

THERAVANCE INC  
Form 10-Q  
November 04, 2014

**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 September 30, 2014

OR

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

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

Commission File Number: 000-30319

**THERAVANCE, INC.**

Edgar Filing: THERAVANCE INC - Form 10-Q

(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   
(Do not check if a smaller reporting company)

Smaller reporting company

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

The number of shares of registrant's common stock outstanding on October 31, 2014 was 115,369,046.



TABLE OF CONTENTS

**PART I FINANCIAL INFORMATION**

<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of September 30, 2014 and December 31, 2013</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2014 and 2013</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2014 and 2013</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and 2013</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>	23
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	34
<u>Item 4. Controls and Procedures</u>	34

**PART II. OTHER INFORMATION**

<u>Item 1A. Risk Factors</u>	35
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	48
<u>Item 3. Defaults Upon Senior Securities</u>	48
<u>Item 4. Mine Safety Disclosures</u>	48
<u>Item 5. Other Information</u>	48
<u>Item 6. Exhibits</u>	49
<u>Signatures</u>	50

## PART I FINANCIAL INFORMATION

## Item 1. Financial Statements

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	September 30, 2014 (Unaudited)	December 31, 2013 *
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 119,575	\$ 143,510
Restricted cash	5,600	
Short-term marketable securities	143,536	321,615
Accounts receivable, net of allowances of \$89 at December 31, 2013		199
Receivables from collaborative arrangements (including amounts from a related party of \$4,012 and \$2,247 at September 30, 2014 and December 31, 2013)	4,012	3,181
Prepaid expenses and other current assets	748	4,287
Inventories		10,406
Total current assets	273,471	483,198
Marketable securities	47,752	55,374
Restricted cash	833	833
Property and equipment, net	64	10,238
Intangible assets, net	211,646	124,257
Other assets	19,947	7,355
Total assets	\$ 553,713	\$ 681,255
<b>Liabilities and stockholders (deficit) equity</b>		
Current liabilities:		
Accounts payable	\$ 573	\$ 7,583
Payable to a related party	10,000	40,000
Accrued personnel-related expenses	1,203	10,881
Accrued clinical and development expenses		9,714
Accrued interest payable	19,467	2,800
Other accrued liabilities	3,773	4,137
Deferred revenue	1,082	9,289
Total current liabilities	36,098	84,404
Convertible subordinated notes	255,109	287,500
Non-recourse notes payable, due 2029	450,000	
Deferred rent	54	4,774
Other long-term liabilities	1,530	
Deferred revenue	4,058	5,455
Commitments and contingencies (Notes 3, 6 and 8)		
Stockholders (deficit) equity:		
Common stock, \$0.01 par value; authorized: 200,000 shares; issued: 115,380 and 111,516 at September 30, 2014 and December 31, 2013	1,154	1,115

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

Treasury stock, 150 and 0 shares at September 30, 2014 and December 31, 2013	(3,263)	
Additional paid-in capital	1,466,911	1,803,048
Accumulated other comprehensive (loss) income	(197)	162
Accumulated deficit	(1,657,741)	(1,505,203)
Total stockholders' (deficit) equity	(193,136)	299,122
Total liabilities and stockholders' (deficit) equity	\$ 553,713	\$ 681,255

---

\* Condensed consolidated balance sheet at December 31, 2013 has been derived from audited consolidated financial statements.

*See accompanying notes to condensed consolidated financial statements.*

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Royalty revenue from a related party, net of intangible assets amortization: three months 2014-\$3,233; 2013-\$0; nine months 2014-\$7,611; 2013-\$0 (Note 3) (1)	\$ 729	\$	\$ 342	\$
Net revenue from collaborative arrangements from a related party	270	415	811	3,059
Total net revenue	999	415	1,153	3,059
Operating expenses:				
Research and development	1,909	2,104	6,721	6,555
General and administrative	8,632	6,018	28,491	17,882
Total operating expenses	10,541	8,122	35,212	24,437
Loss from operations	(9,542)	(7,707)	(34,059)	(21,378)
Other income (expense), net	255	(37)	335	6,734
Interest income	93	192	446	567
Interest expense	(12,355)	(1,902)	(24,326)	(7,662)
Loss from continuing operations before income taxes	(21,549)	(9,454)	(57,604)	(21,739)
Income tax	278			
Loss from continuing operations, net of tax	(21,271)	(9,454)	(57,604)	(21,739)
Loss from discontinued operations (Notes 10 and 11):		(37,531)	(94,934)	(99,033)
Net loss	\$ (21,271)	\$ (46,985)	\$ (152,538)	\$ (120,772)
Basic and diluted net loss per share:				
Continuing operations, net of tax	\$ (0.19)	\$ (0.09)	\$ (0.52)	\$ (0.21)
Discontinued operations		(0.35)	(0.85)	(0.99)
Basic and diluted net loss per share	\$ (0.19)	\$ (0.44)	\$ (1.37)	\$ (1.20)
Cash dividends declared per common share	\$ 0.25	\$	\$ 0.25	\$
Shares used to compute basic and diluted net loss per share	113,100	106,295	111,306	100,321

(1) Gross royalty revenue from a related party for the three and nine months ended September 30, 2014 is \$3,962 and \$7,953, respectively.

