

Theravance Biopharma, Inc.
Form 10-Q
May 13, 2015
[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, 2015

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)

98-1226628
(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

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

As of April 30, 2015, the number of the registrant's outstanding ordinary shares was 33,801,727.

Table of Contents

THERAVANCE BIOPHARMA, INC.

TABLE OF CONTENTS

	Page No.
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2015 and 2014 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014 (unaudited)</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	18
<u>Item 4. Controls and Procedures</u>	18
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	19
<u>Item 1A. Risk Factors</u>	19
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	38
<u>Item 6. Exhibits</u>	39
<u>Signatures</u>	40
<u>Exhibit Index</u>	41

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****THERAVANCE BIOPHARMA, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(In thousands, except per share data)****(Unaudited)**

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 100,899	\$ 89,215
Short-term marketable securities	135,337	165,396
Accounts receivable, net of allowances of \$433 and \$87 at March 31, 2015 and December 31, 2014	565	289
Receivables from collaborative arrangements	19,660	1,840
Prepaid and other current assets	6,758	6,084
Inventories	12,337	12,546
Total current assets	275,556	275,370
Marketable securities	38,521	51,399
Restricted cash	833	833
Property and equipment, net	9,305	9,663
Other assets	686	506
Total assets	\$ 324,901	\$ 337,771
Liabilities and Shareholders Equity:		
Current liabilities:		
Accounts payable	\$ 4,021	\$ 9,921
Accrued personnel-related expenses	10,433	18,156
Accrued clinical and development expenses	6,628	7,871
Other accrued liabilities	7,460	5,219
Deferred revenue	310	89
Total current liabilities	28,852	41,256
Deferred rent	5,044	5,150
Other long-term liabilities	1,890	1,578
Commitments and contingencies (Note 3 and 8)		
Shareholders equity		
Preferred shares, \$0.00001 par value: 230 shares authorized, no shares issued or outstanding at March 31, 2015 and December 31, 2014		
Ordinary shares, \$0.00001 par value: 200,000 shares authorized at March 31, 2015 and December 31, 2014; 33,802 and 32,221 shares issued and outstanding at March 31, 2015 and		

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

December 31, 2014			
Additional paid-in capital		470,895	429,206
Accumulated other comprehensive income (loss)		31	(82)
Accumulated deficit		(181,811)	(139,337)
Total shareholders' equity		289,115	289,787
Total liabilities and shareholders' equity	\$	324,901	\$ 337,771

See accompanying notes to condensed consolidated financial statements.

Table of Contents**THERAVANCE BIOPHARMA, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(Unaudited)**

(In thousands, except per share data)

	Three Months Ended March 31,	
	2015	2014
Revenue:		
Product sales	\$ 1,280	\$ 945
Revenue from collaborative arrangements	19,121	
Total revenue	20,401	945
Costs and expenses:		
Cost of goods sold	371	188
Research and development	36,019	41,723
Selling, general and administrative	21,748	19,052
Total costs and expenses	58,138	60,963
Loss from operations	(37,737)	(60,018)
Interest and other income	211	
Loss before income taxes	(37,526)	(60,018)
Provision for income taxes	4,948	
Net loss	\$ (42,474)	\$ (60,018)
Net loss per share:		
Basic and diluted net loss per share	\$ (1.29)	\$ (1.89)
Shares used to compute basic and diluted net loss per share	32,830	31,741

See accompanying notes to condensed consolidated financial statements.

Table of Contents

THERAVANCE BIOPHARMA, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2015	2014
Net loss	\$ (42,474)	\$ (60,018)
Other comprehensive loss:		
Net unrealized gain on marketable securities	113	
Comprehensive loss	\$ (42,361)	\$ (60,018)

See accompanying notes to condensed consolidated financial statements.

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

(In thousands)

	Three Months Ended March 31,	
	2015	2014
Operating activities		
Net loss	\$ (42,474)	\$ (60,018)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	586	732
Amortization of premium on marketable securities	239	
Share-based compensation	15,626	12,701
Charge to write-down inventory to net realizable value	79	
Excess tax benefit of share-based compensation	(391)	
Changes in operating assets and liabilities:		
Accounts receivable	(276)	196
Receivables from collaborative arrangements	(17,820)	844
Prepaid and other current assets	(674)	(1,811)
Inventories	(41)	(617)
Other assets	(180)	
Accounts payable	(5,431)	(1,094)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	(6,184)	4,563
Deferred rent	(106)	117
Deferred revenue	212	(412)
Other long-term liabilities	321	
Net cash used in operating activities	(56,514)	(44,799)
Investing activities		
Purchases of property and equipment	(657)	(1,620)
Purchases of marketable securities	(10,659)	
Maturities of marketable securities	53,470	
Net cash provided by (used in) investing activities	42,154	(1,620)
Financing activities		
Proceeds from sale of ordinary shares to Mylan, net of premium	25,753	
Excess tax benefit of share-based compensation	391	
Repurchase of shares to satisfy tax withholding	(100)	
Transfers from Theravance, Inc.		46,419
Net cash provided by financing activities	26,044	46,419
Net increase in cash and cash equivalents	11,684	
Cash and cash equivalents at beginning of period	89,215	
Cash and cash equivalents at end of period	\$ 100,899	\$

See accompanying notes to condensed consolidated financial statements.

Table of Contents

THERAVANCE BIOPHARMA, INC.

Notes to the Condensed Consolidated Financial Statements

(Unaudited)

1. Description of Operations and Summary of Significant Accounting Policies

Description of Operations

The mission of Theravance Biopharma, Inc. (Theravance Biopharma, the Company, or we and other similar pronouns) is to create value from a unique and diverse set of assets: an approved product; a development pipeline of late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the United States and Europe for certain difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for chronic obstructive pulmonary disease (COPD). Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GlaxoSmithKline plc (GSK) pursuant to its agreements with Theravance, Inc. (Theravance) relating to certain drug development programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (or the Closed Triple).

On June 1, 2014, pursuant to a Separation and Distribution Agreement between Theravance and Theravance Biopharma (the Separation and Distribution Agreement), Theravance separated its late-stage respiratory assets partnered with GSK from its biopharmaceutical operations by transferring its discovery, development and commercialization operations (the Biopharmaceutical Business) and contributing \$393.0 million of cash, cash equivalents and marketable securities into its then wholly-owned subsidiary Theravance Biopharma. 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). The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly-traded company. Prior to June 2, 2014, Theravance operated the Biopharmaceutical Business.

Basis of Presentation

The condensed consolidated financial information as of March 31, 2015, and the three months ended March 31, 2015 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. 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 consolidated financial statements should be read

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

in conjunction with the audited consolidated December 31, 2014 financial statements and notes thereto included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 13, 2015.

We describe the Biopharmaceutical Business transferred to us by Theravance in connection with the Spin-Off as if the Biopharmaceutical Business were our business for all historical periods presented and described. However, Theravance Biopharma did not conduct any operations prior to the Spin-Off.

Significant Accounting Policies

There have been no revisions in our significant accounting policies described in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014.

2. Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of outstanding, less ordinary shares subject to forfeiture. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares outstanding, less ordinary shares subject to forfeiture, plus all additional ordinary shares that would have been outstanding, assuming dilutive potential common shares had been issued for other dilutive securities.

Table of Contents

For the three months ended March 31, 2015 and 2014, diluted and basic net loss per share was identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive. Prior to the Spin-Off in June 2014, we operated as part of Theravance and not as a separate entity. As a result, the calculation of basic and diluted net loss per share assumes that the 32,260,105 ordinary shares issued to Theravance stockholders in connection with the Spin-Off, less the number of ordinary shares subject to forfeiture, were outstanding from the beginning of all periods presented.

Anti-Dilutive Securities

The following common equivalent shares were not included in the computation of diluted net loss per share because their effect was anti-dilutive:

(In thousands)	Three Months Ended March 31,	
	2015	2014
Awards outstanding under equity incentive plan and ESPP	4,353	
Forfeitable shares	395	519
	4,748	519

3. Collaborative Arrangements***Mylan******Development and Collaboration Arrangement***

In January 2015, Mylan Ireland Limited (Mylan) and we established a strategic collaboration for the development and commercialization of TD-4208 to expand the breadth of our TD-4208 development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV.

Under the terms of the agreement, Mylan and we will co-develop nebulized TD-4208 for COPD and other respiratory diseases. We will lead the U.S. registrational development program and Mylan will be responsible for reimbursement of our costs for that program up until the approval of the first new drug application, after which costs will be shared. If a product developed under the collaboration is approved in the U.S., Mylan will lead commercialization and we will retain the right to co-promote the product in the U.S. under a profit-sharing arrangement. Outside the U.S. (excluding China), Mylan will be responsible for development and commercialization and will pay us a tiered royalty on net sales at percentage royalty rates ranging from low double-digits to mid-teens. Although China is not included in the ex-US territory outright, Mylan does have a right of first negotiation with respect to the development and commercialization of nebulized TD-4208 in China. We retain worldwide rights to TD-4208 delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler (MDI/DPI), while Mylan has certain rights of first negotiation with respect to our development and commercialization of TD-4208 delivered other than via a nebulized inhalation product.

Under the agreement, Mylan will pay us an initial payment of \$15.0 million in cash in the second quarter of 2015. Also, pursuant to an ordinary share purchase agreement entered into on January 30, 2015, Mylan Inc., a subsidiary of Mylan N.V., made a \$30.0 million equity investment in us, buying 1,585,790 ordinary shares from us in early February 2015 in a private placement transaction at a price of approximately \$18.918 per share, which represented a 10% premium over the volume weighted average price per share of our ordinary shares for the five trading days ending on January 30, 2015. We are further eligible to receive from Mylan potential development and sales milestone payments totaling \$220.0 million in the aggregate, with \$175.0 million associated with TD-4208 monotherapy and \$45.0 million for future potential combination products. Development milestones are deemed to be substantive milestones and will be recognized as revenue in the period upon achievement of each respective milestone. Sales milestones are considered contingent payments and are not deemed to be substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to Mylan's performance of future commercial activities.

Under the Mylan Development and Commercialization Agreement, the significant deliverables were determined to be the license, development responsibilities and committee participation. We determined that the license represents a separate unit of accounting as the license, which includes rights to our underlying technologies for TD-4208, has standalone value because the rights conveyed permit Mylan to perform all efforts necessary to use our technologies to bring the compounds through development and, upon regulatory approval, commercialization. We based the best estimate of selling price for the license using a discounted cash flow approach. We determined that development responsibilities and committee participation represent separate units of accounting as Mylan could negotiate for and/or acquire each of these services from other third parties and we based the best estimates of the respective selling prices on the nature and timing of the services to be performed.

Table of Contents

Payments totaling \$19.2 million, consisting of the initial payment of \$15.0 million in cash and the \$4.2 million premium related to the equity investment, which represents the difference between the closing price on January 30, 2015 and the issued price of \$18.918, were allocated to the three units of accounting based on the relative selling price method. In the three months ended March 31, 2015, we recognized \$19.1 million as revenue from collaborative arrangements in the condensed consolidated statements of income as we delivered the license and technological know-how during the period. The amount allocated to the development responsibilities was recognized proportionately with the performance of the underlying services and accounted for as reductions to R&D expense. The amount allocated to committee participation is being recognized ratably over the estimated performance periods as revenue from collaborative arrangements.

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,	
	2015	2014
Mylan	\$ 4,132	\$ 72
Alfa Wassermann	422	18
R-Pharm		
Total reduction to R&D expense	\$ 4,554	\$ 90

4. Marketable Securities and Fair Value Measurements

Our portfolio of cash and investments in marketable securities includes:

(In thousands)	Fair Value Hierarchy Level	Estimated Fair Value	
		March 31, 2015	December 31, 2014
U.S. government securities	Level 1	\$ 32,557	\$ 32,541
U.S. government agencies	Level 2	39,591	39,588
U.S. corporate notes	Level 2	88,725	97,681
U.S. commercial paper	Level 2	12,985	46,985
Marketable securities		173,858	216,795
Money market funds	Level 1	77,451	69,866
Restricted cash	N/A	833	833
Total		\$ 252,142	\$ 287,494

The estimated fair value of marketable securities is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service. The fair value of our marketable securities classified within Level 2 is based upon observable inputs

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

that may include benchmark yields, reported trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers and reference data including market research publications. Gross unrealized gains and losses were not significant at either March 31, 2015 or December 31, 2014 such that amortized cost approximates estimated fair value.

At March 31, 2015, all of the marketable securities had contractual maturities within two years and the average duration of the marketable securities was approximately seven months. We do not intend to sell the investments that are in an unrealized loss position, and it is unlikely that we will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. We have determined that the gross unrealized losses on our marketable securities at March 31, 2015 were temporary in nature. All marketable securities with unrealized losses at March 31, 2015 have been in a loss position for less than twelve months.

During the three months ended March 31, 2015, we did not sell any of our marketable securities. Restricted cash pertained to certain lease agreements and letters of credit where we have pledged cash and cash equivalents as collateral. There were no transfers between Level 1 and Level 2 during the periods presented and there have been no changes to our valuation techniques since we filed our Annual Report on Form 10-K for the year ended December 31, 2014.

Table of Contents**5. Inventories**

Inventories are as follows:

(In thousands)	March 31, 2015	December 31, 2014
Raw materials	\$ 6,751	\$ 6,830
Work-in-process		145
Finished goods	5,586	5,571
Total inventories	\$ 12,337	\$ 12,546

6. Share-Based Compensation

The allocation of share-based compensation expense included in the condensed consolidated statements of operations was as follows:

(In thousands)	Three Months Ended March 31,	
	2015	2014
Research and development	\$ 7,482	\$ 4,721
Selling, general and administrative	8,144	7,980
Total share-based compensation expense	\$ 15,626	\$ 12,701

Total share-based compensation expense capitalized to inventory was not material for any of the periods presented.

7. Income Taxes

The income tax provision was \$4.9 million for the three months ended March 31, 2015. While we incur operating losses on a consolidated basis, we operate in multiple jurisdictions and generate taxable income in our United States operations. The provision for income taxes was primarily due to timing differences between the book and tax treatment of certain income and expenses.

