

THERAVANCE INC  
Form 10-Q  
May 08, 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: 000-30319

# THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**94-3265960**  
(I.R.S. Employer  
Identification No.)

**951 Gateway Boulevard**

**South San Francisco, CA 94080**

(Address of Principal Executive Offices)

**(650) 238-9600**

(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 (§ 232.405 of this chapter) 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 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  Smaller reporting company   
(Do not check if a 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

The number of shares of registrant's common stock outstanding on April 30, 2015 was 116,872,733.



Table of Contents

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014</u>	3
<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2015 and 2014</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7

<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
--	----

<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	24
---	----

<u>Item 4. Controls and Procedures</u>	24
--	----

**PART II. OTHER INFORMATION**

<u>Item 1A. Risk Factors</u>	25
------------------------------	----

<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
--	----

<u>Item 3. Defaults Upon Senior Securities</u>	37
--	----

<u>Item 4. Mine Safety Disclosures</u>	37
--	----

<u>Item 5. Other Information</u>	37
----------------------------------	----

<u>Item 6. Exhibits</u>	38
-------------------------	----

<u>Signatures</u>	39
Exhibits	

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****THERAVANCE, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands, except per share data)

	March 31, 2015 (unaudited)	December 31, 2014 *
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 141,186	\$ 96,800
Short-term marketable securities	109,954	143,698
Related party receivables from collaborative arrangements	10,239	10,550
Prepaid expenses and other current assets	1,013	1,134
Total current assets	262,392	252,182
Marketable securities	3,932	42,856
Property and equipment, net	303	324
Capitalized fees paid to a related party, net	204,735	208,191
Other assets	17,337	18,101
Total assets	\$ 488,699	\$ 521,654
<b>Liabilities and Stockholders Deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,025	\$ 1,056
Payable to Theravance Biopharma, Inc.	126	1,959
Accrued personnel-related expenses	1,063	7,551
Accrued interest payable	6,195	2,108
Other accrued liabilities	1,686	1,082
Deferred revenue	885	13,756
Total current liabilities	10,980	255,109
Convertible subordinated notes, due 2023	255,109	470,527
Non-recourse notes, due 2029	476,954	105
Deferred rent	89	1,718
Other long-term liabilities	1,947	3,788
Deferred revenue	3,763	
Commitments and contingencies (Notes 3, 6, and 9)		
Stockholders Deficit:		
Preferred stock: \$0.01 par value, 230 shares authorized, no shares issued and outstanding		
Common stock: \$0.01 par value, 200,000 shares authorized, 116,920 and 116,445 shares issued as of March 31, 2015 and December 31, 2014, respectively	1,169	1,164
Treasury stock: 150 shares at March 31, 2015 and December 31, 2014	(3,263)	(3,263)
Additional paid-in capital	1,426,297	1,452,504
Accumulated other comprehensive loss	(12)	(87)
Accumulated deficit	(1,684,334)	(1,673,667)

Edgar Filing: THERAVANCE INC - Form 10-Q

Total stockholders' deficit		(260,143)		(223,349)
Total liabilities and stockholders' deficit	\$	488,699	\$	521,654

*See accompanying notes to condensed consolidated financial statements.*

---

\* Condensed consolidated balance sheet at December 31, 2014 has been derived from audited consolidated financial statements.

Table of Contents**THERAVANCE, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share data)

(Unaudited)

	<b>Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Royalty revenue from a related party, net of amortization for capitalized fees paid to a related party of \$3,456 and \$1,780 for the three months ended March 31, 2015 and 2014	\$ 6,674	\$ (1,050)
Revenue from collaborative arrangements from a related party, net	222	270
Total net revenue	6,896	(780)
Operating expenses:		
Research and development	712	2,687
General and administrative	5,439	11,256
Total operating expenses	6,151	13,943
Income (loss) from operations	745	(14,723)
Other income (expense), net	1,178	(3)
Interest income	116	188
Interest expense	(12,706)	(1,644)
Loss from continuing operations	(10,667)	(16,182)
Loss from discontinued operations (Notes 1 and 11)		(51,521)
Net loss	\$ (10,667)	\$ (67,703)
Basic and diluted net loss per share:		
Continuing operations	\$ (0.09)	\$ (0.15)
Discontinued operations		(0.47)
Basic and diluted net loss per share	(0.09)	(0.62)
Cash dividends declared per common share	\$ 0.25	\$
Shares used to compute basic and diluted net loss per share	114,658	109,859

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents

**THERAVANCE, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(In thousands, except per share data)

(Unaudited)

	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Net loss	\$ (10,667)	\$ (67,703)
<b>Other comprehensive income:</b>		
Unrealized gain on marketable securities	1,226	9
Less: Realized gain on marketable securities	(1,151)	
Comprehensive loss	\$ (10,592)	\$ (67,694)

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Three Months Ended March 31,	
	2015	2014
<b>Cash flows from operating activities</b>		
Net loss	\$ (10,667)	\$ (67,703)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,483	2,638
Stock-based compensation	1,933	13,535
Amortization of premium on short term investment	233	762
Interest added to the principal balance of the non-recourse term notes due 2029	6,427	
Realized gain on sale of marketable securities, net	(1,204)	
Amortization of debt issuance costs	764	
Other non-cash items	(2)	(2)
Changes in operating assets and liabilities:		
Accounts receivable		(178)
Receivables from collaborative arrangements	311	2,316
Prepaid expenses and other current assets	121	(2,132)
Inventories		(430)
Other assets		(998)
Accounts payable	1,025	(1,174)
Payable to Theravance Biopharma, Inc., net	(930)	
Accrued personnel-related expenses and other accrued liabilities	(1,516)	4,448
Accrued interest payable	(1,356)	(1,527)
Deferred rent	(16)	116
Deferred revenue	(222)	(308)
Net cash used in operating activities	(1,616)	(50,637)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(6)	(1,620)
Purchases of marketable securities	(8,457)	(56,649)
Maturities of marketable securities	25,075	122,399
Sales of marketable securities	57,098	5,000
Payments for capitalized fees paid to a related party		(55,000)
Net cash provided by investing activities	73,710	14,130
<b>Cash flows from financing activities</b>		
Proceeds from issuances of common stock, net	1,086	18,272
Payments of cash dividends to stockholders	(28,794)	
Net cash (used in) provided by financing activities	(27,708)	18,272
<b>Net increase (decrease) in cash and cash equivalents</b>	44,386	(18,235)
<b>Cash and cash equivalents at beginning of period</b>	96,800	143,510
<b>Cash and cash equivalents at end of period</b>	\$ 141,186	\$ 125,275

**Supplemental disclosure of cash flow information**

Cash paid for interest	\$	6,870	\$	3,055
------------------------	----	-------	----	-------

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents

**THERAVANCE, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(Unaudited)

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

*Description of Operations*

Theravance, Inc. (Theravance, the Company, or we and other similar pronouns) is a royalty management company focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited (GSK), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, FF/VI) and ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, UMEC/VI), with the intention of providing capital returns to stockholders. Under the Long-Acting Beta 2 Agonist (LABA) Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein as the GSK Agreements), Theravance is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and if approved and commercialized, VI monotherapy. Theravance is also entitled to 15% of any future payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC (TRC), relating to the combination FF/UMEC/VI and the Bifunctional Muscarinic Antagonist-Beta 2 Agonist (MABA) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement (LABA Collaboration), which has been assigned to TRC other than RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and VI monotherapy.

*Basis of Presentation*

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In our opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of our financial position, results of operations, comprehensive loss and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2015 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 filed with the Securities and Exchange Commission (SEC) on February 27, 2015.

*Business Separation*

## Edgar Filing: THERAVANCE INC - Form 10-Q

On June 1, 2014, we separated our biopharmaceutical research and drug development operations from our late-stage partnered respiratory assets by transferring our research and drug development operations into our then wholly- owned subsidiary, Theravance Biopharma, Inc. ( Theravance Biopharma ). We contributed \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma and all outstanding shares of Theravance Biopharma were then distributed to Theravance stockholders as a pro-rata dividend distribution on June 2, 2014 by issuing one ordinary share of Theravance Biopharma for every 3.5 shares held of our common stock to stockholders of record on May 15, 2014 (the Spin-Off ). The Spin-Off resulted in Theravance Biopharma operating as an independent, publicly traded company.

The results of operations for the former research and drug development operations conducted by us and by Theravance Biopharma until June 1, 2014 are included as part of this report as discontinued operations. Refer to Note 11 Discontinued Operations for further information.

### *Variable Interest Entities*

We evaluate our ownership, contractual and other interest in entities to determine if they are variable-interest entities ( VIE ), whether we have a variable interest in those entities and the nature and extent of those interests. Based on our evaluations, if we determine we are the primary beneficiary of such VIEs, we consolidate such entities into our financial statements. We consolidate the financial results of TRC, which we have determined to be a VIE, because we have the power to direct the economically significant activities of TRC and the obligation to absorb losses of, or the right to receive benefits from, TRC. The financial position and results of operations of TRC are not material as of and for the three months ended March 31, 2015 and 2014 and as of December 31, 2014.

Table of Contents***Recently Issued Accounting Pronouncements Not Yet Adopted***

In May 2014, the FASB issued Accounting Standards Update 2014-09, *Revenue from Contracts with Customers* ( ASU 2014-09 ), which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. This guidance is effective for the fiscal years and interim reporting periods beginning after December 15, 2016, at which time we may adopt the new standard under the full retrospective method or the modified retrospective method. Early adoption is not permitted. We are currently evaluating the impact of adopting ASU 2014-09 on our consolidated financial statements and related disclosures.

In April 2015, the FASB issued Accounting Standards Update 2015-03, *Interest Imputation of Interest* ( ASU 2015-03 ), in order to simplify the presentation of debt issuance costs. This standard amends existing guidance to require the presentation of debt issuance costs in the balance sheet as a deduction from the carrying amount of the related debt liability instead of a deferred charge. It is effective for annual reporting periods beginning after December 15, 2015, but early adoption is permitted. We plan to adopt ASU 2015-03 on January 1, 2016. Upon adoption of ASU 2015-03, we will present our debt issuance costs, which are currently included in other assets in the condensed consolidated financial statements, as a deduction to our long-term debt.

**2. Net Loss per Share**

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

For the three months ended March 31, 2015 and 2014, diluted and basic net loss per common share were identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

***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(1)	2014
Outstanding options and awards granted under equity incentive plan and ESPP	5,866	5,747
Unvested RSAs	1,930	2,193
Shares issuable upon conversion of convertible subordinated notes	12,494	10,347
	20,290	18,287

- (1) Includes 4.5 million options, 0.6 million restricted stock units, and 1.2 million unvested restricted stock awards retained by former employees who were transferred to Theravance Biopharma in connection with the Spin-Off. Subsequent to the Spin-Off, stock-based compensation expense associated with the awards held by Theravance Biopharma employees granted prior to the Spin-Off is recognized by Theravance Biopharma.

### 3. Collaborative Arrangements

#### *Net Revenue from Collaborative Arrangements*

Net revenue from collaborative arrangements from continuing operations relates to our collaborative arrangement with GSK. Net revenue from other collaborative arrangements is reflected as discontinued operations in the condensed consolidated statements of operations. Refer to Notes 1 and 11, Description of Operations and Summary of Significant Accounting Policies and Discontinued Operations for further information.

Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Three months ended March 31,	
	2015	2014
Royalties from a related party	\$ 10,130	\$ 730
Less: amortization of capitalized fees paid to a related party	(3,456)	(1,780)
Royalty revenue	6,674	(1,050)
Strategic alliance - MABA program license	222	270
Total net revenue from GSK	\$ 6,896	\$ (780)

Table of Contents

*LABA Collaboration*

In November 2002, we entered into our LABA Collaboration Agreement with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disease ( COPD ) and asthma. For the treatment of COPD, the collaboration has developed two combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO® ELLIPTA® (UMEC/VI), a once-daily medicine combining a long-acting muscarinic antagonist ( LAMA ), umeclidinium bromide ( UMEC ), with a LABA, VI. For the treatment of asthma, RELVAR® ELLIPTA® is approved in multiple regions outside of North America and FF/VI was approved as a once-daily inhaled treatment for asthma in patients aged 18 years and older in the U.S.

As a result of the launch and approval of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe, we were obligated to pay milestone fees to GSK totaling \$220.0 million, all of which was paid as of December 31, 2014. Although we have no further milestone payment obligations to GSK pursuant to the LABA Collaboration Agreement, we continue to have ongoing development and commercialization activities under the GSK Agreements that are expected to continue over the life of the agreements. The milestone fees paid to GSK were recognized as capitalized fees paid to a related party, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product.

We are entitled to receive annual royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA Collaboration, such as ANORO® ELLIPTA®, royalties are upward tiering and range from 6.5% to 10%.