*See accompanying notes to condensed consolidated financial statements.*





**THERAVANCE, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss	\$ (21,271)	\$ (46,985)	\$ (152,538)	\$ (120,772)
<b>Other comprehensive (loss) income:</b>				
Net unrealized (loss) gain on marketable securities	(3,903)	217	(359)	103
Comprehensive loss	\$ (25,174)	\$ (46,768)	\$ (152,897)	\$ (120,669)

*See accompanying notes to condensed consolidated financial statements.*

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2014	2013
<b>Cash flows from operating activities</b>		
Net loss	\$ (152,538)	\$ (120,772)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8,720	1,959
Stock-based compensation	26,013	19,704
Amortization of premium on marketable securities	1,539	2,933
Change in fair value of capped-call derivative assets		1,422
Amortization of debt issuance costs	1,550	792
Other non-cash items	(2)	17
Changes in operating assets and liabilities:		
Account receivables	74	
Receivables from collaborative arrangements	(833)	(1,425)
Prepaid expenses and other current assets	(52)	(35)
Inventories	(1,908)	(2,912)
Other assets	561	
Accounts payable	(7,122)	2,040
Payable to Theravance Biopharma, Inc., net	(16,166)	
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	71	4,472
Accrued interest payable	16,667	(1,099)
Deferred rent	224	(416)
Deferred revenue	(2,911)	3,692
Net cash used in operating activities	(126,113)	(89,628)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(556)	(1,667)
Purchases of marketable securities	(228,899)	(354,583)
Maturities of marketable securities	292,666	155,396
Sales of marketable securities	5,000	22,600
Payments for intangible assets	(125,000)	(40,000)
Payments received on notes receivable	140	100
Net cash used in investing activities	(56,649)	(218,154)
<b>Cash flows from financing activities</b>		
Cash and cash equivalents contributed to Theravance Biopharma, Inc.	(277,541)	
Proceeds from issuances of common stock, net	35,629	140,003
Payments of cash dividends to stockholders	(28,338)	
Purchase of capped-call options		(36,800)
Change in restricted cash	(5,600)	
Proceeds from issuances of notes payable, net of debt issuance costs	434,677	281,622
Net cash provided by financing activities	158,827	384,825
Net (decrease) increase in cash and cash equivalents	(23,935)	77,043
Cash and cash equivalents at beginning of period	143,510	94,849
Cash and cash equivalents at end of period	\$ 119,575	\$ 171,892

Edgar Filing: THERAVANCE INC - Form 10-Q

**Supplemental disclosures of noncash information**

Contribution of net assets, excluding cash and cash equivalents to Theravance Biopharma, Inc.	\$	125,337	\$	
Conversion of convertible subordinated notes into common stock	\$	32,391	\$	172,499

*See accompanying notes to condensed consolidated financial statements.*

**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®/BREQ®/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 as the GSK Agreements), Theravance is eligible to receive the associated royalty revenues from RELVAR®/BREQ®/ELLIPTA®, ANORO® ELLIPTA® and if approved and commercialized, VI monotherapy. Theravance is also entitled to a 15% economic interest in 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 of 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 (LABA Collaboration) with us, which has been assigned to TRC other than with respect to RELVAR®/BREQ®/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, 2014 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, 2013 filed with the Securities and Exchange Commission (SEC) on March 3, 2014.

*Business Separation*

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

On June 1, 2014, we separated our late-stage partnered respiratory assets from our biopharmaceutical research and drug development operations by transferring our research and drug development operations into a wholly-owned subsidiary. We contributed \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma, Inc. ( Theravance Biopharma ) and all outstanding shares of Theravance Biopharma were then distributed to our 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 Theravance 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 our 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 Notes 10 and 11, Spin-Off of Theravance Biopharma, Inc., and Discontinued Operations for further information.

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 an option to purchase these shares of Theravance Biopharma from us, but this option expired unexercised. Accordingly, at September 30, 2014, we owned 436,802 ordinary shares of Theravance Biopharma, which are accounted for as marketable securities in the condensed consolidated balance sheet. These equity securities are discussed further in Note 4, Available-for-Sale Securities and Fair Value Measurements .

### ***Fair Value of Financial Instruments***

We define fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Our valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect our market assumptions. We classify these inputs into the following hierarchy:

*Level 1* Quoted prices for identical instruments in active markets.

*Level 2* Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

*Level 3* Unobservable inputs and little, if any, market activity for the assets.

Financial instruments include cash equivalents, marketable securities, accounts receivable, receivables from collaborative arrangements, accounts payable, and accrued liabilities. Marketable securities are carried at estimated fair value. The carrying value of cash equivalents, accounts receivable, receivables from collaborative arrangements, accounts payable, and accrued liabilities approximate their estimated fair value due to the relatively short-term nature of these instruments.

### ***Inventories***

All inventories were related to our former research and drug development operations and, thus, were contributed to Theravance Biopharma in connection with the Spin-Off. Accordingly, we have no inventories as of September 30, 2014.

Prior to the Spin-Off of Theravance Biopharma, our inventories consisted of raw materials, work-in-process and finished goods related to the production of VIBATIV® (telavancin). Raw materials include VIBATIV® active pharmaceutical ingredient (API) and other raw materials. Work-in-process and finished goods included third party manufacturing costs and labor and indirect costs incurred in the production process. Included in inventories were raw materials and work-in-process that may be used as clinical products, which were charged to research and development expense when consumed. In addition, under certain commercialization agreements, we could sell VIBATIV® packaged in unlabeled vials that are recorded in work-in-process. Inventories were stated at the lower of cost or market value. We determined the cost of inventory using the average-cost method for validation batches. We analyzed our inventory levels quarterly and wrote down any inventory that was expected to become obsolete, that had a cost basis in excess of its expected net realizable value or for inventory quantities in excess of expected requirements.

