendments of Theravance's equity incentive plans (and similar programs) or equity awards previously granted by Theravance. Furthermore, in the event Theravance is acquired and the vesting of Theravance equity awards is accelerated in such an acquisition, we may have difficulty retaining our employees and may have to incur additional costs to retain them.

If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities, which may cause the price of our securities to fall.

***We will be required to satisfy certain indemnification obligations to Theravance or may not be able to collect on indemnification rights from Theravance.***

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

We have agreed to indemnify Theravance from and after the spin-off with respect to (i) all debts, liabilities and obligations transferred to us in connection with the spin-off (including our failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the spin-off), (ii) any misstatement or omission of a material fact resulting in a misleading statement in our Information Statement distributed to Theravance stockholders in connection with the spin-off and (iii) any breach by us of certain agreements entered into with Theravance in connection with the spin-off (namely, the Separation and Distribution Agreement, the Transition Services Agreement, the Employee Matters Agreement, the Tax Matters Agreement, and the Facility Sublease Agreement). We are not aware of any existing indemnification obligations at this time, but any such indemnification obligations that may arise could be significant. Under the terms of the Separation and Distribution Agreement, Theravance will indemnify us from and after the spin-off with respect to (i) all debts, liabilities and obligations retained by Theravance after the spin-off (including its failure to pay, perform or otherwise promptly discharge any such debts, liabilities or obligations after the spin-off) and (ii) any breach by Theravance of the Separation and Distribution Agreement, the Transition Services Agreement, the Employee Matters Agreement, the Tax Matters Agreement, and the Facility Sublease Agreement. Our and Theravance's ability to satisfy these indemnities, if called upon to do so, will depend upon our and Theravance's future financial strength. If we are required to indemnify Theravance, or if we are not able to collect on indemnification rights from Theravance, our business prospects and financial condition may be harmed.

*We may have received better terms from unaffiliated third parties than the terms we receive in our agreements with Theravance.*

The agreements we have entered into with Theravance in connection with the spin-off were determined by management and the Theravance board of directors in the context of the spin-off while we were still part of Theravance and, accordingly, may not reflect terms that would have resulted from arm's-length negotiations between unaffiliated third parties. The terms of the agreements relate to, among other things, the licensing of intellectual property and the provision of certain employment and transition services.

Table of Contents

We may have received better terms from third parties because, among other things, third parties may have competed with each other to win our business.

*Certain of our directors and officers may have actual or potential conflicts of interest because of their equity ownership in Theravance, and our Chairman and Chief Executive Officer may have actual or potential conflicts of interest because he also serves as Chairman and Chief Executive Officer of Theravance, which actual or potential conflicts may harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Theravance.*

Rick E Winningham serves as our Chairman and Chief Executive Officer and currently holds the same positions for Theravance. In addition, certain of our directors and executive officers hold shares of Theravance's common stock or rights to acquire such shares, and these holdings may be significant for some of these individuals compared to their total assets. This service to both companies and ownership of Theravance common stock may create, or may create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for Theravance and for us. For example, potential or actual conflicts could arise relating to: our relationship with Theravance, including Theravance's and our respective rights and obligations under agreements entered into in connection with the spin-off; Theravance's management of Theravance Respiratory Company, LLC ( "TRC" ), the Delaware limited liability company to which Theravance assigned its strategic alliance agreement with Glaxo Group Limited ( "GSK" ) and all of its rights and obligations under its LABA collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO ELLIPTA® and vilanterol monotherapy, particularly given that we and Theravance have different economic interests in TRC; the compensation of Mr. Winningham who serves as an officer of both companies; and corporate opportunities that may be available to both companies in the future. Although we and Theravance have implemented policies and procedures to identify and properly address such potential and actual conflicts of interest, there can be no assurance that such conflicts of interest will not harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Theravance.

*We may be treated as a U.S. corporation for U.S. federal income tax purposes.*

For U.S. federal income tax purposes, a corporation generally is considered tax resident in the place of its incorporation. Because Theravance Biopharma is incorporated under Cayman Islands law, it should be deemed a Cayman Islands corporation under this general rule. Section 7874 of the Internal Revenue Code of 1986, as amended (the "Code" ), however, contains rules that could result in a foreign corporation being taxed as a U.S. corporation for U.S. federal income tax purposes. The application of these rules is complex and there is little guidance regarding their application.

Under Section 7874 of the Code, a corporation created or organized outside the U.S. will be treated as a U.S. corporation for U.S. federal tax purposes, when (i) the foreign corporation directly or indirectly acquires substantially all of the assets held directly or indirectly by a U.S. corporation, (ii) the former shareholders of the acquired U.S. corporation hold at least 80% of the vote or value of the shares of the foreign acquiring corporation by reason of holding stock in the U.S. acquired corporation, and (iii) the foreign corporation's expanded affiliated group does not have substantial business activities in the foreign corporation's country of incorporation relative to its expanded affiliated group's worldwide activities. For this purpose, expanded affiliated group generally means the foreign corporation and all subsidiaries in which the foreign corporation, directly or indirectly, owns more than 50% of the stock by vote and value, and substantial business activities generally means at least 25% of employees (by number and compensation), assets and gross income of our expanded affiliated group are based, located and derived, respectively, in the Cayman Islands.

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

We do not expect to be treated as a U.S. corporation under Section 7874 of the Code, because the assets contributed to us by Theravance are not expected to constitute substantially all of the properties of Theravance (as determined on both a gross and net fair market value basis). However, the IRS may disagree with our conclusion on this point and assert that, in its view, the assets contributed to us by Theravance do constitute substantially all of the properties of Theravance. In addition, there have been legislative proposals to expand the scope of U.S. corporate tax residence and there could be changes to Section 7874 of the Code or the Treasury Regulations promulgated thereunder that could result in Theravance Biopharma being treated as a U.S. corporation.

If it were determined that we should be taxed as a U.S. corporation for U.S. federal income tax purposes, we could be liable for substantial additional U.S. federal income tax on our post-spin-off taxable income. In addition, payments of dividends to non-U.S. holders may be subject to U.S. withholding tax.

***We are likely to be classified as a passive foreign investment company, or PFIC, which may have adverse U.S. federal income tax consequences to U.S. holders.***

For U.S. federal income tax purposes, Theravance Biopharma generally would be classified as a PFIC for any taxable year if either (i) 75% or more of its gross income (including gross income of certain 25%-or-more-owned corporate subsidiaries) is passive income (as defined for such purposes) or (ii) the average percentage of its assets (including the assets of certain 25%-or-more-owned corporate subsidiaries) that produce passive income or that are held for the production of passive income is at least 50%.