Amortization expense resulting from the milestone fees paid to GSK, which are recognized as capitalized fees paid to a related party, is a non-cash reduction to royalty revenue. When amortization expense exceeds amounts recognized for royalty revenue, negative revenue would be reported in our condensed consolidated statements of operations.

*2004 Strategic Alliance*

In March 2004, we entered into the Strategic Alliance Agreement with GSK where GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program.

Table of Contents

*Agreements Entered into with GSK in Connection with the Spin-Off*

On March 3, 2014, in contemplation of the Spin-Off of Theravance Biopharma, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies would implement the Spin-Off and operate following the Spin-Off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the Spin-Off provided certain conditions were met. In addition, we and GSK also entered into amendments to the GSK Agreements, and Theravance Biopharma and GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The three-way master agreement was effective on June 1, 2014 when we transferred our research and drug development operations to Theravance Biopharma. Pursuant to a three-way master agreement entered into by and among us, Theravance Biopharma and GSK in connection with the Spin-Off, we agreed to sell a certain number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had a right to purchase these shares of Theravance Biopharma from us, but this right expired unexercised. Accordingly, at December 31, 2014, we owned 436,802 ordinary shares of Theravance Biopharma, which were accounted for as marketable securities in the condensed consolidated balance sheet. During the three months ended March 31, 2015, we sold all of the ordinary shares of Theravance Biopharma, Inc. that we held at December 31, 2014. Refer to Note 4 Available-for-Sale Securities and Fair Value Measurements for further information.

The amendments to the GSK Agreements do not change the economics or royalty rates under the GSK Agreements, though the assignment of the Strategic Alliance Agreement and portions of the LABA Collaboration to TRC do change how the economics are allocated between Theravance Biopharma and us. The amendments to the GSK Agreements do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the United States or the European Union of FF/UMEC/VI or a MABA in combination with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we will retain our full interests upon the Spin-Off and also products in which we will have retained only a portion of our interests upon the planned Spin-Off transaction, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements after the Spin-Off.

*GSK Contingent Payments and Revenue*

The potential future contingent payments receivable related to the MABA program of \$363.0 million are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

**4. Available-for-Sale Securities and Fair Value Measurements**

*Available-for-Sale Securities*

The classification of available-for-sale securities in the condensed consolidated balance sheets is as follows:

Edgar Filing: THERAVANCE INC - Form 10-Q

(In thousands)	March 31, 2015	December 31, 2014
Cash and cash equivalents	\$ 132,007	\$ 95,090
Short-term marketable securities	109,954	143,698
Marketable securities	3,932	42,856
Total	\$ 245,893	\$ 281,644

The estimated fair value of available-for-sale securities is based on quoted market prices for these or similar investments that were based on prices obtained from a commercial pricing service. Available-for-sale securities are summarized below:

(In thousands)	Amortized Cost	March 31, 2015		Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	
U.S. government securities	\$ 12,505	\$ 12	\$	\$ 12,517
U.S. government agencies	18,471	3	(3)	18,471
U.S. corporate notes	72,941	7	(31)	72,917
U.S. commercial paper	9,981			9,981
Money market funds	132,007			132,007
Total	\$ 245,905	\$ 22	\$ (34)	\$ 245,893

Edgar Filing: THERAVANCE INC - Form 10-Q

Table of Contents

(In thousands)	Amortized Cost	December 31, 2014			Estimated Fair Value
		Gross Unrealized Gains	Gross Unrealized Losses	Other Than Temporary Impairment Loss	
U.S. government securities	\$ 30,019	\$ 24	\$	\$	\$ 30,043
U.S. government agencies	34,756	6	(12)		34,750
U.S. corporate notes	80,880	5	(110)		80,775
U.S. commercial paper	34,469				34,469
Ordinary shares of Theravance Biopharma	10,269			(3,752)	6,517
Money market funds	95,090				95,090
Total	\$ 285,483	\$ 35	\$ (122)	\$ (3,752)	\$ 281,644

At March 31, 2015, all of the available-for-sale securities had contractual maturities within two years and the weighted average duration of marketable securities was approximately five 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 sold all of the ordinary shares of Theravance Biopharma, Inc. that we held at December 31, 2014, which resulted in a gain on sale of \$1.2 million, which is included in other income (expense), net in the condensed consolidated statement of operations.

**Fair Value Measurements**

Our available-for-sale securities are measured at fair value on a recurring basis and our debt is carried at the amortized cost basis. The estimated fair values were as follows:

Types of Instruments (In thousands)	Estimated Fair Value Measurements at Reporting Date Using:			Total
	Quoted Price in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	
<i>Assets at March 31, 2015</i>				
U.S. government securities	\$ 12,517	\$	\$	\$ 12,517
U.S. government agencies		18,471		18,471
U.S. corporate notes		72,917		72,917
U.S. commercial paper		9,981		9,981
Money market funds	132,007			132,007
Total assets measured at estimated fair value	\$ 144,524	\$ 101,369	\$	\$ 245,893
<i>Liabilities at March 31, 2015</i>				
Convertible subordinated notes due 2023	\$	\$ 223,220	\$	\$ 223,220
Non-recourse notes due 2029		469,800		469,800
Total fair value of liabilities	\$	\$ 693,020	\$	\$ 693,020



Table of Contents

Types of Instruments (In thousands)	Estimated Fair Value Measurements at Reporting Date Using:			Total
	Quoted Price in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	
<i>Assets at December 31, 2014</i>				
U.S. government securities	\$ 30,043	\$	\$	\$ 30,043
U.S. government agencies		34,750		34,750
U.S. corporate notes		80,775		80,775
U.S. commercial paper		34,469		34,469
Ordinary shares of Theravance Biopharma	6,517			6,517
Money market funds	95,090			95,090
Total assets measured at estimated fair value	\$ 131,650	\$ 149,994	\$	\$ 281,644
<i>Liabilities at December 31, 2014</i>				
Convertible subordinated notes due 2023	\$	\$ 197,095	\$	\$ 197,095
Non-recourse notes due 2029		456,411		456,411
Total fair value of liabilities	\$	\$ 653,506	\$	\$ 653,506

The fair value of our marketable securities classified within Level 2 were derived from observable inputs 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.

The fair value of our convertible subordinated notes due 2023 and non-recourse notes due 2029 is based on recent trading prices of the instruments, if applicable, or pricing models that utilize current observable market characteristics for similar types of instruments.

Table of Contents**5. Capitalized Fees paid to a Related Party**

Capitalized fees paid to a related party, which consist of registrational and launch-related milestone fees paid to GSK, were as follows:

(In thousands)	Weighted Average Remaining Amortization Period (Years)	March 31, 2015			December 31, 2014		
		Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Approval and launch related milestone payments under the LABA Collaboration	14.8	\$ 220,000	(15,265)	\$ 204,735	\$ 220,000	(11,809)	\$ 208,191

These milestone fees are being amortized over their estimated useful lives commencing upon the commercial launch of the product in their respective regions with the amortization expense recorded as a reduction in revenue from collaborative arrangements. Additional information regarding these milestone fees is included in Note 3, Collaborative Arrangements. Amortization expense for the three months ended March 31, 2015 and 2014 was \$3.5 million and \$1.8 million, respectively. The remaining estimated amortization expense is \$10.4 million for 2015, \$13.8 million for each of the years from 2016 to 2020, and \$125.3 million thereafter.

**6. Stock-Based Compensation*****Equity Incentive Plan***

The 2012 Equity Incentive Plan (the 2012 Plan ) provides for the granting of incentive stock options, nonstatutory stock options, restricted stock awards, stock unit awards and SARs to employees, non-employee directors and consultants. As of March 31, 2015, the total shares remaining available for issuance under the 2012 Plan were 2,598,542.

***Employee Stock Purchase Plan***

Under the 2004 Employee Stock Purchase Plan (the ESPP ), our employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The ESPP provides for consecutive and overlapping offering periods of 24 months in duration, with each offering period composed of four consecutive six-month purchase periods. The purchase periods end on either May 15th or November 15th. ESPP contributions are limited to a maximum of 15% of an employee's eligible compensation. The maximum number of shares that an employee may purchase in any purchase period is 2,500. An employee may not purchase shares with a value greater than \$25,000 in any calendar year.

As of March 31, 2015, total shares remaining available for issuance under the ESPP were 284,139.

***Performance-Contingent RSAs***

Since 2011, the Compensation Committee of our Board of Directors (the Compensation Committee ) approved grants of performance-contingent RSAs to senior management and a non-executive officer. Generally, these awards have dual triggers of vesting based upon the achievement of certain performance goals by a pre-specified date, as well as a requirement for continued employment. Recognition of stock based compensation expense begins when the performance goals are deemed probable of achievement.

Included in these performance-contingent RSAs is the grant of 1,290,000 special long-term retention and incentive performance-contingent RSAs to senior management in 2011. The awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011 through December 31, 2016 and require continued employment. As of March 31, 2014, we determined that the achievement of the requisite performance conditions for vesting of the first tranche of these awards was probable and, as a result, \$6.8 million of the total stock-based compensation expense was recognized in the three months ended March 31, 2014. The total stock-based compensation expense of \$7.0 million for the first tranche was recognized through May 2014. In connection with the Spin-Off, our Compensation Committee approved the modification of the remaining tranches related to these awards as the performance conditions associated with the remaining portions of these awards were unlikely to be consistent with the new strategies of each company following the separation. The modification acknowledged the Spin-Off and permitted recognition of achievement of certain of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the equity awards, for which \$3.8 million is expected to be recognized by us during the twelve-month period that commenced in June 2014. The remaining 63,000 RSAs for which service-based vesting was not triggered at the time of the Spin-Off remain subject to new performance conditions (as well as the original service conditions). In addition, the RSAs for which both the performance and service-based conditions were not achieved prior to the Spin-Off were entitled to the pro rata dividend distribution made by Theravance on June 2, 2014 of one ordinary share of Theravance Biopharma for every 3.5 shares of Theravance common stock subject to their awards, which will also be subject to the same new performance and service conditions as the original RSAs to which they relate. As of March 31, 2015, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation cost was recognized for the remaining equity awards.

Table of Contents***Stock-Based Compensation Expense***

Stock-based compensation expense is included in the condensed consolidated statements of operations as follows:

(In thousands)	Three months ended March 31,	
	2015	2014
Research and development	\$ 235	\$ 718
General and administrative	1,698	5,340
Stock-based compensation from continuing operations	1,933	6,058
Stock-based compensation from discontinued operations		7,477
Total stock-based compensation expense	\$ 1,933	\$ 13,535

As of March 31, 2015, unrecognized compensation expense, net of expected forfeitures for awards expected to vest, was as follows: \$2.1 million related to unvested stock options; \$2.1 million related to unvested RSUs; and \$9.1 million related to unvested RSAs (including performance-contingent RSAs for which the performance milestones were determined to be probable of achievement).

***Valuation Assumptions***

No options were granted for the three months ended March 31, 2015.

For the three months ended March 31, 2014, we based the range of weighted-average estimated values of employee stock option grants, as well as the weighted-average assumptions used in calculating these values, on estimates at the date of grant, as follows:

Risk-free interest rate	1.8% - 2.0%
Expected term (in years)	6
Volatility	60%
Dividend yield	
Weighted-average estimated fair value of stock options granted	\$ 21.29

**7. Long-Term Debt**

Our long-term debt consists of:

(In thousands)	March 31, 2015	December 31, 2014
----------------	-------------------	----------------------

## Edgar Filing: THERAVANCE INC - Form 10-Q

Convertible Subordinated Notes due 2023	\$	255,109	\$	255,109
Non-Recourse Notes Payable due 2029		476,954		470,527
Total Long-Term Debt	\$	732,063	\$	725,636

### *Convertible Subordinated Notes Due 2023*

In January 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured convertible subordinated notes, which will mature on January 15, 2023 (the 2023 Notes ). The financing raised proceeds, net of issuance costs, of approximately \$281.2 million, less \$36.8 million to purchase two privately-negotiated capped call option transactions in connection with the issuance of the notes. The 2023 Notes bear interest at the rate of 2.125% per year that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2013.

The 2023 Notes were convertible, at the option of the holder, into shares of our common stock at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the 2023 Notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately \$27.79 per share. Following the separation of Theravance Biopharma, a number of adjustments to the initial conversion rate have been made as described below. Holders of the notes will be able to require us to repurchase some or all of their notes upon the occurrence of a fundamental change at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. We may not redeem the notes prior to their stated maturity date.