Inventories were as follows:

<b>(In thousands)</b>	<b>December 31,</b>	
	<b>2013</b>	
Raw materials	\$	5,138
Work-in-process		360
Finished goods		4,908
Total inventories	\$	10,406

### ***Revenue Recognition***

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

### ***Collaborative Arrangements and Multiple-Element Arrangements***

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

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

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

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

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

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

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



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

Under our collaborative arrangements with GSK, and in accordance with FASB Subtopic ASC 808-10, Collaborative Arrangements, royalty revenue earned is reduced by amortization expense resulting from the fees paid to GSK, which were capitalized as finite-lived intangible assets. When amortization expense exceeds amounts recognized for royalty revenues from GSK, negative revenue would be reported in our consolidated statements of operations.

*Royalties*

We recognize royalty revenue on licensee net sales of products with respect to which we have contractual royalty rights in the period in which the royalties are earned and reported to us and collectability is reasonably assured. Royalties are recognized net of amortization of intangible assets associated with any approval and launch milestone payments made to GSK.

*Product Revenues*

We currently have no product revenues following the Spin-Off of Theravance Biopharma.

Prior to the Spin-Off of Theravance Biopharma, we sold VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transferred upon receipt of the product 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. As VIBATIV® is a product that is sold by Theravance Biopharma, the revenue from product sales are included within discontinued operations in the consolidated statements of operations for the nine months ended September 30, 2014. There was no revenue recognized from product sales for any period in 2013 as all amounts were deferred.

Product sales were recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. We reflected such reductions in revenue either as an allowance to the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales deductions were based on management's estimates that considered payer mix in target markets, industry benchmarks and experience to date. We monitored inventory levels in the distribution channel, as well as sales of VIBATIV® by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances were based on amounts owed or to be claimed on related sales. These estimates took into consideration the terms of our agreements with customers, historical product returns of VIBATIV® experienced by our former collaborative partner, Astellas Pharma, Inc. (Astellas), rebates or discounts taken, estimated levels of inventory in the distribution channel, the shelf life of the product, and specific known market events, such as competitive pricing and new product introductions.

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

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

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

*Distribution Fees and Product Returns:* We had written contracts with our distributors that include terms for distribution-related fees. We recorded distribution-related fees based on a percentage of the product sales price. We offered our distributors a right to return product purchased directly from us, which was principally based upon the product's expiration date. Additionally, we had granted more expansive return rights to our distributors following our product launch of VIBATIV®. Our policy was to accept returns for expired product during the six months prior to and twelve months after the product expiration date on product that had been sold to our distributors. We developed estimates for VIBATIV® product returns based upon historical VIBATIV® sales from our former collaborative partner, Astellas. We recorded distribution fees and product returns as an allowance against accounts receivable.

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

### ***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 and nine months ended September 30, 2014.

### ***Intangible Assets***

We capitalize fees paid to licensors related to agreements for approved products or commercialized products. We capitalize these fees as finite-lived intangible assets and amortize these intangible assets on a straight-line basis over their estimated useful lives upon the commercial launch of the product, which is expected to be shortly after regulatory approval of such product. The estimated useful lives of these intangible assets are based on a country-by-country and product-by-product basis, as the later of the expiration or termination of the last patent right covering the compound in such product in such country and 15 years from first commercial sale of such product in such country, unless the agreement is terminated earlier. Consistent with our policy for classification of costs under the research and development collaborative arrangements, the amortization of these intangible assets will be recognized as a reduction of royalty revenue. We review our intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The recoverability of finite-lived intangible assets is measured by comparing the asset's carrying amount to the expected undiscounted future cash flows that the asset is expected to generate. The determination of recoverability typically requires various estimates and assumptions, including estimating the useful life over which cash flows will occur, their amount, and the asset's residual value, if any. We derive the required cash flow estimates from near-term forecasted product sales and long-term projected sales in the corresponding market.

### ***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.

## **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.

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

For the three months and nine months ended September 30, 2014 and 2013, diluted and basic net loss per share were identical since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

The computations for basic and diluted net loss per share were as follows:

(In thousands, except for per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Numerator:</b>				
Loss from continuing operations, net of tax	\$ (21,271)	\$ (9,454)	\$ (57,604)	\$ (21,739)
Loss from discontinued operations		(37,531)	(94,934)	(99,033)
Net loss	\$ (21,271)	\$ (46,985)	\$ (152,538)	\$ (120,772)
<b>Denominator:</b>				
Weighted-average number of shares used to compute basic and diluted net loss per share	113,100	106,925	111,306	100,321
<b>Basic and diluted net loss per share:</b>				
Continuing operations, net of tax	\$ (0.19)	\$ (0.09)	\$ (0.52)	\$ (0.21)
Discontinued operations		(0.35)	(0.85)	(0.99)
<b>Basic and diluted net loss per share</b>	<b>\$ (0.19)</b>	<b>\$ (0.44)</b>	<b>\$ (1.37)</b>	<b>\$ (1.20)</b>

*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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Shares issuable under equity incentive plans and ESPP	6,771	3,590	6,218	4,161
Unvested RSAs	1,782	2,418	1,782	2,418
Shares issuable upon the conversion of convertible subordinated notes	12,100	10,503	12,100	16,262
Total anti-dilutive securities	20,653	16,511	20,100	22,841

**3. Collaborative Arrangements***Net Revenue from Collaborative Arrangements*

Net revenue from collaborative arrangements from continuing operations relates to our arrangement with GSK. Net revenue from other collaborative arrangements was reflected as discontinued operations in the consolidated statements of operations. Refer to Notes 1, 10 and 11, Description of Operations and Summary of Significant Accounting Policies, Spin-Off of Theravance Biopharma, Inc. and Discontinued Operations for further information.