Our operations have historically been included in Theravance's U.S. federal and state income tax returns. Theravance will include the period from January 1, 2014 to June 1, 2014 on its income tax return. The net operating losses (NOL) generated within Theravance, including our activity prior to the separation will be included within Theravance's return and all NOL carryforwards and research and development tax credits generated by Theravance, including our activity prior to the Spin-Off were retained by Theravance upon the separation of the companies. As part of the Spin-Off, Theravance contributed certain assets and liabilities to us, including the related basis differences, consisting primarily of deferred tax assets of approximately \$12.7 million. These deferred tax assets include accrued liabilities that will be deductible in future periods, stock-based compensation and fixed assets. We had approximately \$22.2 million in deferred tax assets at March 31, 2015, which were subject to a full valuation allowance.

We follow the accounting guidance related to Accounting for Income Taxes which requires that a company reduce its deferred tax assets by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some portion or all of its deferred tax assets will not be realized.

As of March 31, 2015, we had unrecognized tax benefits and related interest and penalties of approximately \$1.4 million. We include any applicable interest and penalties associated with our unrecognized tax benefits within the provision for income taxes in the condensed consolidated statement of operations.

Our future income tax expense may be affected by such factors as changes in tax laws, changes in our business, regulations, or rates, changing interpretation of existing laws or regulations, the impact of accounting for stock-based compensation, the impact of accounting for business combinations, changes in our international organization, shifts in the amount of income before tax earned in the U.S. as compared with other regions in the world, and changes in overall levels of income before tax.

8. Commitments and Contingencies

Guarantees and Indemnifications

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recognized any liabilities relating to these agreements as of March 31, 2015.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Statements

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 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, goal, intends, 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

Our mission is to create value from a unique and diverse set of assets: an approved product; a development pipeline of late-stage assets; and a productive research platform designed for long-term growth.

Our pipeline of internally discovered product candidates includes potential best-in-class opportunities in underserved markets in the acute care setting, representing multiple opportunities for value creation. VIBATIV® (telavancin), our first commercial product, is a once-daily dual-mechanism antibiotic approved in the United States and Europe for certain difficult-to-treat infections. TD-4208 is an investigational long-acting muscarinic antagonist (LAMA) being developed as a potential once-daily, nebulized treatment for COPD. Axelopran (TD-1211) is an investigational potential once-daily, oral treatment for opioid-induced constipation (OIC). Our earlier-stage clinical assets represent novel approaches for potentially treating diseases of the lung and gastrointestinal tract and infectious disease. In addition, we have an economic interest in future payments that may be made by GlaxoSmithKline plc (GSK) pursuant to its agreements with Theravance, Inc. (Theravance) relating to certain drug programs, including the combination of fluticasone furoate, umeclidinium, and vilanterol (or the Closed Triple).

The Separation of Theravance Biopharma from Theravance

On June 1, 2014, Theravance separated its late-stage respiratory assets partnered with GSK from its biopharmaceutical operations by transferring its discovery, development and commercialization operations (the Biopharmaceutical Business) and contributing \$393.0 million of cash, cash equivalents and marketable securities into its then wholly-owned subsidiary Theravance Biopharma. 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). The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly-traded company. Prior to June 2, 2014, Theravance operated the Biopharmaceutical Business.

The Spin-Off was effected pursuant to a Separation and Distribution Agreement between Theravance and Theravance Biopharma (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 after the Spin-Off.

Basis of Presentation

For the periods prior to June 2, 2014, the condensed consolidated 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 Biopharmaceutical Business as a component of Theravance and reflect the results of operations, financial condition and cash flows of the Biopharmaceutical 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 Biopharmaceutical 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.

Table of Contents

The costs historically allocated to us by Theravance for the services it has shared with us may not be indicative of the costs we have incurred or will incur for these services following the Spin-Off.

Program Highlights

VIBATIV® (telavancin)

VIBATIV is a bactericidal, once-daily injectable antibiotic to treat patients with serious, life-threatening 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. VIBATIV is approved in the European Union for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable.

Commercial Program Expansion

In 2014, we implemented a phased launch strategy for VIBATIV in the U.S. that focused on a small number of targeted geographic territories across the country. In the fourth quarter of 2014, we expanded our sales force and medical affairs presence to include additional territories in the U.S. with the goal of strengthening our commercial infrastructure comprised of experienced sales representatives and a significant medical information component focused on the acute care market. Beginning in the second quarter of 2015, we are implementing a next phase of expansion, with a plan to increase our sales force to approximately 50 representatives before the end of the year.

Telavancin Observational Use Registry (TOUR)

Initiated in February 2015, the 1,000-patient TOUR observational use registry study is designed to assess the manner in which VIBATIV is used by healthcare practitioners to treat patients. By broadly collecting and examining data related to VIBATIV treatment patterns, as well as clinical and safety outcomes in the real world, we aim to create an expansive knowledge base to guide future development and optimal use of the drug.

Phase 3 Registrational Study in Staphylococcus aureus Bacteremia

As part of our effort to explore additional settings in which VIBATIV may offer patients therapeutic benefit, in February 2015, we initiated a Phase 3 registrational study for the treatment of patients with *Staphylococcus aureus* bacteremia. The 250-patient registrational study is a multicenter, randomized, open-label study designed to evaluate the non-inferiority of telavancin in treating *Staphylococcus aureus* bacteremia as

compared to standard therapy. Key secondary outcome measures of the study include an assessment of the duration of bacteremia post-randomization and the incidence of development of metastatic complications, as compared to standard therapy.

Long-Acting Muscarinic Antagonist TD-4208

TD-4208 is an investigational, long-acting muscarinic antagonist (LAMA) in development for the treatment of COPD. We believe that TD-4208 may become a valuable addition to the COPD treatment regimen and that it represents a significant commercial opportunity. Our market research indicates approximately 9% of the treated COPD patients in the U.S. either need or prefer nebulized delivery for maintenance therapy. LAMAs are a cornerstone of maintenance therapy for COPD, but existing LAMAs are only available in handheld devices that may not be suitable for every patient. TD-4208 has the potential to be a best-in-class once-daily single-agent product for COPD patients who require, or prefer, nebulized therapy. The therapeutic profile of TD-4208, together with its physical characteristics, suggest that this LAMA could serve as a foundation for combination products and for delivery in metered dose inhaler and dry powder inhaler products.

Table of Contents

Phase 3 Registrational Study in COPD

In December 2014, following the announcement of positive top-line results of our Phase 2b program, we conducted an end-of-Phase 2 meeting with the FDA to discuss the design of the Phase 3 registrational program. We are progressing TD-4208 into a Phase 3 registrational program that will include two replicate three-month efficacy studies and a single twelve-month safety study. Based on our discussion with the FDA, the studies will include approximately 2,200 patients. The studies will test two doses: 88 mcg and 175 mcg administered once-daily. We expect to initiate the Phase 3 program in the second half of 2015.