Table of Contents

In connection with the offering of the 2023 Notes, we entered into two privately-negotiated capped call option transactions with a single counterparty. The capped call option transaction is an integrated instrument consisting of a call option on our common stock purchased by us with a strike price equal to the initial conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share, both of which are subject to adjustments consistent with the 2023 Notes. The cap component is economically equivalent to a call option sold by us for the underlying number of shares with an initial strike price of \$38.00 per share. As an integrated instrument, the settlement of the capped call coincides with the due date of the convertible debt. At settlement, we would receive from our hedge counterparty a number of shares of our common shares that would range from zero, if the stock price was below \$27.79 per share, to a maximum of 2,779,659 shares, if the stock price is above \$38.00 per share. However, if the market price of our common stock, as measured under the terms of the capped call transactions, exceeds \$38.00 per share, there is no incremental anti-dilutive benefit from the capped call. The aggregate cost of the capped call options was \$36.8 million.

In accordance with the agreement for the 2023 Notes, the conversion rate was adjusted as a result of the completion of the Spin-Off of Theravance Biopharma. The conversion rate was adjusted based on the conversion rate immediately prior to the record date for the Spin-Off and the average of the stock dividend distributed to our common stockholders and our stock prices. This resulted in an adjusted conversion rate of 46.9087 shares per \$1,000 principal amount of the 2023 Notes, which represents an adjusted conversion price of approximately \$21.32 per share. As a result of the conversion rate adjustment, the capped call strike price and cap price were also adjusted accordingly as \$21.32 and \$29.16. On July 15, 2014, certain holders of the 2023 Notes converted their notes into 1,519,402 shares of our common stock at the adjusted conversion price of \$21.32 per share. In connection with the partial conversion of the 2023 Notes, we received 149,645 shares of our common stock from our capped call option counterparty and the shares of common stock received were recorded as treasury stock.

In connection with the payments of cash dividends through March 31, 2015, the adjusted conversion rate with respect to our 2023 Notes was further adjusted from 46.9087 shares of our common stock per \$1,000 principal amount of the 2023 Notes to 48.9758 shares of our common stock per \$1,000 principal amount of the 2023 Notes, which represents an adjusted conversion price of approximately \$20.42 per share. As a result of the conversion rate adjustment, the capped call strike price and cap price were also adjusted accordingly to \$20.42 and \$27.92.

***Non-Recourse Notes Due 2029***

In April 2014, we entered into certain note purchase agreements relating to the private placement of \$450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 (the 2029 Notes ) issued by our wholly-owned subsidiary.

The 2029 Notes are secured by a security interest in a segregated bank account established to receive 40% of royalties due to us under the LABA Collaboration with GSK commencing on April 1, 2014 and ending upon the earlier of full repayment of principal or May 15, 2029. The amounts in the segregated bank account can only be used to make interest and principal payments on the 2029 Notes. At March 31, 2015, the balance of the segregated bank account was not material.

The 2029 Notes bear an annual interest rate of 9%, with interest and principal paid quarterly beginning November 15, 2014. The 2029 Notes may be redeemed at any time prior to maturity, in whole or in part, at specified redemption premiums. Prior to May 15, 2016, in the event that the specified portion of royalties received in a quarter is less than the interest accrued for the quarter, the principal amount of the 2029 Notes will increase by the interest shortfall amount for that period. During the three months ended March 31, 2015, \$6.4 million of interest expense was added to the principal balance of the 2029 Notes. Since the principal and interest payments on the 2029 Notes are based on royalties from product sales recorded by GSK, which will vary from quarter to quarter and are unknown to us, the 2029 Notes may be repaid prior to the final maturity date in 2029.

In connection with the sale of the 2029 Notes, we incurred approximately \$15.3 million in transaction costs, which are being amortized to interest expense over the estimated life of the 2029 Notes.

## **8. Shareholders' Equity**

For the three months ended March 31, 2015, GSK purchased 92,674 shares of our common stock pursuant to its periodic top-up rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended, among us, GSK and certain GSK affiliates, for an aggregate purchase price of approximately \$1.7 million.

On February 20, 2015, our Board of Directors declared a quarterly dividend of \$0.25 per share of common stock to stockholders of record as of the close of business on March 12, 2015. During the three months ended March 31, 2015, we paid \$28.8 million in dividends. Unvested RSAs and certain unvested RSUs as of the record date are also entitled to dividends, which will only be paid when the RSAs and such RSUs vest and are released. For further information on the impact of the payments of the cash dividends on the 2023 Notes, refer to Note 7, Long-Term Debt .

Table of Contents

**9. Commitments and Contingencies**

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

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

As of March 31, 2014, we determined that the achievement of the requisite performance conditions for the first tranche of these awards was probable and, as a result, \$9.1 million of cash bonus expense was recognized for the three months ended March 31, 2014, the majority of which is included in discontinued operations in the condensed consolidated statements of operations. In May 2014, the total cash bonus of \$9.5 million for the first tranche was paid.

In connection with the Spin-Off, the Compensation Committee approved the modification of the remaining tranches related to these awards as the performance conditions associated with the remaining portions of these awards were unlikely to be consistent with the new strategies of each company following the separation. The modification acknowledged the Spin-Off and permitted recognition of achievement of certain of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the cash awards. The amount payable by us under these modified cash bonus awards is \$0.5 million. The remaining tranches of the cash awards were forfeited.

**10. Income Taxes**

We did not record a provision for income taxes for the three months ended March 31, 2015 and 2014, because we expect to and did generate a taxable net operating loss for the fiscal years ended December 31, 2015 and 2014. In addition, the deferred tax assets remain fully offset by a valuation allowance or uncertain tax position liabilities.

**11. Discontinued Operations**

On June 1, 2014, we separated our research and drug development businesses from our late-stage partnered respiratory assets. For further information on the Spin-Off, refer to Note 1 Description of Operations and Summary of Significant Accounting Policies . The significant components of the research and drug development operations, which are presented as discontinued operations on the condensed consolidated statements of operations, were as follows:

(In thousands)	Three months ended March 31,	
	2015	2014

## Edgar Filing: THERAVANCE INC - Form 10-Q

Net revenues (1)	\$	\$	945
Loss from discontinued operations (2)			(51,521)

---

(1) Net revenues consist of revenue from product sales. Product sales were generated from sales of VIBATIV in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers ordered VIBATIV through these distributors. Commencing in the first quarter of 2014, revenue on the sale of VIBATIV was recorded on a sell-through basis, once the distributors sold the product to healthcare providers. Product sales were recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions.

(2) Loss from discontinued operations decreased for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 primarily due to there being no impact of discontinued operations after the Spin- Off occurring in June 2014. Included in the loss from discontinued operations for the three months ended March 31, 2014 are external legal and accounting fees in connection with our separation strategy and the additional stock-based compensation and cash bonus expense recognized due to the achievement of performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011.

### 12. Subsequent Event

On April 24, 2015, our Board of Directors declared a quarterly dividend of \$0.25 per share of common stock to stockholders of record as of the close of business on June 12, 2015. Unvested RSAs and certain RSUs as of the record date are also entitled to dividends, which will only be paid when the RSAs and such RSUs vest and are released. The dividend will be paid on June 30, 2015.

Table of Contents

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

**Forward-Looking Statements**

The information in this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements contained herein that are not of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives, may be forward-looking statements. The words anticipates, believes, could, designed, estimates, expects, goal, intends, may, objective, plans, projects, pursue, will, would and similar expressions 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 materially differ 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 below in Risk Factors in Item 1A of Part II and in Management's Discussion and Analysis of Financial Condition and Results of Operations in this Item 2 of Part I. All forward-looking statements in this document are based on information available to us as of the date hereof and we assume no obligation to update any such forward-looking statements on account of new information, future events or otherwise, except as required by law.

**OVERVIEW**

**Executive Summary**

Theravance, Inc. is a royalty management company focused on maximizing the potential value of the respiratory assets partnered with Glaxo Group Limited ( GSK ), including RELVAR®/BREO® ELLIPTA® (fluticasone furoate/ vilanterol, FF/VI ) and ANORO® ELLIPTA® (umeclidinium bromide/ vilanterol, UMEC/VI ), with the intention of providing capital returns to stockholders. Under the Long-Acting Beta2 Agonist ( LABA ) Collaboration Agreement and the Strategic Alliance Agreement with GSK (referred to herein collectively as the GSK Agreements ), Theravance is eligible to receive the associated royalty revenues from RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and if approved and commercialized, VI monotherapy. Theravance is also entitled to 15% of any future payments made by GSK under its agreements originally entered into with us, and since assigned to Theravance Respiratory Company, LLC ( TRC ), relating to the combination FF/UMEC/VI and the Bifunctional Muscarinic Antagonist-Beta2 Agonist ( MABA ) program, as monotherapy and in combination with other therapeutically active components, such as an inhaled corticosteroid, and any other product or combination of products that may be discovered and developed in the future under the LABA Collaboration Agreement, which has been assigned to TRC other than RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and VI monotherapy.

On June 1, 2014, we separated our biopharmaceutical research and drug development operations from our late-stage partnered respiratory assets by transferring our research and drug development operations into our then wholly-owned subsidiary, Theravance Biopharma, Inc. ( Theravance Biopharma ). We contributed \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma and all outstanding shares of Theravance Biopharma were then distributed to Theravance stockholders as a pro-rata dividend distribution on June 2, 2014 by issuing one ordinary share of Theravance Biopharma for every 3.5 shares held of our common stock to stockholders of record on May 15, 2014 (the Spin-Off ). The Spin-Off resulted in Theravance Biopharma operating as an independent publicly-traded company. The results of operations for

## Edgar Filing: THERAVANCE INC - Form 10-Q

the former research and drug development operations conducted by us and by Theravance Biopharma until June 1, 2014 are included as part of this report as discontinued operations.

Pursuant to a three-way master agreement entered into by and among us, Theravance Biopharma and GSK in connection with the Spin-Off, we agreed to sell a certain number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had a right to purchase these shares of Theravance Biopharma from us, but this right expired unexercised. Accordingly, at December 31, 2014, we owned 436,802 ordinary shares of Theravance Biopharma. During the three months ended March 31, 2015, we sold all of the ordinary shares of Theravance Biopharma, Inc. that we held at December 31, 2014.

As a royalty management company, we have designed our company structure and organization to be focused on managing our respiratory assets with GSK, the commercial and developmental obligations associated with the GSK Agreements, intellectual property, licensing operations, and providing for certain essential reporting and management functions of a public company. As of March 31, 2015, we had 12 employees. Our revenues consist of royalties and potential milestone payments, if any, from our respiratory partnership agreements with GSK.

Table of Contents

**Financial Highlights**

For the three months ended March 31, 2015, our net loss from our continuing operations was \$10.7 million, decrease of \$5.5 million from \$16.2 million for the three months ended March 31, 2014, primarily due to an increase in our royalty revenues and lower employee-related expenses, including stock-based compensation expense, as a result of decreased operations post Spin-Off, offset by an increase in interest expense from our non-recourse notes payable due 2029 (the 2029 Notes ). Cash, cash equivalents, and marketable securities, totaled \$255.1 million at March 31, 2015, a decrease of \$28.3 million from December 31, 2014. The decrease was primarily due to net cash used in operations of \$1.6 million and payments of cash dividends of \$28.8 million. These outflows were partially offset by net proceeds of \$1.1 million received from issuances of our common stock.

**Recent Developments**

*Declaration and Payment of Cash Dividends*

On February 23, 2015, our Board of Directors declared a quarterly dividend of \$0.25 per share of common stock to stockholders of record as of the close of business on March 12, 2015. During the three months ended March 31, 2015, we paid \$28.8 million in dividends. Unvested RSAs and certain unvested RSUs as of the record date are also entitled to dividends, which will only be paid when the RSAs and such RSUs vest and are released. In connection with the payments of these cash dividends, the conversion rate with respect to our 2.125% Convertible Subordinated Notes due 2023 (the 2023 Notes ) was adjusted.

**Program Highlights**

- The U.S. Food and Drug Administration approved BREO® ELLIPTA® (FF/VI) for the once-daily treatment of asthma in patients aged 18 years and older. BREO® ELLIPTA® is not indicated for the relief of acute bronchospasm.
- GSK and Theravance announced the launch of REVLAR® ELLIPTA® in Italy for the treatment of asthma in people 12 and over and for the treatment of patients with chronic obstructive pulmonary disease ( COPD ) who have an exacerbation history despite regular bronchodilator therapy.
- GSK and Theravance announced the launch of ANORO® ELLIPTA® in Spain, following the approval in Europe in May 2014 as a once-daily maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD.
- In the first quarter of 2015, net sales of RELVAR®/BREO® ELLIPTA® by GSK were \$59.9 million, composed of \$21.6 million in the U.S. market and \$38.3 million in non-U.S. markets.

- As of March 31, 2015, RELVAR®/BREO® ELLIPTA® has been approved in 64 countries for marketing and has been launched in 38 countries.
- In the first quarter of 2015, sales of ANORO® ELLIPTA® by GSK were \$17.7 million, composed of \$14.0 million in the U.S. market and \$3.7 million in non-U.S. markets.
- As of March 31, 2015, ANORO® ELLIPTA® has been approved in 50 countries for marketing and has been launched in 20 countries.