*Net Royalty Revenue from GSK*

Net revenue recognized under our GSK Agreements was as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Royalty revenue	\$ 3,962	\$ 3,962	\$ 7,953	\$ 7,953
Amortization of intangible assets	(3,233)	(3,233)	(7,611)	(7,611)
Net royalty revenue	729	729	342	342
LABA collaboration				1,814
Strategic alliance MABA program license	270	415	811	1,245
Total net revenue from GSK	\$ 999	\$ 415	\$ 1,153	\$ 3,059

*LABA Collaboration*

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

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) 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 the collaboration is further developing FF/VI for the U.S.

In the event that a product containing VI was successfully developed and commercialized, we were obligated to make milestone payments to GSK totaling \$220.0 million if both a single-agent and a combination product or two different combination products were launched in multiple regions of the world. As of September 30, 2014, we have paid a total of \$210.0 million of these milestones and have a payable of \$10.0 million related to the launch and approval of BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe. The final milestone payment of \$10.0 million was made in October 2014, which completed our obligation to GSK related to these milestone payments. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon the commercial launch of the product.

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

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 capitalized as finite-lived intangible assets, is a reduction to royalty revenue. When amortization expense exceeds amounts recognized for royalty revenue, negative revenue would be reported in our 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. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party. GSK has no further option rights on any of our research or development programs under the strategic alliance.

In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the Additional MABAs). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to GSK961081 (081), the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to us, at which point we may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and we have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing 081 is successfully developed and commercialized, we are entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. If a MABA medicine containing 081 is commercialized as a combination product, such as 081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, we are entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS combination, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If an MABA medicine containing 081 is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If an MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$129.0 million.

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

On March 3, 2014, in contemplation of the Spin-Off, 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 of our GSK Agreements, and Theravance Biopharma and GSK entered into a governance agreement, a registration rights



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

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 an option to purchase these shares of Theravance Biopharma from us, but this option expired unexercised. Accordingly, at September 30, 2014, we owned 436,802 ordinary shares of Theravance Biopharma, which are accounted for as marketable securities in the condensed consolidated balance sheets.

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.

*Purchases of Common Stock under the Company's Governance Agreement and Common Stock Purchase Agreements with GSK*

During the first nine months of 2014, GSK purchased 832,650 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 \$25.3 million.

*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.

*Reimbursement of Research and Development Costs*

Reimbursement of research and development costs from continuing operations is solely related to the GSK Agreements. Under the GSK Agreements, we are entitled to reimbursement of certain research and development costs. For the three months and nine months ended September 30, 2014, research and development costs reimbursed from GSK were not material. For the three and nine months ended September 30, 2013, research and development costs reimbursed from GSK was \$0.2 million and \$0.5 million. Reimbursement of research and development costs from other collaborative arrangements has been reflected as discontinued operations in the condensed consolidated statements of operations. Refer to Notes 1, 10 and 11, Description of Operations and Summary of Significant Accounting Policies, Spin-Off of Theravance Biopharma, Inc. and Discontinued Operations for further information.

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

*Available-for Sale Securities*

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

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

(In thousands)	September 30, 2014	December 31, 2013
Cash and cash equivalents	\$ 119,022	\$ 125,009
Short-term marketable securities	143,536	321,615
Marketable securities	47,752	55,374
Restricted cash	6,433	833
<b>Total</b>	<b>\$ 316,743</b>	<b>\$ 502,831</b>

The estimated fair value of available-for-sales 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)	September 30, 2014				Estimated Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	
U.S. government securities	\$ 33,526	\$ 39	\$ (1)	\$ 33,564	
U.S. government agencies	43,611	9	(6)	43,614	
U.S. corporate notes	59,644	9	(46)	59,607	
U.S. commercial paper	44,434			44,434	
Equity securities	10,269		(201)	10,068	
Money market funds	125,456			125,456	
<b>Total</b>	<b>\$ 316,940</b>	<b>\$ 57</b>	<b>\$ (254)</b>	<b>\$ 316,743</b>	

Edgar Filing: THERAVANCE INC - Form 10-Q

(In thousands)	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	\$ 42,104	\$ 55	\$ (1)	\$ 42,158
U.S. government agencies	141,278	61	(8)	141,331
U.S. corporate notes	94,923	54		94,977
U.S. commercial paper	102,021	2	(1)	102,022
Money market funds	122,343			122,343
Total	\$ 502,669	\$ 172	\$ (10)	\$ 502,831

Equity securities consist of ordinary shares of Theravance Biopharma owned by us as of September 30, 2014. These equity securities are restricted securities and can only be resold pursuant to a registration statement or an exemption from registration under the Securities Act of 1933, as amended (the Securities Act). We expect to be able to sell these shares pursuant to Rule 144 promulgated under the Securities Act after the satisfaction of a six-month holding period and, therefore, have classified them as available-for-sale marketable securities.