Mylan Collaboration

In January 2015, Mylan Ireland Limited (Mylan) and we established a strategic collaboration for the development and, subject to FDA approval, commercialization of TD-4208. Partnering with a world leader in nebulized respiratory therapies enables us to expand the breadth of our TD-4208 development program and extend our commercial reach beyond the acute care setting where we currently market VIBATIV. Funding of the Phase 3 registrational program by Mylan strengthens our capital position and enhances our financial flexibility to advance other high-value pipeline assets alongside TD-4208.

Under the terms of the agreement, Mylan and we will co-develop nebulized TD-4208 for COPD and other respiratory diseases. We will lead the U.S. registrational development program and Mylan will be responsible for reimbursement of our costs for that program up until the approval of the first new drug application, after which costs will be shared. If a product developed under the collaboration is approved in the U.S., Mylan will lead commercialization and we will retain the right to co-promote the product in the U.S. under a profit-sharing arrangement (65% Mylan/35% Theravance Biopharma). Outside the U.S. (excluding China), Mylan will be responsible for development and commercialization and will pay us a tiered royalty on net sales at percentage royalty rates ranging from low double-digits to mid-teens. Although China is not included in the ex-US territory outright, Mylan does have a right of first negotiation with respect to the development and commercialization of nebulized TD-4208 in China.

Under the agreement, Mylan will pay us an initial payment of \$15.0 million in cash in the second quarter of 2015. Also, pursuant to an ordinary share purchase agreement entered into on January 30, 2015, Mylan Inc., a subsidiary of Mylan N.V., made a \$30.0 million equity investment in us, buying 1,585,790 ordinary shares from us in early February 2015 in a private placement transaction at a price of approximately \$18.918 per share, which represented a 10% premium over the volume weighted average price per share of our ordinary shares for the five trading days ending on January 30, 2015. We are eligible to receive from Mylan potential development and sales milestone payments totaling \$220.0 million in the aggregate, with \$175.0 million associated with TD-4208 monotherapy and \$45.0 million for future potential combination products.

We retain worldwide rights to TD-4208 delivered through other dosage forms, such as a metered dose inhaler or dry powder inhaler (MDI/DPI), while Mylan has certain rights of first negotiation with respect to our development and commercialization of TD-4208 delivered other than via a nebulized inhalation product.

Oral Peripherally-Acting Mu Opioid Receptor Antagonist Axelopran (TD-1211)

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

Axelopran is an investigational, once-daily, oral peripherally active mu opioid receptor antagonist for opioid-induced constipation (OIC). The axelopran Phase 2 program demonstrated a clinically meaningful treatment effect in OIC patients compared to placebo. The goal for this program is to demonstrate the ability to normalize bowel function without impacting analgesia and improve a variety of GI symptoms associated with constipation, which could provide axelopran with a competitive advantage in the OIC market if demonstrated in Phase 3 studies and approved by regulatory authorities. We have developed a patient reported outcomes tool designed to measure patient symptoms which would be used in a Phase 3 registrational program and potentially generate data that could differentiate the product from the competition. We are currently refining our development and commercial strategy for axelopran.

Oral Peripherally-Acting Mu Opioid Receptor Antagonist Axelopran Fixed Dose Combination (TD-1211)

In December 2014, we completed a Phase 1 study to determine the relative bioavailability of OxyContin® (oxycodone) and axelopran after oral administration as a fixed dose combination (FDC) relative to the individual components administered together. The study examined a spray-coat application of axelopran to an opioid, OxyContin, to determine the effect of axelopran on OxyContin exposure. The study compared exposure of OxyContin alone, axelopran alone, OxyContin and axelopran administered as two separate tablets, and OxyContin spray-coated with axelopran in a FDC. Study results demonstrated that axelopran does not significantly alter systemic exposure to OxyContin when delivered as a FDC relative to when co-administered as individual tablets. A FDC of axelopran and an opioid could present an important market opportunity, as it has the potential to provide pain relief without constipation in a single abuse-deterrent pill for patients using opioids on a chronic basis.

Table of Contents

Velusetrag

Velusetrag is an oral, investigational medicine developed for gastrointestinal motility disorders. It is a highly selective agonist with high intrinsic activity at the human 5-HT₄ receptor. Velusetrag is being developed in collaboration with Alfa Wassermann S.p.A. (Alfa Wassermann) in a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Positive top-line results from the initial Phase 2 proof-of-concept study under this partnership, which evaluated gastric emptying, safety and tolerability of multiple doses of velusetrag, were announced in April 2014. In March 2015, we initiated a Phase 2b study of velusetrag for the treatment of patients with gastroparesis and other gastrointestinal motility disorders. The 200-patient study is a multicenter, double-blind, randomized, placebo-controlled, parallel-group trial which will explore the efficacy and safety of multiple doses of velusetrag in patients with diabetic or idiopathic gastroparesis. The twelve-week study will test three doses: 5, 15, and 30 mg administered once-daily. The primary endpoint will be the effect of velusetrag on symptoms in subjects with gastroparesis. The study will also evaluate the effect of velusetrag on gastric emptying, and the psychometric properties of the Gastroparesis Rating Scale (GRS), a daily patient-reported outcome (PRO) measure. 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.

Neprilysin (NEP) Inhibitor

Neprilysin is an enzyme that degrades natriuretic peptides. These peptides play a role in blood pressure and cardiovascular tissue remodeling. Inhibition of neprilysin may result in clinical benefit, including diuresis, control of blood pressure, and reversing maladaptive changes in the heart and vascular tissue in patients with congestive heart failure. Our primary objective is to combine a NEP inhibitor with an angiotensin receptor blocker (ARB) to create an oral combination product for the treatment of congestive heart failure targeting a broad population of patients, including those with severe heart failure and additional cardio-renal conditions. Our product candidates could be combined with a wide range of ARBs, including those with demonstrated benefits in heart failure and best-in-class efficacy in hypertension. The angiotensin receptor-neprilysin inhibitor (ARNI) class of medicines has the potential to represent a paradigm shift in the treatment of congestive heart failure. We have identified several proprietary NEP inhibitor product candidates that we are progressing through pre-IND enabling toxicology studies with the goal of advancing one or more product candidates towards a Phase 1 study. We are also considering combinations of a NEP inhibitor with agents having other mechanisms for the treatment of congestive heart failure as well as other indications and routes of administration.

Other Programs

Economic Interest in GSK-Partnered Respiratory Programs

We are entitled to receive an 85% economic interest in any future payments that may be made by GSK (pursuant to its agreements with Theravance) relating to the Closed Triple program and the Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) program, each of which are described in more detail below. We are entitled to this economic interest through our equity ownership in TRC. Our economic interest will not include any payments associated with RELVAR® ELLIPTA®/BREO® ELLIPTA®, ANORO® ELLIPTA® or vilanterol monotherapy. The following information regarding the Closed Triple and the MABA program is based solely upon publicly available information and may not reflect the most recent developments under the programs.