### **Collaborative Arrangements with GSK**

#### ***LABA Collaboration***

In November 2002, we entered into our LABA Collaboration Agreement with GSK to develop and commercialize once-daily LABA products for the treatment of COPD and asthma. For the treatment of COPD, the collaboration has developed two combination products: (1) RELVAR®/BREO® ELLIPTA® (FF/VI) (BREO® ELLIPTA® is the proprietary name in the U.S. and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO® ELLIPTA® (UMEC/VI), a once-daily medicine combining a long-acting muscarinic antagonist ( LAMA ), umeclidinium bromide (UMEC), with a LABA, VI. Under the collaboration agreements between the parties, GSK and Theravance are exploring various paths to create triple therapy medications. For the treatment of asthma, RELVAR® ELLIPTA® is approved in multiple regions outside of North America and the collaboration is further developing FF/VI for the U.S. The FF/VI program is aimed at developing a once-daily combination LABA/ICS to succeed GSK's Advair®/Seretide® (salmeterol and fluticasone as a combination) franchise, which had reported 2014 sales of approximately \$7.0 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2014 sales of approximately \$3.8 billion. ANORO® ELLIPTA®, which is also a combination product, is targeted as an alternative treatment option to Spiriva® (tiotropium), a once-daily, single-mechanism bronchodilator, which had reported 2013 sales of approximately \$4.7 billion.

As a result of the launch and approval of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe, we were obligated to pay milestone fees to GSK totaling \$220.0 million, which we have paid in their entirety in 2014. Although we have no further milestone payment obligations to GSK pursuant to the LABA Collaboration Agreement, we continue to have ongoing development and commercialization activities under the GSK Agreements that are expected to continue over the life of the agreements. The milestone fees paid to GSK were recognized as capitalized fees paid to a related party, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product.

We are entitled to receive annual royalties from GSK on sales of RELVAR®/BREO® ELLIPTA® as follows: 15% on the first \$3.0 billion of annual global net sales and 5% for all annual global net sales above \$3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA collaboration, such as ANORO® ELLIPTA®, royalties are upward tiering and range from 6.5% to 10%.



Table of Contents

***2004 Strategic Alliance***

In March 2004, we entered into the Strategic Alliance Agreement with GSK where GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program. For a detailed discussion of our alliance with GSK, see Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on February 27, 2015.

***Agreements Entered into with GSK in Connection with the Spin-Off***

On March 3, 2014, in contemplation of the Spin-Off of Theravance Biopharma, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies would implement the Spin-Off and operate following the Spin-Off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the Spin-Off provided certain conditions were met. In addition, we and GSK also entered into amendments to the GSK Agreements, and Theravance Biopharma and GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The three-way master agreement was effective on June 1, 2014 when we transferred our research and drug development operations to Theravance Biopharma. Pursuant to a three-way master agreement entered into by and among us, Theravance Biopharma and GSK in connection with the Spin-Off, we agreed to sell a certain number of Theravance Biopharma shares withheld from a taxable dividend of Theravance Biopharma shares to GSK. After such Theravance Biopharma shares were sent to the transfer agent, we agreed to purchase the Theravance Biopharma shares from the transfer agent, rather than have them sold on the open market, in order to satisfy tax withholdings. GSK had a right to purchase these shares of Theravance Biopharma from us, but this right expired unexercised. During the three months ended March 31, 2015, we sold all ordinary shares of Theravance Biopharma that we held at December 31, 2014.

The amendments to the GSK Agreements do not change the economics or royalty rates under the GSK Agreements, though the assignment of the Strategic Alliance Agreement and portions of the LABA Collaboration Agreement to TRC do change how the economics are allocated between Theravance Biopharma and us. The amendments to the GSK Agreements do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the United States or the European Union of FF/UMEC/VI or a MABA in combination with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we will retain our full interests upon the Spin-Off and also products in which we will have retained only a portion of our interests upon the planned Spin-Off transaction, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements after the Spin-Off.

Table of Contents***Purchases of Common Stock by GSK***

Prior to 2015, affiliates of GSK purchased an aggregate of 31.6 million shares of our common stock. For the three months ended March 31, 2015, GSK purchased 92,674 shares of our common stock pursuant to its periodic top-up rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended, among us, GSK and certain GSK affiliates, for an aggregate purchase price of approximately \$1.7 million. As of April 30, 2015, GSK beneficially owned approximately 27% of our outstanding capital stock.

**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.

During the three months ended March 31, 2015, there were no significant changes to our critical accounting policies and estimates. Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on February 27, 2015 provides a more complete discussion of our critical accounting policies and estimates.

**Results of Operations*****Net Revenue***

Total net revenue from continuing operations, as compared to the prior years, was as follows:

(In thousands)	Three Months Ended March 31,		Change	
	2015	2014	\$	%
Royalties from a related party	\$ 10,130	\$ 730	\$ 9,400	1,288
Less: amortization of capitalized fees paid to a related party	(3,456)	(1,780)	(1,676)	94
Royalty revenue	6,674	(1,050)	7,724	(736)
Strategic alliance - MABA program license	222	270	(48)	(18)
Total net revenue from GSK	\$ 6,896	\$ (780)	\$ 7,676	(984)%

## Edgar Filing: THERAVANCE INC - Form 10-Q

Total net revenue increased for the three months ended March 31, 2015 compared to the three months ended March 31, 2014. The increase is primarily due to RELVAR®/BREO® ELLIPTA® being in the early stages of commercial launch at March 31, 2014 and ANORO® ELLIPTA® not having been commercially launched at March 31, 2014. Royalty revenue is reduced by amortization expense for capitalized fees paid to a related party.

### *Research & Development*

Research & Development expenses from continuing operations, as compared to the prior years, were as follows:

(In thousands)	Three Months Ended March 31,		Change	
	2015	2014	\$	%
Research and development expenses	\$ 712	\$ 2,687	\$ (1,975)	(74)%

Research and development expenses decreased for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 primarily due to fewer allocated costs as our ongoing operations are significantly smaller as a result of the Spin-Off.

We expect research and development expenses in 2015 to decrease compared to 2014 due to the Spin-Off of our research and drug development operations. Currently, our research and development expenses are primarily due to expenses related to the late-stage partnered respiratory assets with GSK.

### *General & Administrative*

General and administrative expenses from continuing operations, as compared to the prior years, were as follows:

(In thousands)	Three Months Ended March 31,		Change	
	2015	2014	\$	%
General and administrative expenses	\$ 5,439	\$ 11,256	\$ (5,817)	(52)%

Table of Contents

General and administrative expenses decreased for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 primarily due to lower stock-based compensation expense and employee-related costs. For the three months ended March 31, 2014, stock-based compensation expense and employee-related costs were higher primarily due to the probable achievement of performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011.

We expect general and administrative expenses in 2015 to decrease due to the Spin-Off of our research and drug development operations and the significant reduction in our general and administrative cost structure. Since the Spin-Off, we significantly downsized our operations related to managing our respiratory assets with GSK, managing the commercial and developmental obligations associated with the GSK Agreements, intellectual property, and licensing operations, and providing certain essential reporting and management functions of a public company.

***Other Income (Expense), net and Interest Income***

Other income (expense), net and interest income, as compared to the prior years, were as follows:

(In thousands)	Three Months Ended March 31,		Change	
	2015	2014	\$	%
Other income (expense), net	\$ 1,178	\$ (3)	\$ 1,181	*
Interest income	116	188	(72)	(38)%

Other income (expense), net increased for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 primarily related to a realized gain of \$1.2 million on the sale of all of the ordinary shares of Theravance Biopharma, Inc. that we held at December 31, 2014.

***Interest Expense***

Interest expense, as compared to the prior year period, was as follows:

(In thousands)	Three Months Ended March 31,		Change	
	2015	2014	\$	%
Interest expense	\$ (12,706)	\$ (1,644)	\$ (11,062)	673%

Interest expense increased for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 primarily due to the issuance of our 2029 Notes in April 2014.

***Discontinued Operations***

## Edgar Filing: THERAVANCE INC - Form 10-Q

On June 1, 2014, we separated our research and drug development businesses from our late-stage partnered respiratory assets. The significant components of the research and drug development operations, which are presented as discontinued operations on the condensed consolidated statements of operations, were as follows:

(In thousands)	Three Months Ended March 31,		Change		
	2015	2014	\$	\$	%
Net revenue	\$	\$ 945	\$	(945)	*
Loss from discontinued operations		(51,521)		51,521	(100)%

Table of Contents

Revenue from collaborative arrangements for the three months ended March 31, 2014 includes products sales from sales of VIBATIV® in the U.S. for which revenue recognition commenced in the first quarter of 2014 which was transferred to Theravance Biopharma as a part of the Spin-Off.

Loss from discontinued operations decreased for the three months ended March 31, 2015 compared to the three months ended March 31, 2014 because there was no impact of discontinued operations after the Spin-Off in June 2014. Loss from discontinued operations for the three months ended March 31, 2014 primarily relates to research and development expenses in addition to external legal and accounting fees in connection with our separation strategy and the additional stock-based compensation and cash bonus expense recognized due to the achievement of performance conditions under a special long-term retention and incentive equity and cash bonus awarded to certain employees in 2011 both of which we started to incur in 2013.

**Liquidity and Capital Resources**

*Liquidity*

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under collaborative arrangements. In 2015, we have also received royalty payments from GSK from sales of RELVAR®/BREO® ELLIPTA®, which was launched in the fourth quarter of 2013, and from ANORO® ELLIPTA®, which was launched during 2014. At March 31, 2015, we had \$255.1 million in cash, cash equivalents, and marketable securities.

On February 23, 2015, our Board of Directors declared a quarterly dividend of \$0.25 per share of common stock to stockholders of record as of the close of business on March 12, 2015. During the three months ended March 31, 2015, we paid \$28.8 million in dividends.

On June 1, 2014, we contributed \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma as initial funds for their operations, based on anticipated operating plans and financial forecasts at the separation date. Although our cash on hand was reduced as a result of the Spin-Off, we expect that going forward our operating expenses will decrease significantly as our ongoing operations will be significantly smaller due to our focus on royalty management activities. As a result of the reduction in our operations, we believe that cash from future royalty revenues, net of operating expenses, debt service and cash on hand, will be sufficient to fund our operations for at least the next twelve months.

In April 2014, we entered into certain note purchase agreements relating to the private placement of \$450.0 million aggregate principal amount of non-recourse 9% fixed rate term notes due 2029 ( 2029 Notes ). The 2029 Notes are secured exclusively by a security interest in a segregated bank account established to receive 40% of the royalties from global net sales occurring on or after April 1, 2014 and ending upon the earlier of full repayment of principal or May 15, 2029 due to us under the LABA Collaboration Agreement with GSK. Prior to May 15, 2016, in the event that the specified portion of royalties received in a quarter is less than the interest accrued for the quarter, the principal amount of the 2029 Notes will increase by the interest shortfall amount for that period. As of March 31, 2015, interest expense of \$27.0 million was added to the principal balance of the 2029 Notes. From the net proceeds of the offering of approximately \$434.7 million, we established a milestone payment reserve account to fund 40% of any future milestone payments that could become payable under the LABA Collaboration Agreement with GSK. At March 31, 2015, the balance of the milestone reserve account and royalty collection account was not material. We incurred approximately

## Edgar Filing: THERAVANCE INC - Form 10-Q

\$15.3 million in debt issuance costs, which are being amortized to interest expense over the estimated life of the 2029 Notes.

### *Adequacy of cash resources to meet future needs*

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 based upon current operating plans and financials forecasts. If our current operating plans and financial forecasts change, we may require additional funding sooner in the form of public or private equity offerings or debt financings or may need to reduce or stop our quarterly dividend. 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 currently planned. In addition, we regularly explore debt restructuring and/or reduction alternatives, including through tender offers, redemptions, repurchases or otherwise, all consistent with the terms of our debt agreements.

### *Cash Flows*

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

<b>(In thousands)</b>	<b>Three Months Ended March 31,</b>		<b>Change</b>
	<b>2015</b>	<b>2014</b>	<b>2014</b>
Net cash used in operating activities	\$ (1,616)	\$ (50,637)	\$ 49,021
Net cash provided by investing activities	73,710	14,130	59,580
Net cash (used in) provided by financing activities	(27,708)	18,272	(45,980)

Table of Contents

*Cash Flows from Operating Activities*

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

Net cash used in operating activities for the three months ended March 31, 2015 of \$1.6 million was primarily due to:

- \$4.2 million used for operating expenses, after adjusting for stock-based compensation expense of \$1.9 million
- \$0.9 million decrease in amounts payable to Theravance Biopharma;
- \$6.9 million used for interest payments on convertible subordinated notes, due 2023 and non-recourse notes, due 2029; and
- \$10.4 million provided by receipt of royalties from collaborative arrangements

Net cash used in operating activities for the three months ended March 31, 2014 of \$50.6 million was primarily due to:

- \$49.3 million used for operating expenses, after adjusting for non-cash related items of: \$17.1 million consisting primarily of stock-based compensation expense of \$13.5 million and depreciation and amortization expenses of \$3.4 million;
- \$3.1 million used for interest payments on convertible subordinated notes, due 2023;
- \$2.1 million used to increase prepaid expenses and other current assets;
- \$2.3 million provided by the decrease in related party receivables from collaborative arrangements related to net receipts of royalty revenue and reimbursement of research and development services; and
- \$4.4 million provided by the increase in accrued liabilities.