At September 30, 2014, all of the available-for-sale securities had contractual maturities within two years and the average duration of debt securities was approximately eight 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 September 30, 2014 were temporary in nature. All marketable securities with unrealized losses at September 30, 2014 have been in a loss position for less than twelve months.

During the nine months ended September 30, 2014 and 2013, we sold marketable securities totaling \$5.0 million and \$22.6 million, and the related realized gains and losses were not significant in any of these periods.

**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 Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3		
<i>Assets at September 30, 2014:</i>					
U.S. government securities	\$ 33,564	\$	\$	\$	\$ 33,564
U.S. government agency securities		43,614			43,614
U.S. corporate notes		59,607			59,607
U.S. commercial paper		44,434			44,434
Equity securities	10,068				10,068
Money market funds	125,456				125,456
Total assets measured at estimated fair value	\$ 169,088	\$ 147,655	\$	\$	\$ 316,743
<i>Liabilities at September 30, 2014:</i>					

Edgar Filing: THERAVANCE INC - Form 10-Q

Convertible subordinated notes due 2023	\$	\$	239,339	\$	\$	239,339
Non-recourse notes due 2029			454,500			454,500
Total fair value of liabilities	\$	\$	693,839	\$	\$	693,839

## Estimated Fair Value Measurements at Reporting Date Using

Types of Instruments (In thousands)	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
<i>Assets at December 31, 2013:</i>				
U.S. government securities	\$ 42,158	\$	\$	\$ 42,158
U.S. government agency securities	98,236	43,095		141,331
U.S. corporate notes	61,591	33,386		94,977
U.S. commercial paper	3,499	98,523		102,022
Money market funds	122,343			122,343
Total assets measured at estimated fair value	\$ 327,827	\$ 175,004	\$	\$ 502,831
<i>Liabilities at December 31, 2013:</i>				
Convertible subordinated notes due 2023	\$	\$ 408,250	\$	\$ 408,250

At September 30, 2014, securities with a total fair value of \$5.4 million were measured using Level 2 inputs in comparison to December 31, 2013, at which time the securities had a fair value of \$5.4 million and were measured using Level 1 inputs.

## 5. Intangible Assets

Intangible assets, which consist of registrational and launch-related milestone fees paid or owed to GSK, were as follows:

(In thousands)	Weighted Average Remaining Amortization Period (Years)	September 30, 2014		
		Gross Carrying Value	Accumulated Amortization	Net Carrying Value
FDA approval and launch of BREO® ELLIPTA® in the U.S. Minister of Health, Labor and Welfare ( MHLW ) approval and launch of RELVAR® ELLIPTA® in Japan	16.0	\$ 60,000	\$ (3,411)	\$ 56,589
European Commission approval and launch of RELVAR® ELLIPTA®	14.2	20,000	(1,111)	18,889
FDA approval and launch of ANORO® ELLIPTA® in the U.S. European Commission approval and launch of ANORO® ELLIPTA®	14.3	30,000	(1,500)	28,500
MHLW approval and launch of ANORO® ELLIPTA® in Japan	16.0	60,000	(1,565)	58,435
Total intangible assets	14.9	30,000	(656)	29,344
	15.0	20,000	(111)	19,889
		\$ 220,000	\$ (8,354)	\$ 211,646

(In thousands)	Weighted Average Remaining Amortization	December 31, 2013		
		Gross Carrying Value	Accumulated Amortization	Net Carrying Value

Edgar Filing: THERAVANCE INC - Form 10-Q

	Period (Years)						
FDA approval and launch of BREO® ELLIPTA® in the U.S.	15.7	\$	60,000	\$	(632)	\$	59,368
MHLW approval and launch of RELVAR® ELLIPTA® in Japan	14.9		20,000		(111)		19,889
European Commission approval of RELVAR® ELLIPTA®	15.0		15,000				15,000
FDA approval of ANORO® ELLIPTA® in the U.S.	15.2		30,000				30,000
Total intangible assets		\$	125,000	\$	(743)	\$	124,257

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 and nine months ended September 30, 2014 was \$3.2 million and \$7.6 million. The amortization expense for the same periods in 2013 is zero. The remaining estimated amortization expense of intangible assets is \$3.5 million for 2014, \$13.8 million for each of the years from 2015 to 2018 and \$152.9 million thereafter.

## 6. Stock-Based Compensation

### *Equity Incentive Plan*

The 2012 Equity Incentive Plan ( 2012 Plan ) provides for the grant of stock options, time-based and performance-contingent restricted stock units ( RSUs ), time-based and performance-contingent RSAs, and stock appreciation rights to employees, non-employee directors and consultants. As of September 30, 2014, total shares remaining available for issuance under the 2012 Plan were 2,961,225.

### *Performance-Contingent RSAs*

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

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 first quarter of 2014. The total stock-based compensation expense of \$7.0 million for the first tranche was recognized through May 2014.

In May 2014, our Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off as the performance conditions associated with 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 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 outstanding under this equity award remain subject to performance and service conditions. In addition, the remaining RSAs outstanding under these awards are entitled to the pro rata dividend distribution made by Theravance on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Theravance common stock, which will also be subject to the same performance and service conditions as the RSAs.