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

Closed Triple or FF/UMEC/VI (fluticasone furoate/umeclidinium bromide/vilanterol)

The Closed Triple program seeks to provide the activity of an inhaled corticosteroid (FF) plus two bronchodilators (UMEC, a LAMA, and VI, a long-acting beta2 agonist, or LABA) in a single delivery device. If the Closed Triple is successfully developed and commercialized, we are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales, which royalties are upward-tiering from 6.5% to 10%. In July 2014, Theravance and GSK announced the initiation of a large, global Phase 3 program for the Closed Triple in patients with COPD. In February 2015, Theravance and GSK announced the start of a second global Phase 3 study to evaluate the effects of the Closed Triple in patients with COPD.

Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)

GSK961081 (081) is an investigational, single-molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activity that was discovered by us when we were part of Theravance. In August 2014, Theravance reported that preclinical Phase 3-enabling studies and a Phase 1 study with healthy volunteers of 081/FF are ongoing to explore its potential as a once-daily medicine delivered in GSK's ELLIPTA® inhaler.

If a single-agent MABA medicine containing 081 is successfully developed and commercialized, we are entitled to receive an 85% economic interest in the royalties payable by GSK to TRC on worldwide net sales, which royalties range 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. If a MABA medicine containing 081 is successfully developed and commercialized in multiple regions of the world, GSK will pay TRC contingent milestone 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, and in each case we would be entitled to receive an 85% economic interest in any such payments.

Table of Contents*Theravance Respiratory Company, LLC*

Prior to the Spin-Off, Theravance assigned to TRC, a Delaware limited liability company formed and controlled by Theravance, its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement with GSK other than with respect to RELVAR® ELLIPTA®/BREQ® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy. Our equity interest in TRC is the mechanism by which we are entitled to the 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 the Closed Triple and the MABA program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid (ICS), as well as any other product or combination of products that may be discovered and developed in the future under these GSK Agreements.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our 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 our historical experience 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. There have been no new or material changes to the critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Results of Operations*Product Sales and Revenue from Collaborative Arrangements*

Product sales and revenue from collaborative arrangements, as compared to the prior years, were as follows:

(In thousands)	Three Months Ended March 31,		Change	
	2015	2014	\$	%
Product sales	\$ 1,280	\$ 945	\$ 335	35%
Revenue from collaborative arrangements	19,121		19,121	NA
Total revenue	\$ 20,401	\$ 945	\$ 19,456	2059%

NA: Not Applicable

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

Revenue from product sales increased for the three months ended March 31, 2015 from the comparable period in 2014 primarily due to the continued growth in sales of VIBATIV.

Revenue from collaborative arrangements increased for the three months ended March 31, 2015 as compared to the same period in 2014 primarily due to the recognition of \$19.1 million of upfront payments related to the delivery of the license and technological know-how to Mylan during the period.

Cost of Goods Sold

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

(In thousands)	Three Months Ended March 31,				Change		
	2015		2014		\$	%	
Cost of goods sold	\$	371	\$	188	\$	183	97%

Cost of goods sold increased in the three months ended March 31, 2015 as compared to the comparable period in 2014 primarily due to the increase in sales of VIBATIV.

Table of Contents**Research and Development Expenses**

Our research and development (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) Share-based compensation, which includes expenses associated with our equity plans;
- 3) External costs, which include clinical trial related expenses, other contract research fees, consulting fees, and contract manufacturing fees; 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.

The following table summarizes our R&D expenses incurred during the periods presented:

(In thousands)	Three Months Ended March 31,		Change	
	2015	2014	\$	%
Employee-related	\$ 12,949	\$ 19,299	\$ (6,350)	(33)%
Share-based compensation	7,482	4,721	2,761	58%
External-related	8,936	11,814	(2,878)	(24)
Facilities, depreciation and other allocated	6,652	5,889	763	13
	\$ 36,019	\$ 41,723	\$ (5,704)	(14)%

R&D expenses decreased in the first quarter of 2015 from the comparable period in 2014 primarily due to decreases in employee-related and external-related costs, partially offset by an increase in share-based compensation expense. The decrease in employee-related costs was primarily due to lower costs associated with the long-term retention and incentive awards granted to certain employees in 2011. External-related costs decreased primarily due to the reimbursement of R&D costs primarily associated with the Mylan collaborative arrangement.

Share-based compensation expense increased primarily due to new equity awards issued under our equity plans post spin-off and the re-introduction of ESPP in September 2014, partially offset by lower expense in the first quarter of 2015 related to Theravance share-based compensation awards held by our employees that were granted prior to the Spin-Off.

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	
	2015	2014	\$	%
Selling, general and administrative	\$ 21,748	\$ 19,052	\$ 2,696	14%

Selling, general and administrative expenses increased in the first quarter of 2015 from the comparable period in 2014 primarily due to costs associated with the expansion of our internal sales and marketing organization in relation to VIBATIV commercialization.

Selling, general and administrative expenses include share-based compensation expenses of \$8.1 million and \$8.0 million for the three months ended March 31, 2015 and 2014. Share-based compensation increased primarily due to new equity awards issued under our equity plans post spin-off.

Table of Contents

Provision for Income Taxes

The provision for income taxes of \$4.9 million for the three month ended March 31, 2015 resulted from operating in multiple jurisdictions and generating taxable income in our U.S. operations, although we incurred operating losses on a consolidated basis. There was no provision for income taxes for the three months ended March 31, 2014.

Liquidity and Capital Resources

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, to the extent we advance our product candidates into and through later stage clinical studies without a partner, such as axelopran (TD-1211) in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation, we will incur substantial expenses. We are also making additional investments in telavancin, our approved antibiotic. In February 2015, we announced initiation of a Phase 3 registrational study for bacteremia and initiation of a patient registry study. In addition, we have increased, and will continue to increase, the number of sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV. We are incurring 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.

Adequacy of cash resources to meet future needs

We expect our cash and cash equivalents and marketable securities will fund our operations for at least the next 12 months based on current operating plans and financial forecasts.

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

Cash flows, as compared to the prior year, were as follows:

Three Months Ended March 31,

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

(In thousands)	2015		2014		Change
Net cash used in operating activities	\$	(56,514)	\$	(44,799)	\$ (11,715)
Net cash provided by (used in) investing activities		42,154		(1,620)	43,774
Net cash provided by financing activities		26,044		46,419	(20,375)

Cash flows from operating activities

Net cash used in operating activities increased by \$11.7 million for the three months ended March 31, 2015 as compared to the same period in 2014 primarily from an increase in costs related to VIBATIV commercialization activities and timing of payments of variable compensation.

Cash flows from investing activities

Net cash provided by investing activities increased by \$43.8 million in the three months ended March 31, 2015 as compared to the same period in 2014 primarily due to maturities of marketable securities of \$53.5 million partially offset by purchase of marketable securities of \$10.7 million during the period.

Cash flows from financing activities

Net cash provided by financing activities during the three months ended March 31, 2015 was primarily due to proceeds from the sale of ordinary shares to Mylan, net of premium. During the three months ended March 31, 2014, net cash provided by financing activities was primarily due to net proceeds related to the transfer of assets and liabilities from Theravance.

Table of Contents

Commitments and Contingencies

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of March 31, 2015.

In 2011, Theravance granted special long-term retention and incentive restricted stock awards 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.