*Cash Flows from Investing Activities*

Net cash provided by investing activities for the three months ended March 31, 2015 of \$73.7 million was primarily due to \$82.2 million of proceeds received from the sale of marketable securities and maturities of marketable securities, partially offset by \$8.5 million in purchases of marketable securities.

## Edgar Filing: THERAVANCE INC - Form 10-Q

Net cash provided by investing activities for the three months ended March 31, 2014 of \$14.1 million was primarily due to \$65.8 million of proceeds received from maturities of marketable securities, net of purchases, partially offset by \$55.0 million used for milestone payments to GSK.

### *Cash Flows from Financing Activities*

Net cash used in financing activities for the three months ended March 31, 2015 of \$27.7 million was primarily due to \$28.8 million of cash dividends paid to our stockholders, offset by \$1.1 million of net proceeds received from the issuance of our common stock.

Net cash provided by financing activities for the three months ended March 31, 2014 of \$18.3 million was primarily due to net proceeds from the issuances of our common stock, which includes net proceeds of \$12.9 million received from private placements of our common stock to an affiliate of GSK.

### *Off-Balance Sheet Arrangements*

Due to the Spin-Off, the leases for the facilities in South San Francisco, California, which formerly served as our headquarters, were assigned to Theravance Biopharma. We would be held liable by the landlord if Theravance Biopharma default under its lease obligations, and thus, we have in substance guaranteed the payments under the lease agreements for the South San Francisco facilities. As of March 31, 2015, the total lease payments for the duration of the lease, which runs through May 2020, are approximately \$32.0 million. We would be also responsible for lease related payments including utilities, property taxes, and common area maintenance, which may be as much as the actual lease payments. We recorded a long-term liability of \$1.3 million on our condensed consolidated balance sheet as of March 31, 2015 related to the estimated fair value of this guarantee.

### *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.

Table of Contents

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

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

In connection with the Spin-Off, the Compensation Committee of our Board of Directors approved the modification of the remaining tranches related to these awards as the performance conditions associated with the remaining portions of these awards were unlikely to be consistent with the new strategies of each company following the separation. The modification acknowledged the Spin-Off and permitted recognition of achievement of certain of the original performance conditions that were met prior to the Spin-Off, triggering service-based vesting for a portion of the cash and equity awards. Stock-based compensation expense of \$3.8 million associated with this portion of the equity awards after the modification is expected to be recognized by us during the twelve month period that commenced in June 2014. The remaining 63,000 RSAs for which service-based vesting was not triggered at the time of the Spin-Off remain subject to new performance conditions (as well as the original service conditions). In addition, the RSAs for which both the performance and service-based conditions were not achieved prior to the Spin-Off were entitled to the pro rata dividend distribution made by Theravance on June 2, 2014 of one ordinary share of Theravance Biopharma for every 3.5 shares of Theravance common stock subject to their awards. The Theravance Biopharma shares will be subject to the same new performance and service conditions as the original RSAs to which they relate. The amount payable by us under the modified cash bonus awards is \$0.5 million and the remaining tranches of the cash bonus awards were forfeited.

**Contractual Obligations and Commercial Commitments**

There have been no significant changes in our payments due under contractual obligations, compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

**Item 3. Quantitative and Qualitative Disclosure about Market Risk.**

During the three months ended March 31, 2015, there have been no significant changes in our market risk or how our market risk is managed compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

**Item 4. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures.*

## Edgar Filing: THERAVANCE INC - Form 10-Q

We conducted an evaluation 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, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) 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 levels.

### *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 have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

### *Changes in Internal Control over Financial Reporting*

Effective January 1, 2015, we implemented a new information system to support our financial reporting and reduced our reliance on Theravance Biopharma, Inc. for the financial reporting function which was provided pursuant to our transition service agreement as part of the Spin-Off. There were no other changes 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.

Table of Contents

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

**Risks Related to our Business**

*For the foreseeable future we will derive all of our royalty revenues from GSK and our future success depends on GSK's ability to successfully develop and commercialize the products in the respiratory programs partnered with GSK.*

Pursuant to the GSK Agreements, GSK is responsible for the development and commercialization of products in the partnered respiratory programs. Through March 31, 2015, sales of both BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup> by GSK have been significantly below our expectations which resulted in a decline in our stock price. Although we may receive milestone payments from GSK if certain development milestones are achieved in our MABA program, we believe that royalty revenues from BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup> will represent the majority of our future revenues from GSK. The amount and timing of revenue from such royalties and milestones is unknown and highly uncertain. Our future success depends upon the performance by GSK of its commercial obligations under the GSK Agreements. We have no control over GSK's marketing and sales efforts, and GSK might not be successful, which would harm our business and cause the price of our securities to fall.

The amount of royalties and milestone payments, if any, we receive will depend on many factors, including the following:

- the extent and effectiveness of the sales and marketing and distribution support GSK provides our partnered products;
- the competitive landscape for approved products and developing therapies that compete with our partnered products, including other products owned by GSK (such as Advair<sup>®</sup>) but which are not partnered with us and pricing pressure in the respiratory markets targeted by our partnered products;
- the size of the market for our partnered products;
- decisions as to the timing of product launches, pricing and discounts;
- GSK's ability to expand the indications for which our partnered products can be marketed;

- a satisfactory efficacy and safety profile as demonstrated in a broad patient population;
- acceptance of, and ongoing satisfaction with, our partnered products by the medical community, patients receiving therapy and third party payors;
- acceptance of, and ongoing satisfaction with, our partnered products by the medical community, patients receiving therapy and third party payors;
- the ability of patients to be able to afford our partnered products or obtain health care coverage that covers our partnered products;
- safety concerns in the marketplace for respiratory therapies in general and with our partnered products in particular;
- regulatory developments relating to the manufacture or continued use of our partnered products;
- GSK's ability to successfully achieve development milestones with respect to our partnered MABA program;
- GSK's ability to obtain regulatory approval of our partnered products in additional countries; or
- the unfavorable outcome of any potential litigation relating to our partnered products.

***Reduced prices and reimbursement rates due to the actions of governments, payors, or competition or other healthcare cost containment initiatives such as restrictions on use, may negatively impact royalties generated under the GSK Agreements.***

The continuing efforts of governments, pharmaceutical benefit management organizations (PBMs), insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care has adversely affected the price, market access, and total revenues of BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup> and may continue to adversely affect them in the future. In addition, we have experienced and expect to continue to experience increased competitive activity which has resulted in lower overall prices for our products.

Table of Contents

The Patient Protection and Affordable Care Act and other legislative or regulatory requirements or potential legislative or regulatory actions regarding healthcare and insurance matters, along with the trend toward managed healthcare in the United States (U.S.), could adversely influence the purchase of healthcare products and reduce demand and prices for our partnered products. This could harm GSK's ability to market our partnered products and significantly reduce future revenues. For example, when GSK launched BREO<sup>®</sup> ELLIPTA<sup>®</sup> for the treatment of COPD in the U.S. in October 2013, GSK experienced significant challenges gaining coverage at some of the largest PBMs, healthcare payors, and providers and lower overall prices than expected. Recent actions by U.S. PBMs in particular have increased discount levels for respiratory products resulting in lower net sales pricing realized for products in our collaboration. Further, if the ongoing Phase 3b studies with FF/VI do not show improved outcomes relative to the standard of care, obtaining payor coverage for RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> could become more difficult 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 will continue and may increase. This may make it difficult for GSK to sell our partnered products at a price acceptable to us or GSK or to generate revenues in-line with our analysts' or investors' expectations, which may cause the price of our securities to fall.

***If GSK is unable to successfully complete the Study to Understand Mortality and Morbidity (SUMMIT), or if data generated from the SUMMIT mortality study indicate safety concerns, or if the results do not meet market expectations, sales of RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> could be diminished and our ability to generate royalties from such sales could be negatively affected, and the price of our securities could fall.***

GSK is conducting the SUMMIT mortality study to determine the impact of RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup> on all cause mortality amongst patients with moderate chronic obstructive pulmonary disease (COPD) who have cardiovascular disease (CVD) or are at increased risk for CVD. SUMMIT is a multicenter, double-blind, parallel-group, placebo-controlled study of approximately 16,000 patients who are randomised to receive either once daily treatment with fluticasone furoate/vilanterol (100/25mcg), fluticasone furoate (100mcg), vilanterol (25mcg) or placebo. The primary objective is to evaluate the effect of FF/VI compared with placebo on survival evaluated by the primary endpoint of all-cause mortality. The secondary endpoints are rate of decline in forced expiratory volume in 1 second (FEV1) and a composite cardiovascular endpoint. GSK expects to report results for SUMMIT in 2015.

If the data derived from SUMMIT are negative, demonstrate a mortality signal, or identify other safety or efficacy concerns with RELVAR/BREO ELLIPTA, it could result in, among other things:

- decreased market acceptance and demand for RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>;
- decrease in the size of the market for RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>;
- safety concerns in the marketplace for RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>;
- shifts in the medical community to new treatment paradigms or standards of care;
- changes in the competitive landscape for approved and developing therapies that may compete with RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>;
- GSK's ability to obtain regulatory approval for RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>, in additional jurisdictions;
- the unfavorable outcome or other negative effects of any potential litigation relating to RELVAR<sup>®</sup>/BREO<sup>®</sup> ELLIPTA<sup>®</sup>.

## Edgar Filing: THERAVANCE INC - Form 10-Q

- additional restrictions on the commercialization of RELVAR®/BREO® ELLIPTA® through changes to the approved RELVAR®/BREO® ELLIPTA® labels;
- the imposition of additional post-approval studies or trials; or
- the withdrawal of the approvals of RELVAR®/BREO® ELLIPTA®.

Our business, operations and stock price would be negatively affected if any of these or similar events occur.

***If the commercialization of RELVAR ® /BREO ® ELLIPTA ® or ANORO® ELLIPTA® in the countries in which they have received regulatory approval encounters any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investor, analyst or our expectations, our business will be harmed, and the price of our securities could fall.***

Under the GSK Agreements, GSK has full responsibility for commercialization of RELVAR ® / BREO ® ELLIPTA ® and ANORO® ELLIPTA®. GSK has launched RELVAR ® / BREO ® ELLIPTA ® in a number of countries including the United States (U.S.), Canada, Japan, the United Kingdom, and Germany among others. The commercial launch of both products has been below our expectations primarily due to lower overall pricing levels in the U.S. and a longer timeframes to obtain payor coverage. For example, GSK recently stated that it has experienced more restrictive formulary access and lower net pricing in the U.S. respiratory market than it expected, which may indicate broader weakness in the respiratory markets targeted by RELVAR ® / BREO ® ELLIPTA ® and ANORO® ELLIPTA®. As a result, a number of analysts have adjusted their sales forecasts downward from previous projections. Any further delays or adverse developments or perceived additional delays or adverse developments with respect to the commercialization of RELVAR ® / BREO ® ELLIPTA ® and ANORO® ELLIPTA® including if sales or payor coverage do not meet investor, analyst or our expectations, will significantly harm our business and the price of our securities could fall.

***On April 30, 2015, the U.S. Food and Drug Administration ( FDA ) approved BREO® ELLIPTA® (FF/VI) as a once-daily inhaled treatment for asthma in patients aged 18 years and older in the U.S., if our commercialization efforts to market BREO® ELLIPTA® for asthma encounters any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investor, analyst or our expectations, our business will be harmed, and the price of our securities could fall.***

Table of Contents

On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and it will require manufacturers to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medicines. The FDA now requires that the product labels for LABA medicines reflect, among other things, that the use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, in March 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as clinical trial design ) to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it is requiring the manufacturers of currently marketed LABAs to conduct additional randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. Results from these post-marketing studies are expected in 2017. It is unknown at this time what, if any, effect these or future FDA actions will have on the prospects for FF/VI. The current uncertainty regarding the FDA's position on LABAs for the treatment of asthma and the lack of consensus expressed at the March 2010 Advisory Committee may result in the FDA requiring additional asthma clinical trials in the U.S. for FF/VI and increase the overall risk of FF/VI for the treatment of asthma in the U.S. We cannot predict the extent to which new FDA policy or guidance might significantly impede the discovery, development, production and marketing of FF/VI. Any adverse change in FDA policy or guidance regarding the use of LABAs to treat asthma may significantly harm our business and the price of our securities could fall.