Table of Contents

We believe that Theravance Biopharma is a PFIC and may continue to be a PFIC in subsequent years. If we were to be treated as a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. holder, then the U.S. holder would generally be subject to additional U.S. federal income taxes plus an interest charge with respect to distributions from Theravance Biopharma. U.S. holders of our ordinary shares may wish to file elections to be treated as owning an interest in a qualified electing fund ( QEF ) or to mark-to-market their ordinary shares to avoid the interest charge consequences of the default PFIC treatment. U.S. holders of our ordinary shares should consult their tax advisers regarding the potential PFIC, QEF and Mark-to-Market treatment of their interests in our ordinary shares.

**RISKS RELATING TO THE COMPANY**

*We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability.*

First as Theravance, and since June 2, 2014 as Theravance Biopharma, we have been engaged in discovery and development of compounds and product candidates since mid-1997. We may never generate sufficient revenue from the sale of medicines or royalties on sales by our partners or via our interest in TRC to achieve profitability. During the quarter ended March 31, 2014 and the years ended December 31, 2013 and 2012, we recognized losses of \$60.0 million, \$156.3 million and \$9.6 million, respectively, which are reflected in the Parent Company Deficit on Theravance Biopharma's condensed combined balance sheet. We will reflect cumulative net loss incurred and retained after June 2, 2014, the effective date of the spin-off, as accumulated deficit on Theravance Biopharma's consolidated balance sheets. We expect to continue to incur net losses over the next several years as we continue our drug discovery efforts and incur significant preclinical and clinical development costs related to our current product candidates and commercialization and development costs relating to VIBATIV®. In particular, we will incur substantial expenses to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, in April 2014, we initiated a dose-ranging Phase 2b study with TD-4208, our LAMA compound, as a nebulized aqueous solution in patients with moderate to severe COPD, and announced positive results from a Phase 2 study of TD-9855, an investigational norepinephrine and serotonin reuptake inhibitor, in our MARIN program, in patients with fibromyalgia. Also, in July 2012, Theravance announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we are seeking to partner these programs, we may choose to progress one or more of these programs into later stage clinical studies by ourselves or progress telavancin, our approved antibiotic, into a Phase 3 study for a new indication by ourselves, which could increase our anticipated operating expenses substantially. We currently employ or have contracted with a small number of sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV®. Furthermore, if we cannot or choose not to identify a commercialization partner for VIBATIV® in the U.S. we will not be able to leverage a commercialization partner's capabilities and infrastructure and we will incur all of the costs and expenses associated with the commercialization of VIBATIV® in the U.S., including the creation of an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities, expansion of medical affairs presence, manufacturing and third party vendor logistics and consultant support, and post-marketing studies. Our commitment of resources to VIBATIV® (telavancin), to the continued development of our existing product candidates and to our discovery programs will require significant additional funding. Our operating expenses also will increase if:

- our earlier stage potential products move into later stage clinical development, which is generally a more expensive stage of development;
- additional preclinical product candidates are selected for clinical development;
- we pursue clinical development of our potential products or telavancin, our approved antibiotic, in new indications;

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

- we increase the number of patents we are prosecuting or otherwise expend additional resources on patent prosecution or defense; and
- we acquire additional technologies, product candidates, products or businesses.

Other than potential revenues from VIBATIV®, our only approved drug, and potential contingent payments under collaboration agreements, we do not expect to generate sales revenues from our drug programs for the foreseeable future. Since we or our collaborators or licensees may not successfully develop additional products, obtain required regulatory approvals, manufacture products at an acceptable cost or with appropriate quality, or successfully market such products with desired margins, our expenses may continue to exceed any revenues we may receive.

Table of Contents

In the absence of substantial licensing, contingent payments or other revenues from third-party collaborators, royalties on sales of products licensed under our intellectual property rights, future revenues from our products in development or other sources of revenues, we will continue to incur operating losses and may require additional capital to fully execute our business strategy. The likelihood of reaching, and time required to reach, sustained profitability are highly uncertain. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will ever be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

*If additional capital is not available, we may have to curtail or cease operations or we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.*

Based on our current operating plans and financial forecasts, we believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. If our current operating plans or financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings, debt financings or additional collaborations and licensing arrangements. For example, if we chose to conduct Phase 3 studies with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation, or with telavancin, our approved antibiotic, for a new indication, or progress TD-4208 in our LAMA program or TD-9855 in our MARIN program into later-stage development, and we choose to progress any of these programs on our own, our capital needs would increase substantially.

Although we expect that we will have sufficient cash to fund our operations and working capital requirements for at least the next twelve months based on current operating plans and financial forecasts, we may need to raise additional capital in the future to, among other things:

- fund our discovery efforts and research and development programs;
- progress mid-to-late stage product candidates into Phase 3 development, if warranted;
- progress telavancin into a Phase 3 study for a new indication, if warranted;
- bear the full cost of developing our own sales, marketing and distribution capabilities to commercialize VIBATIV® in the U.S. with appropriate technical expertise and supporting infrastructure, if we cannot or choose not to identify a commercialization partner;
- respond to competitive pressures; and
- acquire complementary businesses or technologies.

Our future capital needs depend on many factors, including:

- the scope, duration and expenditures associated with our discovery efforts and research and development programs;
- continued scientific progress in these programs;
- the extent to which we encounter technical obstacles in our research and development programs;
- the outcome of potential licensing or partnering transactions, if any;
- competing technological developments;
- the extent of our proprietary patent position in our product candidates;
- our facilities expenses, which will vary depending on the time and terms of any facility lease or sublease we may enter into;
- potential litigation and other contingencies; and
- the regulatory approval process for our product candidates.



Table of Contents

We may seek to raise necessary funds through public or private equity offerings, debt financings or additional collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets. We may be required to relinquish rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us, in order to raise additional funds through collaborations or licensing arrangements. If adequate funds are not available, we may have to sequence preclinical and clinical studies as opposed to conducting them concomitantly in order to conserve resources, or delay, reduce or eliminate one or more of our research or development programs and reduce overall overhead expenses. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery and development efforts and exploiting other corporate opportunities. This would likely harm our business, prospects and financial condition and cause the price of our securities to fall.

***We may obtain future financing through the issuance of debt or equity, which may have an adverse effect on our shareholders or may otherwise adversely affect our business.***

If we raise funds through the issuance of debt, convertible debt or equity, any debt securities or preferred shares issued will have rights, preferences and privileges senior to those of holders of our ordinary shares in the event of liquidation. In such event, there is a possibility that once all senior claims are settled, there may be no assets remaining to pay out to the holders of ordinary shares. In addition, if we raise funds through the issuance of additional equity, whether through private placements or public offerings, such an issuance would dilute ownership of current shareholders in us.