In May 2014, Theravance's Compensation Committee approved the modification of the remaining tranches related to these awards 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 12-month service-based vesting for a portion of the equity and cash awards. The share-based compensation expense of \$6.9 million associated with a portion of these awards after the modification is expected to be recognized by us during the 12-month service period commencing in June 2014.

During the fourth quarter of 2014, we determined that it was probable that the performance conditions associated with the remaining 417,000 RSAs outstanding under these awards would be achieved. In addition, the remaining RSAs outstanding under these awards are entitled to the pro rata dividend distribution made by Theravance on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Theravance common stock. As a result, for the three months ended March 31, 2015 and December 31, 2014, we recognized \$1.7 million and \$1.4 million of the total share-based compensation expense of \$9.5 million related to these remaining RSAs and pro rata dividends. The RSAs and pro rata dividend remain subject to a twelve-month service period, which commenced in February 2015.

Off-Balance Sheet Arrangements

There have been no material changes in our off-balance sheet arrangements from those set forth in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 13, 2015.

Contractual Obligations and Commercial Commitments

There have been no material changes in our contractual obligations and commercial commitments from those set forth in our Annual Report on Form 10-K filed with the SEC on March 13, 2015.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks at March 31, 2015 have not changed significantly from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2014 on file with the Securities and Exchange Commission.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act as of March 31, 2015, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined under Rule 13a-15(e) of the Exchange Act), which are 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) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief 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 Chief 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.

Table of Contents

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during our most recent fiscal quarter which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 COMPANY

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

First as Theravance, Inc. (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 Theravance Respiratory Company, LLC (TRC) to achieve profitability. During the three months ended March 31, 2015 and years ended December 31, 2014 and 2013, we recognized losses of \$42.5 million, \$237.0 million and \$156.3 million, respectively, which are reflected in the Shareholders' Equity on our condensed consolidated balance sheets. We reflect cumulative net loss incurred and retained after June 2, 2014, the effective date of the Spin-Off, as accumulated deficit on our 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® (telavancin). In particular, to the extent we advance our product candidates into and through later stage clinical studies without a partner, such as axelopran (TD-1211) in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation, we will incur substantial expenses. We are also making additional investments in telavancin, our approved antibiotic. For example, in February 2015 we announced initiation of a Phase 3 registrational study for bacteremia and initiation of a patient registry study. In addition, we have increased the number of sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV and we have announced that, beginning in the second quarter of 2015, we are implementing a next phase of expansion, with a plan to increase our sales force to approximately 50 representatives before the end of 2015. We are incurring 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, to the continued development of our existing

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

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 in new indications;
- 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 revenues from sales of VIBATIV, our only approved medicine, and potential contingent payments under collaboration agreements, we do not expect to generate sales revenues from our 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 will 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 choose to progress axelopran (TD-1211) in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation into later-stage development on our own, our capital needs would increase substantially. We also are making additional investments in telavancin, our approved antibiotic, which will increase our operating expenses. For example, in February 2015 we announced initiation of a Phase 3 registrational study for bacteremia and initiation of a patient registry study. In addition, we have increased the number of sales representatives and medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV and we have announced that, beginning in the second quarter of 2015, we are implementing a next phase of expansion, with a plan to increase our sales force to approximately 50 representatives before the end of 2015.

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 later stage development, if warranted;
- respond to competitive pressures; and
- acquire complementary businesses or technologies.

Our future capital needs depend on many factors, including:

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

- 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 additional capital or obtain future funding 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 or obtain future funding 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 seek to 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 our current shareholders that do not participate in the issuance. For example, in connection with entering into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our long-acting muscarinic antagonist (LAMA) TD-4208 in February 2015, Mylan made a \$30.0 million equity investment in us by purchasing 1,585,790 newly issued ordinary shares, which issuance resulted in dilution of ownership to our shareholders. In addition, if we seek to raise funds and this becomes known publicly, the market price of our shares could decline upon the expectation of dilution, regardless of whether dilution actually occurs. If we are unable to obtain any needed additional funding, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities or to license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize ourselves or on terms that are less attractive than they might otherwise be, any of which could materially harm our business.

Furthermore, the terms of debt securities may impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, pay dividends on or repurchase our share capital, or 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.

We do not control TRC and, in particular, have no control over or access to non-public information about the respiratory programs that Theravance partnered with GSK and assigned to TRC in connection with the Spin-Off (the GSK-Partnered Respiratory Programs).

Theravance has assigned to TRC its strategic alliance agreement with GSK and all of its rights and obligations under its LABA collaboration agreement other than with respect to RELVAR® ELLIPTA®/BREQ® 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 GSK Agreements). These other drug programs include the Closed Triple combination of fluticasone furoate (FF)/umeclidinium (UMEC)/vilanterol (VI) (ICS/LAMA/LABA) 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®/BREQ® 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

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

the exclusive right to appoint TRC's manager who, among other things, is responsible for the day-to-day management of the GSK-Partnered Respiratory Programs and exercises the rights relating to the GSK-Partnered Respiratory Programs. As a result, we have no rights to participate in or access to non-public information about the development and commercialization of the GSK-Partnered Respiratory 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 and TRC's dependence on GSK as we have with respect to our dependence on our own partners.

Table of Contents

If the GSK-Partnered Respiratory Programs in which we have a substantial economic interest, including the Closed Triple program and MABA program, encounter delays, do not demonstrate safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to these programs, our business will be harmed, and the price of our securities could fall.

We have no access to confidential information regarding the progress of, or plans for, the GSK-Partnered Respiratory Programs, including the Closed Triple program and the MABA program, and we have little, if any, ability to influence the progress of those programs because our interest in these programs is only through our economic interest in TRC, which is controlled by Theravance. However, if any of the GSK-Partnered Respiratory Programs assigned to TRC in which we have a substantial economic interest, including the Closed Triple program and MABA program, encounter delays, do not demonstrate safety and efficacy, are terminated, or if there are any adverse developments or perceived adverse developments with respect to such programs, our business will be harmed, and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

- GSK deciding to delay or halt development of any of the GSK-Partnered Respiratory Programs assigned to TRC in which we have a substantial economic interest, including the Closed Triple, GSK961081 (081), the lead compound in the MABA program, or 081/FF;
- the U.S. Food and Drug Administration (FDA) and/or other regulatory authorities determining that any of the studies under these programs do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to such programs;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs; or
- any particular FDA requirements or changes in FDA policy or guidance regarding these programs.

VIBATIV may not be broadly accepted by physicians, patients, third party payors, or the medical community in general and if we fail to meet our publicly announced net sales targets for VIBATIV or other expectations about our VIBATIV business, the price of our securities could fall.