***Any adverse developments to the regulatory status of either RELVAR® /BREO® ELLIPTA® or ANORO® ELLIPTA® in the countries in which they have received regulatory approval including labeling restrictions, safety findings, or any other limitation to usage, will harm our business and may cause the price of our securities to fall.***

Although RELVAR®/BREO® ELLIPTA® or ANORO® ELLIPTA® are approved and marketed in a number of countries, it is possible that adverse changes to the regulatory status of these products could occur in the event new safety issues are identified, treatment guidelines are changed, or new studies fail to demonstrate product benefits. A number of notable pharmaceutical products have experienced adverse developments during commercialization that have resulted in the product being withdrawn, approved uses being limited, or new warnings being included. In the event that any adverse regulatory change were to occur to any of our products, our business will be harmed and the price of our securities will fall.

***Any adverse developments or results or perceived adverse developments or results with respect to the SUMMIT mortality study with RELVAR/BREO ELLIPTA in COPD, ongoing studies for FF/VI in asthma or COPD, for UMEC/VI in COPD, or any future studies will significantly harm our business and the price of our securities could fall, and if regulatory authorities in those countries in which approval has not yet been granted determine that the Phase 3 programs for FF/VI in asthma or COPD or the Phase 3 programs for UMEC/VI for COPD do not demonstrate adequate safety and efficacy, the continued development of FF/VI or UMEC/VI or both may be significantly delayed, they may not be approved by these regulatory authorities, and even if approved it may be subject to restrictive labeling, any of which will harm our business, and the price of our securities could fall.***

Although we have announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma, a number of additional studies of FF/VI are underway including the SUMMIT mortality study in COPD which is expected to read out in 2015. Any adverse developments or perceived adverse developments with respect to SUMMIT or any other current or future studies in these programs will significantly harm our business and the price of our securities could fall.

Although the FDA, the European Medicines Agency, the Japanese Ministry of Health, Labour and Welfare and Health Canada have approved ANORO® ELLIPTA®, it has not yet been approved in other countries. Any adverse developments or results or perceived adverse developments

## Edgar Filing: THERAVANCE INC - Form 10-Q

or results with respect to other pending or future regulatory submissions for the FF/VI program or the UMEC/VI program will significantly harm our business and the price of our securities could fall. Examples of such adverse developments include, but are not limited to:

Table of Contents

- not every study, nor every dose in every study, in the Phase 3 programs for FF/VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs having to do with the LABA VI, which is a component of FF/VI and UMEC/VI;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs;
- regulatory authorities determining that the Phase 3 programs in asthma or in COPD raise safety concerns or do not demonstrate adequate efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs to treat asthma or the use of LABAs combined with a LAMA to treat COPD.

***RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® face substantial competition for their intended uses in the targeted markets from products discovered, developed, launched and commercialized both by GSK and by other pharmaceutical companies, which could cause the royalties payable to us pursuant to the LABA Collaboration Agreement to be less than expected, which in turn would harm our business and the price of our securities could fall.***

GSK has responsibility for obtaining regulatory approval, launching and commercializing RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® for their intended uses in the targeted markets around the world. While these products have received regulatory approval and been launched and commercialized in the U.S. and certain other targeted markets, the products face substantial competition from existing products previously developed and commercialized both by GSK and by other competing pharmaceutical companies and can expect to face additional competition from new products that are discovered, developed and commercialized by the same pharmaceutical companies and other competitors going forward. For example, sales of Advair®, GSK's approved medicine for both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®.

Many of the pharmaceutical companies competing in respiratory markets are international in scope with substantial financial, technical and personnel resources that permit them to discover, develop, obtain regulatory approval and commercialize new products in a highly efficient and low cost manner at competitive prices to consumers. In addition, many of these competitors have substantial commercial infrastructures that facilitate commercializing their products in a highly efficient and low cost manner at competitive prices to consumers. The market for products developed for treatment of COPD and asthma continues to experience significant innovation and reduced cost in bringing products to market over time. There can be no assurance that RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® will not be replaced by new products that are deemed more effective at lower cost to consumers. The ability of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® to succeed and achieve the anticipated level of sales depends on the commercial and development performance of GSK to achieve and maintain a competitive advantage over other products with the same intended use in the targeted markets.

If sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than anticipated because of existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, our royalty payments will be less than anticipated, which in turn would harm our business and the price of our securities could fall.

***We and GSK are developing UMEC/VI/FF (LAMA/LABA/ICS) and MABA/FF as potential triple combination treatments for COPD and, potentially, asthma. As a result of the Spin-Off, most of our economic rights in these programs were assigned to Theravance Biopharma. If these programs are successful and GSK and the respiratory market in general views triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, our business could be harmed, and the price of our securities could fall.***

Under our LABA Collaboration Agreement with GSK, we and GSK are exploring various paths to create triple therapy respiratory medications. The use of triple therapy is supported by the GOLD ( Global initiative for chronic Obstructive Lung Disease ) guidelines in high-risk patients with severe COPD and a high risk of exacerbations. One potential triple therapy path is the combination of UMEC/VI (two separate bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA ® dry powder inhaler, referred to as UMEC/VI/FF or the closed triple. Prior to the Spin-Off, we were entitled to receive 100% of any royalties payable under the GSK Agreements arising from sales of UMEC/VI/FF (as well as MABA and MABA/FF) if such products were successfully developed, approved and commercialized. In July 2014, we and GSK announced the initiation of a large, global Phase 3 study for the closed triple in patients with COPD. If this Phase 3 study (or any other closed triple Phase 3 studies that may be initiated in the future) is successful, GSK and the respiratory market in general may view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and

Table of Contents

ANORO® ELLIPTA®. In such event the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® could be adversely affected, which in turn could result in lower royalties to us. Furthermore, if the closed triple (or MABA /FF) receives regulatory approval in either the U.S. or the EU, GSK's diligent efforts obligations regarding commercialization matters will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future. As a result of the transactions effected by the Spin-Off, however, we are now only entitled to receive 15% of any contingent payments and royalties payable by GSK from sales of FF/UMEC/VI (and MABA, and MABA/FF) while Theravance Biopharma receives 85% of those same payments.

***On June 2, 2014, we completed the separation of our businesses into two independent, publicly traded companies by separating our late-stage partnered respiratory assets from our biopharmaceutical operations; the lengthy, complicated process to separate the two businesses has diverted the attention of our management and employees, and has increased our professional services expenses in 2014 and in the early part of 2015.***

On April 25, 2013, we announced our intention to separate our businesses into two independent, publicly traded companies. On August 1, 2013, the company to be spun-off, Theravance Biopharma, filed a preliminary Form 10 with the SEC, and subsequent amendments throughout 2013 and the spring of 2014. The Spin-Off was completed on June 2, 2014. Theravance continues to be responsible for all development and commercial activities under the GSK Agreements. Theravance is eligible to receive the associated royalty revenues from FF/VI (RELVAR®/BREO® ELLIPTA®), UMEC/VI (ANORO® ELLIPTA®) and potentially VI monotherapy and 15% of the aggregate potential royalty revenues payable to Theravance Respiratory Company, LLC from UMEC/VI/FF, MABA, and MABA/FF and other products that may be developed under the GSK Agreements. Theravance Biopharma is now a separate and independent publicly traded biopharmaceutical company focusing on the discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need.

In conjunction with the Spin-Off of Theravance Biopharma, on March 3, 2014, we, Theravance Biopharma and GSK entered into a series of agreements clarifying how the companies would implement the separation and operate following the Spin-Off. We, Theravance Biopharma and GSK entered into a three-way master agreement providing for GSK's consent to the Spin-Off provided certain conditions were met. We and GSK also entered into amendments of the GSK Agreements. The master agreement and the other agreements are all currently effective.

The amendments to the GSK Agreements do not change the royalty rates or other economic terms. The amendments do provide that GSK's diligent efforts obligations regarding commercialization matters under both agreements will change upon regulatory approval in either the U.S. or the EU of UMEC/VI/FF or a MABA combined with FF. Upon such regulatory approval, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a small portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the GSK Agreements in the future.

We cannot assure you that we will not undertake additional restructuring activities, that the business separation will succeed in meeting our objectives and increasing stockholder value, or that the actual results will not differ materially from the results that we anticipate.

## Edgar Filing: THERAVANCE INC - Form 10-Q

We have incurred and may continue to incur significant expenditures for professional services in connection with the business separation and our post-separation operations, including financial advisory, accounting and legal fees.

Under the terms of a separation and distribution agreement entered into between us and Theravance Biopharma, Theravance Biopharma will indemnify us from (i) all debts, liabilities and obligations transferred to Theravance Biopharma in connection with the Spin-Off (including its 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 in its information statement filed with the SEC, resulting in a misleading statement and (iii) any breach by it of certain agreements entered into between the parties in connection with the Spin-Off. Theravance Biopharma's ability to satisfy these indemnities, if called upon to do so, will depend upon its future financial strength and if we are not able to collect on indemnification rights from Theravance Biopharma, our financial condition may be harmed.

*We may not be able to utilize all of our net operating loss carryforwards.*

We have net operating loss carryforwards and other significant U.S. tax attributes that we believe could offset otherwise taxable income in the U.S. As a part of the overall Spin-Off transaction, the transfer of certain assets by us to Theravance Biopharma and our distribution of Theravance Biopharma ordinary shares resulted in taxable transfers pursuant to applicable provisions of the Internal Revenue Code of 1986, as amended (the Code) and Treasury Regulations. The taxable gain recognized by us attributable to the transfer of certain assets to Theravance Biopharma will generally equal the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. Although we will not recognize any gain with respect to the cash we transferred to Theravance Biopharma, we may recognize substantial gain based on the fair market value of the other assets (other than cash) transferred to Theravance Biopharma. The determination of the fair market value of these assets is subjective and could be subject to adjustments or future challenge by the Internal Revenue Service (IRS), which could result in

Table of Contents

an increase in the amount of gain realized by us as a result of the transfer. Our U.S. federal income tax resulting from any gain recognized upon the transfer of our assets to Theravance Biopharma (including any increased U.S. federal income tax that may result from a subsequent determination of higher fair market values for the transferred assets), may be reduced by our net operating loss carryforward. The net operating loss carryforwards available in any year to offset our net taxable income will be reduced following a more than 50% change in ownership during any period of 36 consecutive months (an ownership change) as determined under the Internal Revenue Code of 1986 (the Code). As of December 31, 2014, we have conducted an analysis to determine whether an ownership change had occurred since inception through December 31, 2014, and concluded that we had undergone two ownership changes in prior years. We have approximately \$1.4 billion of net operating loss carryforward available to us as of December 31, 2014. We currently expect our net operating losses to be fully available to offset current year net taxable income after taking into account the taxable nature of the Spin-Off. With respect to our remaining net operating losses of approximately \$1.2 billion as of December 31, 2014, there may be certain annual limitations for utilization based on the above-described ownership change provisions. In addition, we may not be able to have sufficient future taxable income prior to their expiration because net operating losses have carryforward periods. Future changes in federal and state tax laws pertaining to net operating loss carryforwards may also cause limitations or restrictions from us claiming such net operating losses. If the net operating loss carryforwards become unavailable to us or are fully utilized, our future taxable income will not be shielded from federal and state income taxation absent certain U.S. federal and state tax credits, and the funds otherwise available for general corporate purposes would be reduced.

***The Spin-Off resulted in substantial changes in our Board, management, and employees. If we fail to hire and effectively integrate new executive officers into our organization, the future development and commercialization of our product candidates may suffer, harming future regulatory approvals, sales of our product candidates or our results of operations.***

Since the Spin-Off, substantially all of our directors and senior management team has changed. Our current board and management team has only been working together for a relatively short period of time. In addition, Rick E Winningham resigned as our president and chief executive officer effective as of August 15, 2014 and as chairman of our Board and as a director effective as of October 30, 2014. We have appointed Michael W. Aguiar as our chief executive officer and as a member of our Board and appointed Eric d Esparbes as our chief financial officer. We expect to continue to expand our management team in the future. Our future performance will depend significantly on our ability to successfully integrate our new directors into our Board and our new chief executive officer, chief financial officer and other recently and subsequently hired executive officers into our management team, and on those individuals' ability to develop and maintain an effective working relationship. Our failure to integrate recently and subsequently appointed directors and executive officers, including our new chief executive officer and chief financial officer, with other members of management could result in inefficiencies in the conduct of our business, which can adversely affect our results of operations.

***If any product candidates in any respiratory program partnered with GSK are not approved by regulatory authorities or are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.***

The FDA must approve any new medicine before it can be marketed and sold in the U.S. Our partner GSK must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that the product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. GSK will not obtain this approval for a partnered product candidate unless and until the FDA approves a 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 medicines in foreign countries, separate regulatory approvals must be obtained 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 country may make approval in other countries more difficult.