The terms of debt securities may also impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, to pay dividends on or repurchase our share capital, or to make certain acquisitions or investments. In addition, we may be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control.

***In February 2014, GSK noted an intention to move the UMEC/VI/FF (LABA/LAMA/ICS) program being developed under Theravance's LABA collaboration into Phase 3 in 2014 or 2015. If GSK is unable to meet that goal, if the program encounters delays, does not demonstrate safety and efficacy, is terminated, or if there are any adverse developments or perceived adverse developments with respect to the program, our business will be harmed, and the price of our securities could fall.***

Under the LABA collaboration and strategic alliance agreements between the parties, GSK and Theravance are exploring various paths to create triple therapy respiratory medications. The use of triple therapy is supported by the GOLD (Global initiative for chronic Obstructive Lung Disease) guidelines in high-risk patients with severe COPD and a high risk of exacerbations. One potential triple therapy path is the combination of UMEC/VI (two separate bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA® dry powder inhaler, referred to as UMEC/VI/FF. In February 2014, GSK noted an intention to move UMEC/VI/FF into Phase 3 in 2014 or 2015. If GSK is unable to meet that goal, if the program encounters delays, does not demonstrate safety and efficacy, is terminated, or if there are any adverse developments or perceived adverse developments with respect to the program, our business will be harmed, and the price of our securities could fall.

***If the MABA program for the treatment of chronic obstructive pulmonary disease ( COPD ) encounters further delays, does not demonstrate safety and efficacy or is terminated, our business will be harmed, and the price of our securities could fall.***

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

The lead compound, GSK961081 ( 081), in the MABA program that Theravance partnered with GSK and to which we have certain economic rights, has completed a Phase 2b study, a Phase 1 study in combination with the inhaled corticosteroid, fluticasone propionate ( FP ), and a number of Phase 3-enabling non-clinical studies. 081 is now being progressed as a combination with fluticasone furoate ( FF ) delivered once-daily in the ELLIPTA® inhaler which requires additional work on non-clinical studies, manufacturing and a Phase 1 bioequivalence study. As a result, it is unlikely that a Phase 3 study with 081 will commence in 2014. Any further delays or adverse developments or results or perceived adverse developments or results with respect to the MABA program will harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- GSK deciding to further delay or halt development of 081 or 081/FF;
- the U.S. Food and Drug Administration ( FDA ) and/or other regulatory authorities determining that any of these studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the MABA program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program; or

Table of Contents

- any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

Furthermore, we have no access to confidential information regarding the progress of, or plans for, the MABA program and we have little, if any, ability to influence the progress of the MABA program, because our interest in this program is only through our economic interest in TRC, which is controlled by Theravance.

***We currently employ or have contracted a small number of sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV®. If we cannot or choose not to identify a commercialization partner for VIBATIV® in the U.S. we will bear the full cost of developing the capability to market, sell and distribute the product.***

We evaluate commercial strategy on a product by product basis either to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products or to commercialize a product ourselves. However, we may not be able to establish these sales and distribution relationships on acceptable terms, or at all, or may encounter difficulties in commercializing a product ourselves. For any of our product candidates that receive regulatory approval in the future and are not covered by our current collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. VIBATIV® was returned to Theravance by Astellas Pharma Inc. ( Astellas ), Theravance's former VIBATIV® collaboration partner, in January 2012. Astellas had the right to terminate the agreement if a VIBATIV® new drug application was not approved by the FDA within two years of submission, or if VIBATIV® was not approved by the FDA for both complicated skin and skin structure infections ( cSSSI ) and hospital-acquired pneumonia by December 31, 2008. Both of these conditions giving rise to Astellas' termination rights existed in January 2012 when Astellas exercised its right to terminate the agreement. On August 14, 2013 Theravance announced the reintroduction of VIBATIV® to the U.S. market with the commencement of shipments into the wholesaler channel. While we have contracted a small sales force and are expanding our medical affairs presence, other commercialization alternatives for the U.S. market are being evaluated. The risks of commercializing VIBATIV® in the U.S. without a partner include:

- costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, which costs and expenses could, depending on the scope and method of the marketing effort, exceed any product revenue from VIBATIV® for several years;
- our unproven ability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the unproven ability of sales personnel to obtain access to or educate adequate numbers of physicians about prescribing VIBATIV® in appropriate clinical situations; and
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines.

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

If we cannot or choose not to partner VIBATIV® in the U.S. with a third party with marketing, sales and distribution capabilities and if we are not successful in recruiting sales and marketing personnel or in building an internal sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, we will have difficulty commercializing VIBATIV® in the U.S., which would adversely affect our business and financial condition and which could cause the price of our securities to fall.

*With regard to all of our programs, any delay in commencing or completing clinical studies for product candidates and any adverse results from clinical or non-clinical studies or regulatory obstacles product candidates may face, would harm our business and could cause the price of our securities to fall.*

Each of our product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. Non-clinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies or decisions to terminate programs. The commencement and completion of clinical studies for our product candidates may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness of product candidates during clinical studies (for example, as Theravance experienced when TD-9855 did not meet the primary efficacy endpoints in the Phase 2 study in adult patients with Attention-Deficit/Hyperactivity Disorder);
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;

Table of Contents

- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in non-clinical and clinical studies;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- failure of our partners to advance our product candidates through clinical development;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and
- a regional disturbance where we or our collaborative partners are enrolling patients in clinical trials, such as a pandemic, terrorist activities or war, political unrest or a natural disaster.

***If our product candidates that we develop on our own or with collaborative partners are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.***

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

The FDA must approve any new medicine before it can be marketed and sold in the U.S. We must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a new drug application, or NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. In order to market our medicines in foreign jurisdictions, we must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult.

Clinical studies involving our product candidates may reveal that those candidates are ineffective, inferior to existing approved medicines, unacceptably toxic, or that they have other unacceptable side effects. In addition, the results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical studies may not produce the same results as earlier-stage clinical studies.

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical or non-clinical studies. In addition, clinical and non-clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these studies are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates. Further, the implementation of new laws and regulations, and revisions to FDA clinical trial design guidance, have increased uncertainty regarding the approvability of a new drug. In addition, over the past decade, the FDA has implemented additional requirements for approval of new drugs, including advisory committee meetings for new chemical entities, and formal risk evaluation and mitigation strategy at the FDA's discretion. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our and our collaborative partner's product candidates, which would materially harm our business and financial condition and could cause the price of our securities to fall.