### *Stock-Based Compensation Expense*

In connection with the Spin-Off of Theravance Biopharma, all outstanding shares of Theravance Biopharma were distributed to our stockholders as a pro-rata dividend distribution on June 2, 2014 by issuing one share of Theravance Biopharma common stock for every 3.5 shares held of Theravance common stock to stockholders of record on May 15, 2014. Outstanding stock options and RSUs that were not eligible for the dividend distribution were adjusted for the Spin-Off of Theravance Biopharma. The number of shares and exercise price for all outstanding stock options were adjusted and the number of shares for all outstanding RSUs was adjusted. All other terms of these grants remain the same; provided, however, that the vesting and expiration of these grants are based on the holder's continuing employment or service with us or



Theravance Biopharma, as applicable.

Although the anti-dilution adjustments were required pursuant to the terms of each stock plan, the anti-dilution adjustments were calculated using a volume-weighted average stock price, rather than the stock price as of the date of the dividend distribution, which resulted in incremental compensation expense. The accounting impact of the adjustment to the outstanding stock options and RSUs that occurred in connection with the Spin-Off of Theravance Biopharma was measured by comparing of the fair values of the modified stock options and RSUs to our employees and directors immediately before and after the adjustment. As a result, we recognized incremental stock-based compensation expense of \$1.2 million in the second quarter of 2014, of which \$0.9 million is included in discontinued operations. All remaining unrecognized stock-based compensation expense associated with this adjustment will be recognized by Theravance Biopharma as it pertains to stock options and RSUs held by individuals now employed by Theravance Biopharma or one of its affiliates.

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

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	\$ 1,357	\$ 118	\$ 2,589	\$ 426
General and administrative	3,375	1,850	11,795	5,445
Stock-based compensation expense from continuing operations	4,732	1,968	14,384	5,871
Stock-based compensation from discontinued operations		4,478	11,629	13,833
Total stock-based compensation expense	\$ 4,732	\$ 6,446	\$ 26,013	\$ 19,704

Total stock-based compensation expense capitalized to inventory was not material for the three and nine months ended September 30, 2014 and 2013. Inventories were contributed to Theravance Biopharma in connection with the Spin-Off.

As of September 30, 2014, unrecognized compensation expense, net of expected forfeitures, was as follows: \$3.5 million related to unvested stock options; \$1.5 million related to unvested RSUs; and \$3.6 million related to unvested RSAs (excludes performance-contingent RSAs).

### *Valuation Assumptions*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b><i>Employee stock options</i></b>				
Risk-free interest rate	1.97%	1.68%-2.02%	1.64%-2.05%	0.76%-2.02%
Expected term (in years)	6	6	5-6	5-6
Volatility	58%	60%	52%-60%	58%-60%
Dividend yield	4%	%	4%	%
Weighted-average estimated fair value of stock options granted	\$ 13.23	\$ 21.63	\$ 15.92	\$ 18.11

### *Stockholders Equity*

For the nine months ended September 30, 2014, options to purchase 1,127,000 shares of our common stock were exercised at a weighted-average exercise price of \$14.09 per share for total cash proceeds of approximately \$15.9 million.

## 7. Income Taxes

As a part of the overall Spin-Off transaction, certain assets that were transferred by us to Theravance Biopharma resulted in taxable transfers pursuant to Section 367 of the Internal Revenue Code of 1986, as amended (the Code), or other applicable provisions of the Code and Treasury Regulations. The taxable gain attributable to the transfer of the certain assets to Theravance Biopharma was the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. The U.S. federal income and state tax gain on transfer of the assets to Theravance Biopharma was approximately \$0.4 billion and \$0.1 billion. This taxable income is expected to be substantially offset by current year losses and our net operating loss carryforwards from prior years resulting in a net impact of zero to income tax expense.

As a result of the Spin-Off, we reversed approximately \$0.1 billion of our valuation allowance on certain deferred tax assets, primarily federal net operating losses, as of September 30, 2014. Our ability to utilize net operating losses is dependent upon the change in control provisions in Section 382 of the Code. We are preparing a study of the potential limitation under Section 382 as of December 31, 2013. While a formal update of the study has not been completed, we believe that we will not have limitations on the use of our net operating losses under Section 382 for the purposes of computing our income tax payable for the year ended December 31, 2014. As a result of our history of prior year losses and lack of available evidence supporting future taxable income, we believe that a valuation allowance on our remaining deferred tax assets as of September 30, 2014 remains appropriate. In addition, we also transferred gross deferred tax assets of approximately \$9 million with the corresponding full valuation allowance to Theravance Biopharma as a result of the Spin-Off because the underlying tax benefits have been transferred to Theravance Biopharma.

## 8. Commitments and Contingencies

### *Lease Guarantee*

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 defaults under its lease obligations, and thus, we have in substance guaranteed the payments under the lease agreements for these facilities. As of September 30, 2014, the total lease payments for the duration of the lease, which runs through May 2020, were \$34.6 million. We would be 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 non-current liability of \$1.3 million in our condensed consolidated balance sheet as of September 30, 2014 related to the estimated fair value of this lease guarantee. We prepared a discounted, probability-weighted cash flow analysis to calculate the estimated fair value of the lease guarantee as of the Spin-Off. We were required to make assumptions regarding the probability of Theravance Biopharma's default on the lease payments, the likelihood of a sublease being executed, and the times at which these events could occur. The fair value of this lease guarantee was charged to additional paid in capital upon the Spin-Off, and any future adjustments to the carrying value of the obligation will be recorded in the consolidated statements of operations.