## Edgar Filing: THERAVANCE INC - Form 10-Q

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

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical or non-clinical studies. In addition, clinical and non-clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these studies are substantially delayed or fail to prove the safety and effectiveness of product candidates in development partnered with GSK, GSK may not receive regulatory approval for such product candidates and our business and financial condition will be materially harmed and the price of our securities may fall.

Several well-publicized Complete Response letters issued by the FDA and safety-related product withdrawals, suspensions, post-approval labeling revisions to include boxed warnings and changes in approved indications over the last several years, as well as growing public and governmental scrutiny of safety issues, have created a conservative regulatory environment. The implementation of new laws and regulations and revisions to FDA clinical trial design guidance have increased uncertainty regarding the approvability of a new drug. Further, there are 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 any product candidates in any respiratory program partnered with GSK.

Table of Contents

***Even if product candidates in any respiratory program partnered with GSK receive regulatory approval, as is the case with RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®, commercialization of such products may be adversely affected by regulatory actions and oversight.***

Even if GSK receives regulatory approval for product candidates in any respiratory program partnered with GSK, this approval may include limitations on the indicated uses for which GSK can market the medicines or the patient population that may utilize the medicines, which may limit the market for the medicines or put GSK at a competitive disadvantage relative to alternative therapies. These restrictions make it more difficult to market the approved products.

For example, at the joint meeting of the Pulmonary-Allergy Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA regarding the sNDA for BREO® ELLIPTA® as a treatment for asthma, the advisory committee recommended that a large LABA safety trial with BREO® ELLIPTA® should be required in adults and in 12-17 year olds, similar to the ongoing LABA safety trials being conducted as an FDA Post-Marketing Requirement by each of the manufacturers of LABA containing asthma treatments.

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 or GSK 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 GSK, including requiring it 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. GSK is 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 as well as governmental authorities in those foreign countries in which any of the product candidates in any respiratory program partnered with GSK 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. Any failure to maintain regulatory approval will limit GSK's ability to commercialize the product candidates in any respiratory program partnered with GSK, which would materially and adversely affect our business and financial condition and which may cause the price of our securities to fall.

***We have incurred operating losses in each year since our inception and will continue to incur losses until royalties from the sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® exceed total expenses, including interest expenses, and our revenues and operating results will likely fluctuate in future periods.***

From mid-1997 until the Spin-Off, we were engaged in discovering and developing compounds and product candidates and we never generated sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve sustained profitability. As of March 31, 2015, we had an accumulated deficit of approximately \$1.7 billion. Although we expect to have a substantial reduction in our expenses in future periods as a result of the Spin-Off, we will continue to incur losses until royalties from the sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® exceed total expenses, including interest expenses, and our revenues and operating results will likely fluctuate from period to period. We are uncertain when or if we will be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities, our ability to return capital to stockholders and continue operations.

***We may not be successful in our efforts to expand our portfolio of royalty generating products.***

In the future, we may choose to acquire rights to one or more additional royalty generating products. However, we may be unable to license or acquire rights to suitable royalty generating products for a number of reasons. In particular, the licensing and acquisition of pharmaceutical product rights is a competitive area. Several more established companies are also pursuing strategies to license or acquire rights to royalty generating products. These established companies may have a competitive advantage over us. Other factors that may prevent us from licensing or otherwise acquiring rights to suitable royalty generating products include the following:

- we may be unable to license or acquire the rights on terms that would allow us to make an appropriate return from the product;
- companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or
- we may be unable to identify suitable royalty generating products.

If we are unable to acquire or license rights to suitable royalty generating product candidates, our business may suffer.

Table of Contents

***We have a significant amount of debt including Convertible Subordinated Notes and Non-Recourse Notes that are senior in capital structure and cash flow, respectively, to our common stockholders. Satisfying the obligations relating to our debt could adversely affect the amount or timing of distributions to our stockholders.***

As of March 31, 2015 we had approximately \$737.9 million in total long-term liabilities outstanding, comprised primarily of \$255.1 million in principal that remains outstanding under our 2.125% Convertible Subordinated Notes due 2023 (the 2023 Notes ) and \$477.0 million in principal that remains outstanding under our 9% Fixed Rate Royalty term notes due 2029 (the 2029 Notes and with the 2023 Notes, the Notes ). The 2023 Notes are unsecured debt and are not redeemable by us prior to the maturity date. Holders of the Notes may require us to purchase all or any portion of their Notes at 100% of their principal amount, plus any unpaid interest, upon a fundamental change. A fundamental change is generally defined to include a merger involving us, an acquisition of a majority of our outstanding common stock, and the change of a majority of our board without the approval of the board. In addition, to the extent we pursue and complete a monetization transaction, the structure of such transaction may qualify as a fundamental change under the Notes, which could trigger the put rights of the holders of the Notes, in which case we would be required to use a portion of the net proceeds from such transaction to repurchase any Notes put to us. Our 2029 Notes have rights to 40% of all royalty payments received from GSK related to RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA®, and VI monotherapy until the notes are paid in full.

Satisfying the obligations of this debt could adversely affect the amount or timing of any distributions to our stockholders. We may choose to satisfy repurchase, or refinance this debt through public or private equity or debt financings if we deem such financings available on favorable terms. If any or all of the Convertible Subordinated Notes are not converted into shares of our common stock before the maturity date, we will have to pay the holders the full aggregate principal amount of the Notes then outstanding. If the Fixed Rate Royalty are not refinanced or paid in full, then they will receive 40% of all future economics associated with RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA®, and VI monotherapy, until the notes are paid in full. Any of the above payments could have a material adverse effect on our cash position. If we fail to satisfy these obligations, it may result in a default under the indenture, which could result in a default under certain of our other debt instruments, if any. Any such default would harm our business and the price of our securities could fall.

***If we lose key management personnel, or if we fail to retain our key employees, our ability to manage our business will be impaired.***

Following the Spin-Off, we have a much smaller management team and very few employees. We are highly dependent on principal members of our management team and a small group of key employees to operate our business. Our company is located in northern California, which is headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market remains 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 business operations, which may cause the price of our securities to fall.

***We rely and will continue to rely on outsourcing arrangements for many of our activities, including financial reporting and accounting and human resources.***

We currently have only twelve full-time employees and, as a result, we rely, and expect to continue to rely, on outsourcing arrangements for a significant portion of our activities, including financial reporting and accounting and human resources, as well as for certain functions as a public company. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner.

*As we continue to develop our business, our mix of assets and our sources of income may require that we register with the SEC as an investment company in accordance with the Investment Company Act of 1940.*

We have not been and have no current intention to register as an investment company under the Investment Company Act of 1940, or the 40 Act, because we believe the nature of our assets and the sources of our income currently exclude us from the definition of an investment company pursuant to Sections (3)(a)(1)(A), (3)(a)(1)(C) under the 40 Act and Rule 270.3a-1 of Title 17 of the Code of Federal Regulations. Accordingly, we are not currently subject to the provisions of the 40 Act, such as compliance with the 40 Act's registration and reporting requirements, capital structure requirements, affiliate transaction restrictions, conflict of interest rules, requirements for disinterested directors, and other substantive provisions. Generally, to avoid being a company that is an investment company under the 40 Act, it must both: (a) not be or hold itself out as being engaged primarily in the business of investing, reinvesting or trading in securities, and (b) either (i) not be engaged or propose to engage in the business of investing in securities or own or propose to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis or (ii) not have more than 45% of the value of its total assets (exclusive of Government securities and cash items) consist of or more than 45% of its net income after taxes (for the last four fiscal quarters combined) be derived from securities. In addition, we would not be an investment company if an exception, exemption, or safe harbor under the 40 Act applies.

We monitor our assets and income for compliance with the tests under the 40 Act and seek to conduct our business activities to ensure that we do not fall within its definitions of investment company. If we were to become an investment company and be subject to the strictures of the 40 Act, the restrictions imposed by the 40 Act would likely require changes in the way we do business and add significant administrative burdens to our operations. In order to ensure that we do not fall within the 40 Act, we may need to take various actions which we might otherwise not pursue. These actions may include restructuring the Company and/or modifying our mixture of assets and income.

Table of Contents

Specifically, our mixture of debt vs. royalty assets is important to our classification as an investment company or not. In this regard, while we currently believe that none of the definitions of investment company apply to us, we may in the future rely on an exception under the 40 Act provided by Section 3(c)(5)(A). To qualify for Section 3(c)(5)(A), as interpreted by the staff of the SEC, we would be required to have at least 55% of our total assets in notes, drafts, acceptances, open accounts receivable, and other obligations representing part or all of the sales price of merchandise, insurance, and services (or Qualifying Assets). In a no-action letter issued to Royalty Pharma on August 13, 2010, the staff stated that royalty interests are Qualifying Assets under this exception. If the SEC or its staff in the future adopts a contrary interpretation or otherwise restricts the conclusions in the staff's no-action letter such that our royalty interests are no longer Qualifying Assets for purposes of Section 3(c)(5)(A), we could be required to register under the 40 Act.

The rules and interpretations of the SEC and the courts, relating to the definition of investment company are highly complex in numerous respects. While we currently intend to conduct our operations so that we will not be deemed an investment company, we can give no assurances that we will not determine it to be in the Company's and our stockholders' interest to register as an investment company, not be deemed an investment company and not be required to register under the 40 Act.

**Risks Related to our Alliance with GSK**

*Because all our current and projected revenues are derived from products under the GSK Agreements, disputes with GSK could harm our business and cause the price of our securities to fall.*

All of our current and projected revenues are derived from products under the GSK Agreements. Any action or inaction by either GSK or us that results in a material dispute, allegation of breach, litigation, arbitration, or significant disagreement between the 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 our partnered products and other GSK respiratory products, disputes over public statements, and similar matters. In addition, while we obtained GSK's consent to the Spin-Off as structured, GSK could decide to challenge various aspects of our post-Spin-Off operation of Theravance Respiratory Company, LLC (TRC), the limited liability company jointly owned by us and Theravance Biopharma as violating or allowing it to terminate the GSK Agreements. Although we believe our operation of TRC fully complies with the GSK Agreements and applicable law, there can be no assurance that we would 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 market or investor uncertainty about the respiratory programs partnered with GSK or the enforceability of the GSK Agreements could result in significant reduction in the market price of our securities and other material harm to our business.

*Because GSK is a strategic partner as well as a significant stockholder, it may take actions that in certain cases are materially harmful to both our business or to our other stockholders.*

Although GSK beneficially owns approximately 27% of our outstanding capital stock as of April 30, 2015, it is also a strategic partner with rights and obligations under the GSK Agreements that cause its interests to differ from the interests of us and our other stockholders. In particular, GSK has a substantial respiratory product portfolio in addition to the partnered products that are covered by the GSK Agreements. GSK may make respiratory product portfolio decisions or statements about its portfolio which may be, or may be perceived to be, harmful to the respiratory products partnered with us. For example, GSK could promote its non-GSK/THRAX respiratory products, delay or terminate the development or commercialization of the respiratory programs covered by the GSK Agreements, or take other actions, such as making public statements, that have a negative effect on our stock price. In this regard and by way of example, sales of Advair®, GSK's approved medicine for

both COPD and asthma, continue to be significantly greater than sales of RELVAR®/BREO® ELLIPTA®, and GSK has indicated publicly that it intends to continue commercializing Advair®. Also, given the potential future royalty payments GSK may be obligated to pay under the GSK Agreements, GSK may seek to acquire us to reduce those payment obligations. The timing of when GSK may seek to acquire us could potentially be when it possesses information regarding the status of drug programs covered by the GSK Agreements that has not been publicly disclosed and is not otherwise known to us. As a result of these differing interests, GSK may take actions that it believes are in its best interest but which might not be in the best interests of either us or our other stockholders. In addition, upon regulatory approval of UMEC/VI/FF or a MABA/ICS in either the U.S. or the EU, GSK's diligent efforts obligations as to commercialization matters under the GSK Agreements will have the objective of focusing on the best interests of patients and maximizing the net value of the overall portfolio of products under the GSK Agreements. Since GSK's commercialization efforts following such regulatory approval will be guided by a portfolio approach across products in which we have retained our full interest and also products in which we now have only a portion of our former interest, GSK's commercialization efforts may have the effect of reducing the overall value of our remaining interests in the products covered by the GSK Agreements in the future.