The commercial success of VIBATIV depends upon its acceptance by physicians, patients, third party payors and the medical community in general. VIBATIV may not be sufficiently 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 complicated skin and skin structure infections (cSSSI) and HABP/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. If we fail to meet our publicly announced net sales targets for VIBATIV or other expectations about our VIBATIV commercialization strategy, the price of our securities could fall. The degree of market acceptance of VIBATIV depends on a number of factors, including, but not limited to:

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

- the demonstration of the clinical efficacy and safety of VIBATIV;
- the experiences of physicians, patients and payors with the use of VIBATIV;
- 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 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;
- any adverse developments or perceived adverse developments with respect to whether Pfizer's planned acquisition of Hospira may lead to changes in Hospira's operations which may adversely impact our single source of supply for VIBATIV drug product;
- 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;
- our ability to attract, train and retain targeted numbers of sales and marketing personnel;
- our ability to retain medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV;
- the effectiveness of sales personnel, and particularly newly hired personnel, to obtain access to or educate adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations;
- the lack of complementary products to be offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- the reimbursement policies of government and third party payors; and

- the market price of VIBATIV relative to competing therapies.

We are bearing the full cost of developing the capability to market, sell and distribute VIBATIV in the U.S.

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, and Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV. On August 14, 2013, Theravance announced the reintroduction of VIBATIV to the U.S. market with the commencement of shipments into the wholesaler channel and we have increased, and we have announced plans to more than double our VIBATIV sales force in the U.S. 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, including third party vendor logistics and consultant support, 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 retain adequate numbers of effective sales and marketing personnel;
- our unproven ability to retain medical science liaisons in the U.S. supporting physician education on the proper usage of VIBATIV;
- the unproven ability of sales personnel to obtain access to or educate adequate numbers of physicians about prescribing VIBATIV in appropriate clinical situations;
- 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; and
- bearing the full costs of further U.S. development of telavancin.

If we are not successful 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 the price of our securities could fall.

Table of Contents

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 the price of our securities could 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;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- our inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- 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.

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.

Table of Contents

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 new drugs. 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 the price of our securities could fall.

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 the price of our securities could 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 for well over a year. 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 us. 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 will be adversely affected. In addition, in February 2015 it was announced that Pfizer plans to acquire Hospira later this year and we cannot predict whether the acquisition will lead to changes in Hospira's operations which may adversely impact our single source of supply for VIBATIV drug product. Given the time required to locate and qualify another acceptable drug product manufacturer, any supply delay, suspension or cessation by Hospira (whether or not resulting from or related to the proposed acquisition by Pfizer) would adversely affect the commercialization of VIBATIV and our obligations to our partners and the price of our securities could fall.

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 and prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition,

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

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;
- 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;

Table of Contents

- 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 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.

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 and the price of our securities could 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.

Table of Contents

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 S.p.A. (Alfa Wassermann) for velusetrag, our lead compound in the 5-HT4 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 and Clinigen agreements were assigned to us in the Spin- Off. 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. In January 2015, we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of our LAMA TD-4208. Under the terms of the agreement, we and Mylan will co- develop nebulized TD-4208 for COPD and other respiratory diseases.

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.

Table of Contents

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 and to our other shareholders.

As of April 30, 2015, GSK beneficially owned approximately 24.6% of our outstanding ordinary shares. GSK is also a strategic partner to Theravance with rights and obligations under the strategic alliance agreement and under the collaboration agreement assigned to TRC (the "GSK-Theravance Agreements") that may cause GSK's interests to differ from the interests of us and our other shareholders. In particular, if the Closed Triple or a MABA/ICS in either the U.S. or the European Union is approved, GSK's diligent efforts obligations under the GSK-Theravance 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-Theravance 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-Theravance 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-Theravance Agreements. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK-Theravance 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 are limited under 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-Theravance 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 or Theravance's post-Spin-Off operations as violating or allowing it to terminate the GSK-Theravance 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-Theravance 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 other action or inaction by either GSK or Theravance that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between those parties may be interpreted negatively by the market or by our investors, could harm our business and cause the price of our securities to fall. Examples of these kinds of issues include but are not limited to non-performance of contractual obligations and allegations of non-performance, disagreements over the relative marketing and sales efforts for Theravance's partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In general, any uncertainty about the respiratory programs partnered with GSK, the enforceability of the GSK-Theravance Agreements or the relationship/partnership between Theravance and GSK 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) 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 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-Theravance 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.

Table of Contents

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 all of 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 the GSK-Partnered Respiratory Programs. In addition, in January 2015 we entered into a collaboration agreement with Mylan for the development and commercialization of a nebulized formulation of TD-4208, our LAMA compound. Additional collaborations will be needed to fund later-stage development of our product candidates that have not been licensed to a collaborator, such as axelopran (TD-1211) for opioid-induced constipation, TD-9855 for fatigue/pain, and TD-6450 for hepatitis C, or for a territory that is not covered by existing collaborations, and to commercialize these product candidates if approved by the necessary regulatory authorities. 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, 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 and the price of our securities could 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 the price of our securities could 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.

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

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

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.

Table of Contents

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.

Certain of our directors and officers may have actual or potential conflicts of interest because of their equity ownership in Theravance, which actual or potential conflicts may harm our business, prospects and financial condition and result in the diversion of corporate opportunities to Theravance.

Certain of our directors and all of our 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 ownership of Theravance common stock by our officers and most of our directors 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 TRC, particularly given that we and Theravance have different economic interests in TRC; 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.

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.

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

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

In addition, our U.S. operating subsidiary's facility and most of its employees are located in northern California, 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 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 and the price of our securities could fall.

Our business and operations would suffer in the event of system failures or security breaches.

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 or other losses. We rely extensively on computer systems to process payment transactions, maintain information and manage our business. Although we have security and fraud prevention measures in place, the Company has been subject to immaterial payment fraud activity. If we suffered material electronic security breaches, we could incur significant liability or significant 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, inadvertent disclosure of confidential or proprietary information, or other harm to our business, 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). Therefore, the information that we intend to provide shareholders will be different than what is available with respect to some other public companies. We cannot predict if investors will find our ordinary shares less attractive because we 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 were 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, (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) December 31, 2019, 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.

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 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 expected 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 have incurred and will continue to incur significant costs, including those described elsewhere herein, which may exceed our estimates. As a separate company, we will not receive potential royalty revenue derived from certain of Theravance's late-stage partnered respiratory assets (the Royalty Business).

Table of Contents

Our historical financial information prior to the Spin-Off 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 prior to the Spin-Off 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;
- prior to the Spin-Off, certain general administrative functions were performed by Theravance for the combined entity. Our historical consolidated 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
- following the Spin-Off, 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 become 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 in the future we are unable to conclude that our internal control over financial reporting is effective (or if the auditors

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

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.

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 only been operating as a stand-alone entity since June 2, 2014 and therefore we have a limited history operating as an independent company upon which you can evaluate us.

We have only been operating as a stand-alone entity since June 2, 2014 and therefore we have a limited operating history as an independent company upon which you can evaluate us. While our biopharmaceutical 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 biopharmaceutical 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.

Table of Contents

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 a non-U.S. corporation under this general rule. Section 7874 of the Internal Revenue Code of 1986, as amended (the Code), however, contains rules that may result in a foreign corporation being treated 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 certain aspects of 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 properties 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 country of incorporation.

We do not expect to be treated as a U.S. corporation under Section 7874 of the Code, because we do not believe that the assets contributed to us by Theravance constituted 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 did constitute substantially all of the properties of Theravance. In addition, there could be 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 treated 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.

Taxing authorities, such as the U.S. Internal Revenue Service may challenge our structure and transfer pricing arrangements.