### *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 in the first quarter of 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 May 2014, the Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off as the performance conditions associated with 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 the original performance conditions that were met prior to the Spin-Off, triggering a twelve-month service-based vesting for a portion of the cash awards. The maximum amount payable by us under these modified cash bonus awards is \$0.5 million. The remaining tranches of the cash awards were forfeited.

## 9. Long-Term Debt

Our long-term debt consists of:

Edgar Filing: THERAVANCE INC - Form 10-Q

(In thousands)	September 30, 2014		December 31, 2013	
Convertible Subordinated Notes due 2023	\$	255,109	\$	287,500
Non-Recourse Notes Payable due 2029		450,000		
Total Long-Term Debt	\$	705,109	\$	287,500

***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 are 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. 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.

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 conversion price of \$27.79 per share for the underlying number of shares and a cap price of \$38.00 per share. The cap component is economically equivalent to a call option sold by us for the underlying number of shares with a 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 payment of the cash dividend during the three months ended September 30, 2014, which is further discussed in Note 12, Dividends Declared and Paid, 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 47.4323 shares of our common stock per \$1,000 principal amount of the 2023 Notes, which represents an adjusted conversion price of approximately \$21.08 per share. As a result of the conversion rate adjustment, the capped call strike price and cap price were also adjusted accordingly to \$21.08 and \$28.83.

#### ***Private Placement of \$450 Million of 9% Non-Recourse Notes***

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. At September 30, 2014, the balance of the segregated bank account was \$1.6 million, which is classified as restricted cash in the current assets on our condensed consolidated balance sheet as these funds can only be used to make principal and interest payments on the 2029 Notes.

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. Since the principal and interest payments on the 2029 Notes are based on royalties from product sales, which will vary from quarter to quarter, the 2029 Notes may be repaid prior to the final maturity date in 2029.

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

From the net proceeds of the offering of approximately \$434.7 million, we established a \$32.0 million milestone payment reserve account to fund 40% of any future milestone payments that could become payable under the LABA Collaboration Agreement with GSK. This milestone reserve account is a segregated bank account and at September 30, 2014, the balance of this account is \$4.0 million. The milestone reserve account and royalty collection account is classified as restricted cash in the current assets on our condensed consolidated balance sheet.

As part of this sale, we incurred approximately \$15.3 million in transaction costs, which will be amortized to interest expense over the estimated life of the 2029 Notes.

**10. Spin-Off of Theravance Biopharma, Inc.**

On June 1, 2014, we separated our late-stage partnered respiratory assets from our biopharmaceutical research and drug development operations. We contributed the assets and certain liabilities from the research and drug development operations and \$393.0 million of cash, cash equivalents and marketable securities to Theravance Biopharma. All outstanding shares of Theravance Biopharma were then distributed to our stockholders of record on May 15, 2014 as a pro-rata dividend distribution of one ordinary share of Theravance Biopharma for every 3.5 shares held of our common stock.

On June 1, 2014, we entered into a Separation and Distribution Agreement with Theravance Biopharma that set forth the terms and conditions of the separation of Theravance Biopharma from us. The Separation and Distribution Agreement sets forth a framework for the relationship between us and Theravance Biopharma following the separation regarding principal transactions necessary to separate Theravance Biopharma from us. This agreement also sets forth other provisions that govern certain aspects of our relationship with Theravance Biopharma after the completion of the separation from us and provides for the allocation of assets, liabilities and obligations between Theravance Biopharma and us in connection with the Spin-Off.

In addition, we entered into other definitive agreements in connection with the Spin-Off, including (1) a Transition Services Agreement pursuant to which Theravance Biopharma and we will provide each other with a variety of administrative services, including financial, tax, accounting, information technology, legal and human resources services, for a period of time of up to 12 months following the Spin-Off, (2) a Tax Matters Agreement that generally governs the parties' respective rights, responsibilities and obligations after the separation with respect to taxes, (3) a Sublease Agreement that provides for the sublease from Theravance Biopharma to us for certain office space to be utilized in our operations and (4) an Employee Matters Agreement that allocates liabilities and responsibilities relating to employee compensation, benefit plans, programs and other related matters in connection with the separation, including the treatment of outstanding incentive awards and certain retirement and welfare benefit obligations. These arrangements contain the provisions related to the Spin-Off and the distribution of Theravance Biopharma's ordinary shares to our stockholders.

The total amount of the Theravance Biopharma share dividend of \$402.9 million was based on the net book value of the net assets that were contributed to Theravance Biopharma in connection with the Spin-Off, as follows:

<b>(In thousands)</b>	<b>June 2, 2014</b>
Cash and cash equivalents	\$ 277,541
Marketable investment securities	115,129
Accounts receivable	125
Reimbursement of certain liabilities	16,983
Prepaid and other current assets	3,172
Inventories	14,328
Fixed assets, net	9,580
Accrued liabilities	(22,342)
Deferred revenue	(6,694)
Other liabilities	(4,944)
Net book value of assets contributed	\$ 402,878

Theravance Biopharma's historical results of operations have been presented as discontinued operations in our condensed consolidated statement of operations for the three and nine months ended September 30, 2014 and 2013. See Note 11, Discontinued Operations, for further information.