Table of Contents

***We rely on a single manufacturer for the Active Pharmaceutical Ingredient ( API ) for telavancin and a separate, single manufacturer for VIBATIV® drug product supply. Our business will be harmed if either of these single-source manufacturers are not able to satisfy demand and alternative sources are not available.***

We have a single source of supply of API for telavancin and another, separate single source of supply of VIBATIV® drug product. If, for any reason, either single-source third party manufacturer of telavancin API or of VIBATIV® drug product is unable or unwilling to perform, or if its performance does not meet regulatory requirements, including maintaining current Good Manufacturing Practice ( cGMP ) compliance, we may not be able to locate alternative manufacturers, enter into acceptable agreements with them or obtain sufficient quantities of API or finished drug product in a timely manner. Any inability to acquire sufficient quantities of API or finished drug product in a timely manner from current or future sources would adversely affect the commercialization of VIBATIV® and our obligations to our partners and could cause the price of our securities to fall.

Theravance's previous VIBATIV® commercialization partner failed to maintain a reliable source of drug product supply which resulted in critical product shortages and, eventually, suspension of commercialization. In May 2012, Theravance entered into an agreement with Hospira Worldwide, Inc. ( Hospira ) to supply VIBATIV® drug product. In June 2013, the FDA approved Hospira as a VIBATIV® drug product manufacturer, and this agreement with Hospira has been assigned to Theravance Biopharma. Although we believe that Hospira will be a reliable supplier of VIBATIV® drug product, if it cannot perform or if its performance does not meet regulatory requirements, including maintaining cGMP compliance, and if commercial manufacture of VIBATIV® drug product cannot be arranged elsewhere on a timely basis, the commercialization of VIBATIV® in the U.S. will continue to be adversely affected and the commercial introduction of VIBATIV® in the European Union and Canada will be further delayed.

***We rely on a single source of supply for a number of our product candidates, and our business will be harmed if any of these single-source manufacturers are not able to satisfy demand and alternative sources are not available.***

We have limited in-house production capabilities for preclinical and clinical study purposes, and depend primarily on a number of third-party API and drug product manufacturers. We may not have long-term agreements with these third parties and our agreements with these parties may be terminable at will by either party at any time. If, for any reason, these third parties are unable or unwilling to perform, or if their performance does not meet regulatory requirements, we may not be able to locate alternative manufacturers or enter into acceptable agreements with them. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay preclinical and clinical studies, prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our API and drug product are subject to the FDA's cGMP regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of many of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer;

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;
- some of the manufacturing processes for our APIs and drug products have not been scaled to quantities needed for continued clinical studies or commercial sales, and delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and
- because some of the third-party manufacturers are located outside of the U.S., there may be difficulties in importing our APIs and drug products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

*Even if our product candidates receive regulatory approval, as VIBATIV® has, commercialization of such products may be adversely affected by regulatory actions and oversight.*

Even if we receive regulatory approval for our product candidates, this approval may include limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies. For example, the U.S. labeling for VIBATIV® contains a number of boxed warnings. Products with boxed warnings are subject to more restrictive advertising regulations than



Table of Contents

products without such warnings. In addition, the VIBATIV® labeling for hospital-acquired and ventilator associated pneumonia ( HAP/VABP ) in the U.S. and the European Union specifies that VIBATIV® should be reserved for use when alternative treatments are not suitable. These restrictions make it more difficult to market VIBATIV®. With VIBATIV® approved in certain countries, we are subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing.

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at contract manufacturers' facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities. For example, during the fourth quarter of 2011, the third party manufacturer of VIBATIV® drug product utilized by Theravance's former commercialization partner notified the FDA of an ongoing investigation related to its production equipment and processes. In response to this notice, Theravance's former VIBATIV® commercialization partner placed a voluntary hold on distribution of VIBATIV® to wholesalers and cancelled pending orders for VIBATIV® with this manufacturer. In April 2013, Theravance was advised by the FDA that its consent decree with the manufacturer prohibited the distribution of the VIBATIV® drug product lots previously manufactured but unreleased by this manufacturer. As a result of this supply termination, commercialization of VIBATIV® ceased for well over a year.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies with respect to VIBATIV®, as well as governmental authorities in those foreign countries in which any of our product candidates are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition, which may cause the price of our securities to fall.

The risks identified in this risk factor relating to regulatory actions and oversight by agencies in the U.S. and throughout the world also apply to the commercialization of any partnered products by our collaboration partners, and such regulatory actions and oversight may limit our collaboration partners' ability to commercialize such products, which could materially and adversely affect our business and financial condition, which may cause the price of our securities to fall.

***VIBATIV® may not be accepted by physicians, patients, third party payors, or the medical community in general.***

The commercial success of VIBATIV® depends upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that VIBATIV® will be accepted by these parties. VIBATIV® competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV® for the treatment of cSSSI and HAP/VABP caused by susceptible Gram-positive bacteria in adult patients is a suitable alternative to vancomycin and other antibacterial drugs in certain clinical situations, we may never generate meaningful revenue from VIBATIV® which could cause the price of our securities to fall. The degree of market acceptance of VIBATIV® depends on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of VIBATIV®;
- the experiences of physicians, patients and payors with the use of VIBATIV® in the U.S.;
- potential negative perceptions of physicians related to product shortages and regional supply outages that halted commercialization of VIBATIV®, stemming from the manufacturing issues at the previous drug product supplier;
- potential negative perceptions of physicians related to the European Commission's previous suspension of marketing authorization for VIBATIV® (which suspension was recently lifted in March 2014) because the prior VIBATIV® commercialization partner's single-source VIBATIV® drug product supplier did not meet the cGMP requirements for the manufacture of VIBATIV®;

Table of Contents

- the advantages and disadvantages of VIBATIV® compared to alternative therapies;
- our ability to educate the medical community about the appropriate circumstances for use of VIBATIV®;
- the reimbursement policies of government and third party payors; and
- the market price of VIBATIV® relative to competing therapies.