***GSK has also indicated to us that it believes its consent may be required before we can engage in certain royalty monetization transactions with third parties, which may inhibit our ability to engage in these transactions.***

In the course of our discussions with GSK concerning the Spin-Off of Theravance Biopharma, GSK indicated to us that it believes that its consent may be required before we can engage in certain transactions designed to monetize the future value of royalties that may be payable to us from GSK under the GSK Agreements. GSK has informed us that it believes that there may be certain covenants included in these types of transactions that might violate certain provisions of the GSK Agreements. Although we believe that we can structure royalty monetization transactions in a manner that fully complies with the requirements of the GSK Agreements without GSK's consent, a third party in a proposed monetization transaction may nonetheless insist that we obtain GSK's consent for the transaction or re-structure the transaction on less favorable terms. We have obtained GSK's agreement that (i) we may grant certain pre-agreed covenants in connection with monetization of our interests in RELVAR®/BREO® ELLIPTA®, ANORO® ELLIPTA® and vilanterol monotherapy and portions of our interests in TRC, and

Table of Contents

(ii) it will not unreasonably withhold its consent to our requests to grant other covenants, provided, among other conditions, that in each case, the covenants are not granted in favor of pharmaceutical or biotechnology company with a product either being developed or commercialized for the treatment of respiratory disease. If we seek GSK's consent to grant covenants other than pre-agreed covenants, we may not be able to obtain GSK's consent on reasonable terms, or at all. If we proceed with a royalty monetization transaction that is not otherwise covered by the GSK Agreement without GSK's consent, GSK could request that its consent be obtained or seek to enjoin or otherwise challenge the transaction as violating or allowing it to terminate the GSK Agreements. Regardless of the merit of any claims by GSK, we would incur significant cost and diversion of resources in defending against GSK's claims or asserting our own claims and GSK may seek concessions from us in order to provide its consent. Any uncertainty about whether or when we could engage in a royalty monetization transaction, the potential impact on the enforceability of the GSK Agreements or the loss of potential royalties from the respiratory programs partnered with GSK, could impair our ability to pursue a return of capital strategy for our stockholders ahead of our receipt of significant royalties from GSK, result in significant reduction in the market price of our securities and cause other material harm to our business.

***GSK's ownership of a significant percentage of our stock and its ability to acquire additional shares of our stock may create conflicts of interest, and may inhibit our management's ability to continue to operate our business in the manner in which it is currently being operated.***

As of April 30, 2015, GSK beneficially owned approximately 27% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock in certain circumstances. GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business.

In addition, GSK may make an offer to our stockholders to acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to no greater than 60%, provided that:

- the offer includes no condition as to financing;
  
- the offer is approved by a majority of our independent directors;
  
- the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer; and
  
- the shares purchased will be subject to the same provisions of the governance agreement as are the shares of voting stock currently held by GSK.

If pursuant to the provision described above GSK's ownership of us is greater than 50.1%, then GSK is allowed to make an offer to our stockholders to acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to 100%, provided that;

- the offer includes no condition as to financing;
- the offer is approved by a majority of our independent directors; and
- the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer.

The procedures governing GSK offers to our stockholders to acquire outstanding voting stock set forth in the preceding two paragraphs are applicable until the termination of the governance agreement on September 1, 2015 and thereafter the foregoing restrictions will not apply.

Further, pursuant to our Certificate of Incorporation, we renounce our interest in and waive any claim that a corporate or business opportunity taken by GSK constitutes a corporate opportunity of ours unless such corporate or business opportunity is expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

***GSK's significant ownership position and its rights under the governance agreement may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.***

As of April 30, 2015, GSK beneficially owned approximately 27% of our outstanding capital stock. GSK may vote at its sole discretion on any proposal to effect a change of control of us or for us to issue equity securities to one or more parties that would result in that party or parties beneficially owning more than 20% of our outstanding capital stock. Our governance agreement with GSK requires us to exempt GSK from any stockholder rights plan we may adopt in the future, affords GSK certain rights to offer to acquire us in the event third parties seek to acquire our stock and contains other provisions that could deter or prevent another company from seeking to acquire us.

Table of Contents

For example, GSK may offer to acquire 100% of our outstanding stock from stockholders in certain circumstances, such as if we are faced with a hostile acquisition offer or if our Board acts in a manner to facilitate a change in control of us with a party other than GSK. As a result of GSK's significant ownership and its rights under the governance agreement, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

***GSK could sell or transfer a substantial number of shares of our common stock, which could depress the price of our securities or result in a change in control of our company.***

Under our governance agreement with GSK, GSK could previously sell or transfer our common stock only pursuant to a public offering registered under the Securities Act or pursuant to Rule 144 of the Securities Act. GSK no longer has contractual restrictions on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party. Sales by GSK of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

**Risks Related to Legal and Regulatory Uncertainty**

***If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to products in any respiratory program partnered with GSK are not adequate, the future commercialization of any such product could be delayed, limited or prevented, which would materially harm our business and the price of our securities could fall.***

To the extent the intellectual property protection of products in any respiratory program partnered with GSK are successfully challenged or encounter problems with the U.S. Patent and Trademark Office or other comparable agencies throughout the world, the commercialization of these products could be delayed, limited or prevented. Any challenge to the intellectual property protection of a late-stage development asset or approved product arising from any respiratory program partnered with GSK could harm our business and cause the price of our securities to fall.

Our commercial success depends in part on products in any respiratory program partnered with GSK not infringing the patents and proprietary rights of third parties. Third parties may assert that these products are using their proprietary rights without authorization. In addition, third parties may obtain patents in the future and claim that use of GSK's technologies infringes upon these patents. Furthermore, parties making claims against GSK may obtain injunctive or other equitable relief, which could effectively block GSK's ability to further develop or commercialize one or more of the product candidates or products in any respiratory program partnered with GSK.

In the event of a successful claim of infringement against GSK, it 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, GSK may need to obtain licenses from third parties to advance its research or allow commercialization of the products. GSK may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, GSK would be unable to further develop and commercialize one or more of the products, which could harm our business significantly. In addition, in the future GSK could be required to initiate litigation to enforce its proprietary rights against infringement by third parties. Prosecution of these claims to enforce its rights against others would involve substantial litigation expenses. If GSK fails to effectively

enforce its proprietary rights related to our partnered respiratory programs against others, our business will be harmed, and the price of our securities could fall.

### **Risks Related to Ownership of our Common Stock**

*The price of our securities has been extremely volatile and may continue to be so, and purchasers of our securities could incur substantial losses.*

The price of our securities has been extremely volatile and may continue to be so. Between January 1, 2015 and March 31, 2015, the high and low sales prices of our common stock as reported on The NASDAQ Global Market varied between \$10.58 and \$21.16 per share. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last several years. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our securities:

- any adverse developments or results or perceived adverse developments or results with respect to the commercialization of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® with GSK, including, without limitation, if payor coverage is lower than anticipated or if sales of RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA® are less than anticipated because of pricing pressure in the respiratory markets targeted by our partnered products or existing or future competition in the markets in which they are commercialized, including competition from existing and new products that are perceived as lower cost or more effective, and our royalty payments are less than anticipated;
- any positive developments or results or perceived positive developments or results with respect to the development of UMEC/VI/FF with GSK, including, without limitation if the new Phase 3 study (or any other closed triple Phase 3 studies that may be initiated in the future) is successful and GSK and the respiratory market in general view this triple combination therapy as significantly more beneficial than existing therapies, including RELVAR®/BREO® ELLIPTA® and ANORO® ELLIPTA®;

Table of Contents

- any adverse developments or results or perceived adverse developments or results with respect to the on-going development of FF/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to SUMMIT, the regulatory path for FF/VI or any indication from clinical or non-clinical studies, including the large Phase 3b program, that FF/VI is not safe or efficacious or does not sufficiently differentiate itself from alternative therapies;
- any adverse developments or results or perceived adverse developments or results with respect to the on-going development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, any indication from clinical or non-clinical studies that UMEC/VI is not safe or efficacious;
- any adverse developments or results or perceived adverse developments or results with respect to the sNDA submitted to the FDA for a fixed dose combination of FF/VI as a once-daily treatment for asthma in patients aged 12 years and older;
- any adverse developments or perceived adverse developments in the field of LABAs, including any change in FDA policy or guidance (such as the pronouncement in February 2010 warning that LABAs should not be used alone in the treatment of asthma and related labeling requirements, the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma outcomes or the FDA's April 2011 announcement that manufacturers of currently marketed LABAs conduct additional clinical studies comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone);
- GSK's decisions whether or not to purchase, on a quarterly basis, sufficient shares of our common stock to maintain its ownership percentage taking into account our preceding quarter's option exercise, equity vesting and debt conversion activity;
- the occurrence of a fundamental change triggering a put right of the holders of the Notes or our inability, or perceived inability, to satisfy the obligations under the Notes when they become due;
- our incurrence of expenses in any particular quarter that are different than market expectations;
- the extent to which GSK advances (or does not advance) FF/VI, UMEC/VI, UMEC/VI/FF, VI monotherapy and the MABA program through development into commercialization in all indications in all major markets;
- any adverse developments or perceived adverse developments with respect to our relationship with GSK, including, without limitation, disagreements that may arise between us and GSK;

## Edgar Filing: THERAVANCE INC - Form 10-Q

- announcements regarding GSK generally;
- announcements of patent issuances or denials, technological innovations or new commercial products by GSK;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by GSK;
- regulatory developments in the U.S. and foreign countries;
- economic and other external factors beyond our control;
- sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934;
- relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 42% of our outstanding capital stock as of February 12, 2015 based on our review of publicly available filings);
- any adverse developments or perceived adverse developments with respect to the business separation; and
- potential sales or purchases of our capital stock by GSK.

Table of Contents

***We may be unable to or elect not to continue returning capital to our stockholders***

We have a corporate goal of returning capital to stockholders and have paid quarterly dividends during the 3rd and 4th quarters of 2014 and during the 1st quarter of 2015. The payment of, or continuation of, capital returns to stockholders is at the discretion of our board of directors and is dependent upon our financial condition, results of operations, capital requirements, general business conditions, tax treatment of capital returns, potential future contractual restrictions contained in credit agreements and other agreements and other factors deemed relevant by our board of directors. Future capital returns may also be affected by, among other factors: our views on potential future capital requirements for investments in acquisitions and our working capital and debt maintenance requirements; legal risks; stock repurchase programs; changes in federal and state income tax laws or corporate laws; and changes to our business model. Our capital returns may change from time to time, and we cannot provide assurance that we will continue to provide any particular amounts. A reduction or suspension in our capital returns programs could have a negative effect on our stock price.

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

As of April 30, 2015, GSK beneficially owned approximately 27% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 1% of our outstanding capital stock. Based on our review of publicly available filings as of April 30, 2015, our three largest stockholders other than GSK collectively owned approximately 42% of our outstanding capital stock. These stockholders could control the outcome of actions taken by us that require stockholder approval, including a transaction in which stockholders might receive a premium over the prevailing market price for their shares.

***Anti-takeover provisions in our charter and bylaws, in our rights agreement and in Delaware law could prevent or delay a change in control of our company.***

Provisions of our Certificate of Incorporation and Bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- requiring supermajority stockholder voting to effect certain amendments to our Certificate of Incorporation and Bylaws;
  
- restricting the ability of stockholders to call special meetings of stockholders;
  
- prohibiting stockholder action by written consent; and
  
- establishing advance notice requirements for nominations for election to the Board or for proposing matters that can be acted on by stockholders at meetings.

In addition, our Board has adopted a rights agreement that may prevent or delay a change in control of us. Further, some provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

On March 5, 2015, we completed the sale of 92,674 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of \$18.06 per share, resulting in aggregate gross proceeds of \$1.7 million before deducting transaction expenses. Neither we nor the affiliate of GSK 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.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

Table of Contents**Item 6. Exhibits.****(a) Index to Exhibits**

<b>Exhibit Number</b>	<b>Description</b>	<b>Form</b>	<b>Incorporated by Reference Filing Date/Period End Date</b>
3.3	Amended and Restated Certificate of Incorporation	S-1	7/26/04
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3/31/07
3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)	10-Q	9/30/08
4.1	Specimen certificate representing the common stock of the registrant	10-K	12/31/06
4.2	Amended and Restated Rights Agreement between Theravance, Inc. and The Bank of New York, as Rights Agent, dated as of June 22, 2007	10-Q	6/30/07
4.3	Amendment to Amended and Restated Rights Agreement between the registrant and The Bank of New York Mellon Corporation, as Rights Agent, dated November 21, 2008	8-K	11/25/08
4.4	Indenture dated as of January 24, 2013 by and between Theravance, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	1/25/13
4.5	Form of 2.125% Convertible Subordinated Note Due 2023 (included in Exhibit 4.4)		
10.64	Amendment to Transition Services Agreement between Theravance and Theravance Biopharma, dated March 2, 2015		
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 Chief 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 three months and nine months ended March 31, 2015, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to the Condensed Consolidated Financial Statements		



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, Inc.

Date: May 8, 2015

/s/ Michael W. Aguiar  
**Michael W. Aguiar**  
Chief Executive Officer

Date: May 8, 2015

/s/ Eric d Esparbes  
**Eric d Esparbes**  
Senior Vice President, Finance and Chief Financial Officer