We are incorporated in the Cayman Islands and maintain subsidiaries in the Cayman Islands, United States and the United Kingdom. We are able to achieve a low annual average tax rate through the performance of certain functions and ownership of certain assets in tax-efficient jurisdictions such as the Cayman Islands, together with intra-group service and transfer pricing agreements, each on an arm's length basis. Taxing authorities, such as the U.S. Internal Revenue Service, or the IRS, may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future which could result in reduced cash flows and have a material adverse effect on our business, financial condition and growth prospects.

We believe that our company (and one of our subsidiaries) is a passive foreign investment company, or PFIC, for 2014, which may have adverse U.S. federal income tax consequences to U.S. holders.

For U.S. federal income tax purposes, we generally would be classified as a PFIC for any taxable year if either (i) 75% or more of our 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 our 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%. In addition, whether our company will be a PFIC for any taxable year depends on our assets and income over the course of each such taxable year and, as a result, cannot be predicted with certainty until after the end of the year.

Based upon our assets and income during the course of 2014, we believe that our company is a PFIC for the 2014 taxable year and may continue to be a PFIC in subsequent years. In addition, we believe that one of our company's wholly-owned subsidiaries, Theravance Biopharma R&D, Inc. is also a PFIC for the 2014 taxable year. For any taxable year (or portion thereof) in which our company is a PFIC that is included in the holding period of a U.S. holder, the U.S. holder is generally subject to additional U.S. federal income taxes plus an interest charge with respect to certain distributions from Theravance Biopharma or gain recognized on a sale of Theravance Biopharma shares. Similar rules would apply with respect to distributions from or gain recognized on an indirect sale of Theravance Biopharma R&D, Inc. U.S. holders of our ordinary shares may wish to file an election to be treated as owning an interest in a qualified electing fund (QEF) or to mark-to-market their ordinary shares to avoid the otherwise-applicable interest charge consequences of PFIC treatment with respect to our ordinary shares. 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, as well as the application of the PFIC rules with respect to their indirect interests in Theravance Biopharma R&D, Inc.

Table of Contents

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 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 agreed to 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.

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 March 31, 2015, we or one of our wholly-owned subsidiaries owned 392 issued United States patents and 1,362 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.

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.

Table of Contents

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 and the price of our securities could 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 commercial reintroduction of VIBATIV. 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.

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 and the price of our securities could 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.

Table of Contents

The Patient Protection and Affordable Care Act and other potential legislative or regulatory actions 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 and 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

The market price for our shares has and may continue to fluctuate widely, and may result in substantial losses for purchasers of our ordinary shares.

Our ordinary shares began trading on June 3, 2014, and the market price for our shares has and may continue to fluctuate widely, and may result 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. To the extent that historically low trading volumes for our ordinary shares continues, our stock price may fluctuate significantly more than the stock market as a whole or the stock prices of similar companies. Without a larger public float of actively traded shares, our ordinary shares are likely to be more sensitive to changes in sales volumes, market fluctuations and events or perceived events with respect to our business, than the shares of common stock of companies with broader public ownership, and as a result, the trading prices for our ordinary shares may be more volatile. Among other things, trading of a relatively small volume of ordinary shares may have a greater effect on the trading price than would be the case if our public float of actively traded shares were larger.

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.

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

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 GSK-Partnered Respiratory Programs, including, without limitation, any delays in development in these programs, any halting of development in these programs, any difficulties or delays encountered with regard to the FDA or other regulatory authorities in these programs, or any indication from clinical or non-clinical studies that the compounds in such programs are not safe or efficacious;
- any further adverse developments or perceived adverse developments with respect to the commercialization of VIBATIV, including whether Pfizer's planned acquisition of Hospira later this year will lead to changes in Hospira's operations which may adversely impact our single source of supply for VIBATIV drug product;
- 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;

Table of Contents

- 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;
- regulatory developments in the United States and foreign countries;
- announcements of equity or debt financings;
- economic and other external factors beyond our control;
- loss of key personnel;
- low public market trading volumes for our ordinary shares related in part to the concentration of ownership of our shares;
- developments or disputes as to patent or other proprietary rights;

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

- 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 adversely affecting clinical or commercial operations;
- fluctuations in our operating results;
- market reaction to announcements by other biotechnology or pharmaceutical companies;
- 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.

Table of Contents

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

As of April 30, 2015, GSK beneficially owned approximately 24.6% of our outstanding ordinary shares and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 3.3% of our outstanding ordinary shares. Based on our review of publicly available filings as of April 30, 2015, our two largest shareholders other than GSK collectively owned approximately 24.0% of our outstanding ordinary shares. 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.

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.

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

Our corporate affairs are governed by our amended and restated memorandum and articles of association, by the Companies Law (2013 Revision) (as amended) of the Cayman Islands and by 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.

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.

Table of Contents

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. 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.

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

On February 2, 2015, we completed the sale of 1,585,790 of our ordinary shares to Mylan Inc., at a price of approximately \$18.918 per share, resulting in aggregate gross proceeds of \$30.0 million before deducting transaction expenses. Neither we nor Mylan Inc. engaged any investment advisors with respect to the sale and no underwriting discounts or commissions were paid or will be paid to any party in connection with the sale. We issued and sold the shares in reliance upon an exemption from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

Table of Contents

ITEM 6. EXHIBITS

Exhibit No.	Description of Exhibit
10.1	Development and Commercialization Agreement by and between Theravance Biopharma R&D, Inc. and Mylan Ireland Limited, dated January 30, 2015(1)*.
10.2	Ordinary Share Purchase Agreement by and between Theravance Biopharma, Inc. and Mylan Inc., dated January 30, 2015(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, 2015, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations (iii) the Condensed Consolidated Statement of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to the Condensed Consolidated Financial Statements

(1) Incorporated by reference to an exhibit filed with the Current Report on Form 8-K/A of Theravance Biopharma, Inc., filed with the Securities and Exchange Commission on April 24, 2015.

* Confidential treatment has been requested from the Securities and Exchange Commission as to certain portions of this exhibit.

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: May 13, 2015

/s/ Rick E Winningham

Rick E Winningham

Chairman of the Board and Chief Executive Officer

(Principal Executive Officer)

Date: May 13, 2015

/s/ Renee D. Gala

Renee D. Gala

Senior Vice President and Chief Financial Officer

(Principal Financial Officer)

Table of Contents

EXHIBIT INDEX

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

Exhibit No.	Description of Exhibit
10.1	Development and Commercialization Agreement by and between Theravance Biopharma R&D, Inc. and Mylan Ireland Limited, dated January 30, 2015(1)*.
10.2	Ordinary Share Purchase Agreement by and between Theravance Biopharma, Inc. and Mylan Inc., dated January 30, 2015(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, 2015, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations (iii) the Condensed Consolidated Statement of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to the Condensed Consolidated Financial Statements

(1) Incorporated by reference to an exhibit filed with the Current Report on Form 8-K/A of Theravance Biopharma, Inc., filed with the Securities and Exchange Commission on April 24, 2015.

* Confidential treatment has been requested from the Securities and Exchange Commission as to certain portions of this exhibit.