***If our partners do not satisfy their obligations under our agreements with them, or if they terminate our partnerships with them, we may not be able to develop or commercialize our partnered product candidates as planned.***

In October 2012, Theravance entered into an exclusive development and commercialization agreement with Alfa Wassermann società per azioni (S.p.A.) (Alfa Wassermann) for velusetrag, our lead compound in the 5-HT<sub>4</sub> program, covering the European Union, Russia, China, Mexico and certain other countries, and Theravance entered into a research collaboration and license agreement with Merck to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease on an exclusive, worldwide basis. In March 2013, Theravance entered into a commercialization agreement with Clinigen Group plc (Clinigen) for VIBATIV® in the European Union and certain other European countries (including Switzerland and Norway). In connection with these agreements, Theravance granted to these parties certain rights regarding the use of its patents and technology with respect to the compounds in our development programs, including development and marketing rights. In September 2013, Merck terminated its research collaboration and license agreement with Theravance. The Alfa Wassermann agreement provides research and development funding for the program under license, and if it decides not to progress the licensed program, we may not be able to develop or commercialize the program on our own. The Alfa Wassermann and Clinigen agreements were assigned to us in the spin-off.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they may terminate our partnership with them as Astellas did to Theravance in January 2012 with its VIBATIV® agreement and as Merck did to Theravance in September 2013 with the cardiovascular disease collaboration. In either event, we may be unable to assume the development and commercialization of the product candidates covered by the agreements or enter into alternative arrangements with a third party to develop and commercialize such product candidates. If a partner elected to promote its own products and product candidates in preference to those licensed from us, the development and commercialization of product candidates covered by the agreements could be delayed or terminated, and future payments to us could be delayed, reduced or eliminated and our business and financial condition could be materially and adversely affected. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements is dependent on the efforts of our partners. If a partner terminates or breaches its agreements with us, otherwise fails to complete its obligations in a timely manner or alleges that we have breached our contractual obligations under these agreements, the chances of successfully developing or commercializing product candidates under the collaboration could be materially and adversely affected. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration.

***Because GSK is a strategic partner of Theravance, a strategic partner of TRC and a significant shareholder of us, it may take actions that in certain cases are materially harmful to both our business or to our other shareholders.***

Based on our review of publicly available filings as of June 4, 2014, GSK beneficially owned approximately 25.7% of our outstanding ordinary shares. GSK is also a strategic partner to Theravance with rights and obligations under its collaboration agreement with Theravance and its strategic alliance agreement with TRC (collectively, the "GSK Agreements") that may cause GSK's interests to differ from the interests of us and our other shareholders. In particular, upon the regulatory approval of UMEC/VI/FF or a MABA/ICS in either the U.S. or the European Union, GSK's diligent efforts obligations under the GSK Agreements with regard to commercialization matters will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Following such regulatory approval, GSK's commercialization efforts will be guided by a portfolio approach across products in which we have an indirect interest through TRC and products in which we have no interest. Accordingly, GSK's commercialization efforts may have the effect of reducing the value of our interest in TRC. Furthermore, GSK has a substantial respiratory product portfolio in addition to the products covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with Theravance and TRC. For example, GSK could promote its own respiratory products and/or delay or terminate the development or commercialization of the respiratory programs covered by the GSK agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us or acquire our interests in TRC in order to effectively reduce those payment obligations, though the actions GSK may take to acquire us will be limited under

Table of Contents

our governance agreement with GSK which will expire on December 31, 2017 (the Governance Agreement ). The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other shareholders. In addition, GSK could also seek to challenge our post-spin-off operations as violating or allowing it to terminate the GSK Agreements, including by violating the confidentiality provisions of those agreements or the master agreement between GSK, Theravance and us entered into in connection with the spin-off, or otherwise violating its legal rights. While we believe our operations fully comply with the GSK Agreements, the master agreement and applicable law, there can be no assurance that we or Theravance will prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any uncertainty about the respiratory programs partnered with GSK or the enforceability of the GSK Agreements could result in significant reduction in the market price of our securities and other material harm to our business.

***Agreements entered into with or for the benefit of GSK in connection with the spin-off may significantly restrict our business and affairs.***

On March 3, 2014, in connection with the spin-off, we, Theravance and GSK entered into a number of agreements that may significantly restrict our business and affairs. In particular, we, Theravance and GSK entered into a three-way master agreement (the Master Agreement ) that, among other things, requires GSK's consent to make any changes to (A) the Separation and Distribution Agreement, Transition Services Agreement, Employee Matters Agreement and Tax Matters Agreement that would, individually or in the aggregate, reasonably be expected to adversely affect GSK in any material respect or (B) to the TRC Limited Liability Company Agreement, which consent is not to be unreasonably withheld, conditioned or delayed, provided that GSK may withhold, condition or delay such consent in its sole discretion with respect to certain sections of the TRC Limited Liability Company Agreement and any changes to the governance structure of TRC, the confidentiality restrictions, the consent rights, and the transfer restrictions in the TRC Limited Liability Company Agreement. The Master Agreement also limits Mr. Winningham's ability to act as Chief Executive Officer of both us and Theravance to a period of nine months following the spin-off and also limits the periods of time that Theravance employees may provide services to us pursuant to the transition services agreement between Theravance and us. We and GSK also entered into (i) the Governance Agreement that, among other things, provides share purchase rights to GSK and exempts GSK from triggering our Rights Agreement until December 31, 2017, (ii) a registration rights agreement that gives GSK certain registration rights with respect to our ordinary shares held by GSK and (iii) an extension agreement that extends to us certain restrictive covenants similar to those applicable to Theravance under the GSK Agreements. There can be no assurance that these restrictions will not materially harm our business, particularly given that GSK's interests may not be aligned with the interests of our business or our other shareholders.

***We do not control TRC and, in particular, have no control over or access to non-public information about the GSK-partnered respiratory programs assigned to TRC in which we have a substantial economic interest.***

Theravance has assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO ELLIPTA® and vilanterol monotherapy. Our equity interest in TRC entitles us to an 85% economic interest in any future payments made by GSK under the strategic alliance agreement with GSK and under the portion of the collaboration agreement with GSK assigned to TRC. These other drug programs include UMEC/VI/FF and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (ICS), and any other product or combination of products that may be discovered and developed in the future under the GSK Agreements. Our economic interest does not include any payments by GSK associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO ELLIPTA® or vilanterol monotherapy. Theravance controls TRC and, except for certain limited consent rights, we have no right to participate in the business and affairs of TRC. Theravance has the exclusive right to appoint TRC's manager who, among other things, is responsible for the day-to-day management of the drug programs assigned to TRC and exercises the rights relating to the drug programs under the GSK Agreements assigned to TRC by Theravance. As a result, we have no rights to participate in or access to non-public information about the development and commercialization of the drug programs and no right to enforce rights under the GSK Agreements assigned to TRC. Moreover, we have many of the same risks with respect to our dependence on GSK as we have with respect to our dependence on our own partners.

*If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, we will be unable to fully develop and commercialize our product candidates and our business will be adversely affected.*

Theravance's collaborations with Alfa Wassermann for velusetrag, with Clinigen for VIBATIV® for the European Union, and with other companies for regional development and commercialization of VIBATIV® were assigned to us in connection with the spin-off. Also, through our interest in TRC we may participate economically in Theravance's collaborations with GSK with respect to certain GSK-partnered respiratory programs. Additional collaborations will be needed to fund later-stage development of our product

Table of Contents

candidates that have not been licensed to a collaborator or for territory that is not covered by existing collaborations, and to commercialize these product candidates if approved by the necessary regulatory authorities. For example, in April 2014, Theravance announced positive results from a Phase 2 study of TD-9855, an investigational norepinephrine and serotonin reuptake inhibitor, in our MARIN program, in patients with fibromyalgia. Velusetrag, our lead compound in the 5-HT4 program, and TD-1792, our investigational antibiotic, have successfully completed Phase 2 proof-of-concept studies and currently are not partnered in the U.S. In July 2012 Theravance reported positive results from a Phase 2b study with TD-1211, the lead compound in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation and in September 2013 Theravance reported positive top-line results from a Phase 2b study with TD-4208 LAMA compound which Theravance recently progressed into a larger Phase 2b study in COPD patients. In some instances, we may seek additional third parties with which to pursue collaboration arrangements for the development and commercialization of our development programs and for the future commercialization of VIBATIV® in regions where it is not currently partnered. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than the arrangements Theravance negotiated and assigned to us, or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to prioritize alternative programs. Our inability to successfully collaborate with third parties would increase our development costs and would limit the likelihood of successful commercialization of our product candidates which may cause the price of our securities to fall.

***We depend on third parties in the conduct of our clinical studies for our product candidates.***

We depend on independent clinical investigators, contract research organizations and other third-party service providers in the conduct of our non-clinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our non-clinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that our clinical studies are conducted in accordance with good clinical practices ( GCPs ) and other regulations as required by the FDA and foreign regulatory authorities, and the applicable protocol. Failure by these parties to comply with applicable regulations, GCPs and protocols in conducting studies of our product candidates can result in a delay in our development programs or non-approval of our product candidates by regulatory authorities.

The FDA enforces GCPs and other regulations through periodic inspections of trial sponsors, clinical research organizations ( CROs ), principal investigators and trial sites. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GCPs, the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, could result in significant additional costs and could cause the price of our securities to fall.

***We face substantial competition from companies with more resources and experience than we have, which may result in others discovering, developing, receiving approval for or commercializing products before or more successfully than we do.***

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery and development of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety using our proprietary insight in chemistry, biology and multivalency, where applicable. We expect that any medicines that we commercialize with our collaborative partners will compete with existing or future market-leading medicines.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development to:

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals; and



Table of Contents

- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

Established pharmaceutical companies, including companies with which we collaborate, may invest heavily to quickly discover and develop or in-license novel compounds that could make our product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do. Other companies are engaged in the discovery of medicines that would compete with the product candidates that we are developing.

Any new medicine that competes with a generic or proprietary market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. VIBATIV® must demonstrate these advantages in certain circumstances, as it competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

As the principles of multivalency become more widely known, we expect to face increasing competition from companies and other organizations that pursue the same or similar approaches. Novel therapies, such as gene therapy or effective vaccines for infectious diseases, may emerge that will make both conventional and multivalent medicine discovery efforts obsolete or less competitive.

***Our Chief Executive Officer is working only part-time for us while continuing to work part-time for Theravance during a transition period following the spin-off. Our business may suffer due to lack of time or attention from him or potential conflicts of interest.***

Rick E Winningham, our Chief Executive Officer, is working part-time for us and part-time for Theravance and this arrangement is expected to last until the earlier of the recruitment and transition of a new chief executive officer of Theravance or, pursuant to the terms of our master agreement with Theravance and GSK, up to nine months following the spin-off. While we benefit from his deep knowledge of our current programs, partners and personnel, as well as his familiarity with our systems, policies, procedures and mode of operation, the lack of his full time focus on our business may dilute his effectiveness on our behalf and therefore hurt our business.

***If we lose key management or scientific personnel, or if we fail to retain our key employees, our ability to discover and develop our product candidates will be impaired.***

We are highly dependent on principal members of our management team and scientific staff, and in particular, our Chief Executive Officer, Rick E Winningham, to operate our business. Mr. Winningham has significant pharmaceutical industry experience. The loss of Mr. Winningham's services could impair our ability to discover, develop and market new medicines.

Our U.S. operating subsidiary's facility and most of its and our employees are located in northern California, which is headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market is intense. None of our employees have employment commitments for any fixed period of time and they all may leave

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

our employment at will. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities, which may cause the price of our securities to fall.

***Our business and operations would suffer in the event of system failures.***

Although we have security measures in place, our internal computer systems and those of our CROs and other service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any material system failure, accident or security breach could result in a material disruption to our business. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a disruption or security breach results in a loss of or damage to our data or regulatory applications, or inadvertent disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and the price of our securities could fall.

Table of Contents

*Our U.S. operating subsidiary's facility is located near known earthquake fault zones, and the occurrence of an earthquake, extremist attack or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.*

Our U.S. operating subsidiary's facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore will be vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our research activities and of much of our equipment could make it difficult for us to recover from this type of disaster. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition, which could cause the price of our securities to fall.

*We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.*

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We plan to avail ourselves of this exemption from new or revised accounting standards and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory shareholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). If we do, the information that we provide shareholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our ordinary shares less attractive because we will rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

We expect to be an emerging growth company for all of 2014 and will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our ordinary shares that is held by non-affiliates exceeds \$700 million as of the end of the second fiscal quarter and we have been subject to public company reporting obligations for at least twelve calendar months as of the end of the fiscal year, (ii) the end of the fiscal year in which we have total annual gross revenues of \$1 billion or more during such fiscal year, (iii) the date on which we issue more than \$1 billion in non-convertible debt in a three-year period or (iv) the end of the fiscal year following the fifth anniversary of the date of the first sale of our ordinary shares pursuant to an effective registration statement filed under the Securities Act.

**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, we may not be able to compete effectively in our market.*

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of June 11, 2014, we or one of our wholly owned subsidiaries owned 357 issued United States patents and 1,256 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

Table of Contents

In addition, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery and development processes that involve proprietary know-how, information and technology that is not covered by patent applications. Although we require our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations, which could cause the price of our securities to fall.

***Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our drug discovery and development efforts.***

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. Third parties may assert that we or our partners are using their proprietary rights without authorization. There are third party patents that may cover materials or methods for treatment related to our product candidates. At present, we are not aware of any patent claims with merit that would adversely and materially affect our ability to develop our product candidates, but nevertheless the possibility of third party allegations cannot be ruled out. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us or our partners may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third parties. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our business will be harmed, which may cause the price of our securities to fall.

***If the efforts of our partners or future partners to protect the proprietary nature of the intellectual property related to collaboration assets are not adequate, the future commercialization of any medicines resulting from collaborations could be delayed or prevented, which would materially harm our business and could cause the price of our securities to fall.***

The risks identified in the two preceding risk factors may also apply to the intellectual property protection efforts of our partners or future partners and to GSK with respect to the GSK-partnered respiratory programs in which we hold an economic interest. To the extent the intellectual property protection of any partnered assets are successfully challenged or encounter problems with the United States Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset, particularly those of the GSK-partnered respiratory programs in which we hold an economic interest, could harm our business and cause the price of our securities to fall.

*Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our medicines.*

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products and have likely increased with the reintroduction of VIBATIV® to the U.S. market. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits tends to increase. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. Also, changes in laws outside the U.S. are expanding our potential liability for injuries that occur during clinical trials. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Table of Contents

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities and we cannot be sure that our insurer will not disclaim coverage as to a future claim. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business. The cost of defending any product liability litigation or other proceeding, even if resolved in our favor, could be substantial and uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability claims could also harm our reputation, which may adversely affect our and our partners' ability to commercialize our products successfully, which could cause the price of our securities to fall.

***Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.***

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following:

- our or our collaborators' ability to set a price we believe is fair for our products, if approved;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

The Patient Protection and Affordable Care Act and other potential legislative or regulatory action regarding healthcare and insurance matters, along with the trend toward managed healthcare in the United States, could influence the purchase of healthcare products and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market our potential medicines and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of the Patient Protection and Affordable Care Act and further agency regulations that are likely to emerge in connection with the passage of this act could significantly reduce potential revenues from the sale of any product candidates approved in the future. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the state and federal level, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential medicines that may be approved in the future at a price acceptable to us or our collaborators, which may cause the price of our securities to fall.

***If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with these and other

applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

## **RISKS RELATING TO OUR ORDINARY SHARES**

*Our ordinary shares only recently began trading on June 3, 2014, and the market price for our shares may fluctuate widely, resulting in substantial losses for purchasers of our ordinary shares.*

Our ordinary shares only recently began trading on June 3, 2014, and the market price for our shares may fluctuate widely, resulting in substantial losses for purchasers of our ordinary shares. To date, there is limited securities analyst coverage of our company. Limited securities analyst coverage of our company and shares is likely to reduce demand for our shares from potential investors, which likely will reduce the market price for our shares.

Market prices for securities of biotechnology and biopharmaceutical companies have been highly volatile, and we expect such volatility to continue for the foreseeable future, so that investment in our ordinary shares involves substantial risk. By separating from Theravance, there is a risk that our company may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Theravance. Additionally, the stock market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. Also, the trading price of shares of newly



Table of Contents

public companies distributed in spin-off transactions, as our shares have been distributed, can often be very volatile and subject to sharp declines, particularly shortly following the spin-off. The following are some of the factors that may have a significant effect on the market price of our ordinary shares:

- any adverse developments or results or perceived adverse developments or results with respect to the MABA program with GSK, including, without limitation, any further delays encountered in progressing 081 and/or 081/FF, any difficulties or delays encountered with regard to the regulatory path for 081, either alone or in combination with other therapeutically active ingredients, or any indication from non-clinical studies of 081 that the compound is not safe or efficacious;
- the extent to which GSK advances (or does not advance) UMEC/VI/FF through development into commercialization in all indications in all major markets;
- any further adverse developments or perceived adverse developments with respect to the commercialization of VIBATIV®;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development or have commercialized;
- any adverse developments or agreements or perceived adverse developments or agreements with respect to the relationship of Theravance or TRC, on the one hand, and GSK, on the other hand, including any such developments or agreements resulting from or relating to the spin-off;
- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners, including, without limitation, disagreements that may arise between us and any of those partners, including any such developments resulting from or relating to the spin-off;
- any adverse developments or perceived adverse developments in our programs with respect to partnering efforts or otherwise;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

- regulatory developments in the United States and foreign countries;
- economic and other external factors beyond our control;
- loss of key personnel;
- relative illiquidity in the public market for our ordinary shares related to the concentration of ownership;
- developments or disputes as to patent or other proprietary rights;
- approval or introduction of competing products and technologies;
- results of clinical trials;
- failures or unexpected delays in timelines for our potential products in development, including the obtaining of regulatory approvals;
- delays in manufacturing or clinical trial plans;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;

Table of Contents

- initiation, termination or modification of agreements with our collaborators or disputes or disagreements with collaborators;
- litigation or the threat of litigation;
- public concern as to the safety of drugs developed by us; and
- comments and expectations of results made by securities analysts or investors.

If any of these factors causes us to fail to meet the expectations of securities analysts or investors, or if adverse conditions prevail or are perceived to prevail with respect to our business, the price of the ordinary shares would likely drop significantly. A significant drop in the price of a company's securities often leads to the filing of securities class action litigation against the company. This type of litigation against us could result in substantial costs and a diversion of management's attention and resources.

***Concentration of ownership will limit your ability to influence corporate matters.***

Theravance Biopharma's ownership at the time of the spin-off reflected the ownership composition of Theravance. Based on our review of publicly available filings as of June 4, 2014, GSK beneficially owned approximately 25.7% of our outstanding ordinary shares. Based on our review of publicly available filings as of March 31, 2014, the three largest Theravance, Inc. stockholders other than GSK collectively owned approximately 36.6% of its outstanding capital stock. Assuming these shareholders held a similar percentage as of the record date to determining the Theravance, Inc. stockholders that would receive our shares in the spin-off, these shareholders and GSK could control the outcome of actions taken by us that require shareholder approval, including a transaction in which shareholders might receive a premium over the prevailing market price for their shares.

***Your percentage ownership in Theravance Biopharma will be diluted in the future.***

Your percentage ownership in Theravance Biopharma will be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees in the future, as well as other equity instruments such as debt and equity financing. We have adopted an equity incentive plan that provides for the grant of equity-based awards, including restricted shares, restricted share units, options, share appreciation rights and other equity-based awards, to our directors, officers and other employees and advisors. Shortly after the spin-off, we granted share options to our directors pursuant to our outside director automatic grant program and to our employees joining Theravance Biopharma, and we expect to grant additional share options as we continue to build out our leadership team.

*Certain provisions in our constitutional documents may discourage our acquisition by a third party, which could limit your opportunity to sell shares at a premium.*

Our constitutional documents include provisions that could limit the ability of others to acquire control of us, modify our structure or cause us to engage in change-of-control transactions, including, among other things, provisions that:

- require supermajority shareholder voting to effect certain amendments to our amended and restated memorandum and articles of association;
- establish a classified board of directors;
- restrict our shareholders from calling meetings or acting by written consent in lieu of a meeting;
- limit the ability of our shareholders to propose actions at duly convened meetings; and
- authorize our board of directors, without action by our shareholders, to issue preferred shares and additional ordinary shares.

These provisions could have the effect of depriving you of an opportunity to sell your ordinary shares at a premium over prevailing market prices by discouraging third parties from seeking to acquire control of us in a tender offer or similar transaction.

*Our shareholders may face difficulties in protecting their interests because we are incorporated under Cayman Islands law.*

Our corporate affairs will be governed by our amended and restated memorandum and articles of association to be effective following the spin-off, by the Companies Law (2012 Revision) (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under the laws of the Cayman Islands are different from those under statutes or judicial precedent in existence in jurisdictions in the U.S. Therefore, you may have more difficulty in protecting your interests than would shareholders of a corporation incorporated in a jurisdiction in the U.S., due to the different nature of Cayman Islands law in this area.

Table of Contents

While Cayman Islands law allows a dissenting shareholder to express the shareholder's view that a court sanctioned reorganization of a Cayman Islands company would not provide fair value for the shareholder's shares, Cayman Islands statutory law does not specifically provide for shareholder appraisal rights on a merger or consolidation of a company. This may make it more difficult for you to assess the value of any consideration you may receive in a merger or consolidation or to require that the offeror give you additional consideration if you believe the consideration offered is insufficient.

Shareholders of Cayman Islands exempted companies such as our company have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders. Our directors have discretion under our amended and restated memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Our Cayman Islands counsel, Maples and Calder, is not aware of any reported class action having been brought in a Cayman Islands court. Derivative actions have been brought in the Cayman Islands courts, and the Cayman Islands courts have confirmed the availability for such actions. In most cases, the company will be the proper plaintiff in any claim based on a breach of duty owed to it, and a claim against (for example) the company's officers or directors usually may not be brought by a shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority and be applied by a court in the Cayman Islands, exceptions to the foregoing principle apply in circumstances in which:

- a company is acting, or proposing to act, illegally or beyond the scope of its authority;
- the act complained of, although not beyond the scope of the authority, could be effected if duly authorized by more than the number of votes which have actually been obtained; or
- those who control the company are perpetrating a fraud on the minority.

A shareholder may have a direct right of action against the company where the individual rights of that shareholder have been infringed or are about to be infringed.

***There is uncertainty as to shareholders' ability to enforce certain foreign civil liabilities in the Cayman Islands.***

We are incorporated as an exempted company limited by shares with limited liability under the laws of the Cayman Islands. A material portion of our assets are located outside of the United States. As a result, it may be difficult for our shareholders to enforce judgments against us or judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States or any state of the United States.

We have been advised by our Cayman Islands legal counsel, Maples and Calder, that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against Theravance Biopharma judgments of courts of the United States predicated upon the civil liability provisions of the securities laws of the United States or any State; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against Theravance Biopharma predicated upon the civil liability provisions of the securities laws of the United States or any State, on the grounds that such provisions are penal in nature. However, in the case of laws that are not penal in nature, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, and or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere. There is also recent English authority which suggests that due to the universal nature of bankruptcy/insolvency proceedings, foreign judgments obtained in foreign bankruptcy/insolvency proceedings may be enforced by the English courts automatically without applying the principles outlined above. This decision would be persuasive in the Cayman Islands but not binding. To date it has not been considered by the Cayman Islands courts. This decision has also been appealed to the Supreme Court in England and judgment is pending. The Grand Court of the Cayman Islands may stay proceedings if concurrent proceedings are being brought elsewhere, which would delay proceedings and make it more difficult for our shareholders to bring action against us.

Table of Contents

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
4.1	Registration Rights Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (1)
10.1	Master Agreement by and between Theravance, Inc., Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (2)
10.2	Extension Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (1)
10.3	Governance Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (1)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended

## Edgar Filing: Theravance Biopharma, Inc. - Form 10-Q

- 31.2 Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
- 32 Certifications Pursuant to 18 U.S.C. Section 1350
- 101 Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2014, formatted in XBRL: (i) the Condensed Combined Balance Sheets, (ii) the Condensed Combined Statements of Operations and Comprehensive Loss, (iii) the Condensed Combined Statements of Cash Flows and (iv) the Notes to the Condensed Combined Financial Statements

---

(1) Incorporated by reference to an exhibit filed with the Amendment No. 4 to the Registration Statement on Form 10 of Theravance Biopharma, Inc., filed with the Securities and Exchange Commission on April 4, 2014.

(2) Incorporated by reference to an exhibit filed with the Current Report on Form 8-K/A of Theravance, Inc., filed with the Securities and Exchange Commission on March 6, 2014.



Table of Contents

**SIGNATURES**

Pursuant to the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Theravance Biopharma, Inc.

Date: June 24, 2014

/s/ Rick E Winningham  
**Rick E Winningham**  
Chief Executive Officer

Date: June 24, 2014

/s/ Renee D. Gala  
**Renee D. Gala**  
Vice President, Finance

Table of Contents

**EXHIBIT INDEX**

Listed and indexed below are all Exhibits filed as part of this report.

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
4.1	Registration Rights Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (1)
10.1	Master Agreement by and between Theravance, Inc., Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (2)
10.2	Extension Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (1)
10.3	Governance Agreement by and between Theravance Biopharma, Inc. and Glaxo Group Limited, dated March 3, 2014 (1)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended
32	Certifications Pursuant to 18 U.S.C. Section 1350
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2014, formatted in XBRL: (i) the Condensed Combined Balance Sheets, (ii) the Condensed Combined Statements of Operations and Comprehensive Loss, (iii) the Condensed Combined Statements of Cash Flows and (iv) the Notes to the Condensed Combined Financial Statements

---

(1) Incorporated by reference to an exhibit filed with the Amendment No. 4 to the Registration Statement on Form 10 of Theravance Biopharma, Inc., filed with the Securities and Exchange Commission on April 4, 2014.

(2) Incorporated by reference to an exhibit filed with the Current Report on Form 8-K/A of Theravance, Inc., filed with the Securities and Exchange Commission on March 6, 2014.