## 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 Notes 1 and 10, Description of Operations and Summary of Significant Accounting Policies and Spin-Off of Theravance Biopharma, Inc. . 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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net revenues (1)	\$	\$ 24	\$ 3,129	\$ 51
Loss from discontinued operations (2)	\$	\$ (37,531)	\$ (94,934)	\$ (99,033)

(1) Net revenues primarily consist of revenue from collaborative arrangements and product sales. Revenue from collaborative arrangements was primarily related to revenue recognized from our agreement with R-Pharm CJSC, which was transferred to Theravance Biopharma as a part of the Spin-Off. Products 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 includes the reimbursement of research and development costs from our former collaborative arrangements, excluding GSK, which we accounted for as reductions to research and development expense. Reimbursement of research and development costs from discontinued operations from our collaborative arrangements was \$2.0 million and \$5.6 million for the three and nine months ended September 30, 2013, and was not material for the nine months ended September 30, 2014.

In addition, the loss from discontinued operations for the nine months ended September 30, 2014 includes the 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 in the first quarter of 2014, the majority of which is included in discontinued operations. In May 2014, the total cash bonus of \$9.5 million for the first tranche was paid.

## 12. Dividends Declared and Paid

On July 25, 2014, our Board of Directors declared a \$0.25 per share dividend for the third quarter of 2014 for all stockholders of record as of the close of business on August 28, 2014 for a total of \$28.8 million. Unvested RSAs as of the record date are also entitled to dividends, which will only be paid when the RSAs vest and are released. The dividend was paid to our stockholders on September 18, 2014. For further information on

the impact of the payment of the cash dividend on the 2023 Notes, refer to Note 9, Long-Term Debt .

On October 16, 2014, our Board of Directors declared a \$0.25 per share dividend for the fourth quarter of 2014 for all stockholders of record as of the close of business on November 25, 2014, which was publicly announced on October 30, 2014. The dividend will be paid on December 23, 2014. In connection with the payment of the fourth quarter 2014 dividend, the conversion rate with respect to our 2023 Notes will be adjusted.

### **13. Subsequent Events**

#### *Purchases of Common Stock under the Company's Governance Agreement and Common Stock Purchase Agreements with GSK*

In November 2014, we entered into an agreement with GSK pursuant to which GSK agreed to purchase through an affiliate, in a private placement, 832,456 shares of our common stock for an aggregate purchase price of approximately \$12.8 million, pursuant to its rights under our Amended and Restated Governance Agreement, dated as of June 4, 2004, as amended.

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

**Forward-Looking Statements**

The information in this discussion 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, expect, goal, intends, may, objective, plans, projects, pursue, will, would and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could 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.

**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 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 late-stage partnered respiratory assets from our biopharmaceutical research and drug development operations 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.

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 an option to purchase these shares of Theravance Biopharma from us, but this option expired unexercised. Accordingly, at September 30, 2014, we owned 436,802 ordinary shares of Theravance Biopharma.

Since the Spin-Off, we have significantly downsized our operations and, as of October 31, 2014, we had nine employees managing our intellectual property, licensing operations, late-stage partnered respiratory assets with GSK as well as providing for certain essential reporting and management functions of a public company. Our revenues consist of royalties from our respiratory partnership agreements with GSK.

For the first nine months of 2014, our net loss from our continuing operations was \$57.6 million, an increase of \$35.9 million from \$21.7 million for the first nine months of 2013 primarily due to higher employee-related expenses, including stock-based compensation expense, and an increase in interest expense from our non-recourse notes due 2029. Cash, cash equivalents, and marketable securities, excluding restricted cash, totaled \$310.9 million on September 30, 2014, a decrease of \$209.6 million from December 31, 2013. The decrease was due primarily to the contribution of \$393.0 million to Theravance Biopharma in connection with the Spin-Off, cash used in operations of \$126.1 million, registrational and launch-related milestone payments to GSK of \$125.0 million and payments of cash dividends of \$28.3 million. These outflows were partially offset by net proceeds of \$434.7 million from the issuance of our non-recourse notes due 2029 and net proceeds of \$35.6 million received from issuances of our common stock.

## Recent Developments

### *Declaration and Payment of Cash Dividends*

On October 16, 2014, Theravance's Board of Directors declared a \$0.25 per share dividend for the fourth quarter of 2014. The dividend will be paid on December 23, 2014 to all stockholders of record as of the close of business on November 25, 2014. The dividend was publicly announced by Theravance on October 30, 2014. In connection with the payment of the fourth quarter 2014 dividend, the conversion rate with respect to our 2023 Notes will be adjusted.

On July 25, 2014, Theravance's Board of Directors declared a \$0.25 per share dividend for the third quarter of 2014 for all stockholders of record as of the close of business on August 28, 2014. A total of \$28.3 million was paid to our stockholders on September 18, 2014. In connection with the payment of the cash dividend, the conversion rate with respect to our 2023 Notes was adjusted from 46.9087 shares of our common stock per \$1,000 principal amount of the 2023 Notes to 47.4323 shares of our common stock per \$1,000 principal amount of the 2023 Notes, which represents an adjusted conversion price of approximately \$21.08 per share.

## Product Highlights

- In the third quarter of 2014, GSK achieved product sales of \$25.6 million for RELVAR®/BREO® ELLIPTA® and sales of \$1.8 million for ANORO® ELLIPTA®.
- As of September 30, 2014, RELVAR®/BREO® ELLIPTA® has been approved in 53 countries for marketing and has been launched in 30 countries, including the U.S., Canada, U.K., Germany and Japan.
- As of September 30, 2014, ANORO® ELLIPTA® has been approved in 42 countries for marketing and has been launched in 9 countries, including the U.S., Canada, U.K., Germany and Japan.

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

- GSK presented data supporting the efficacy and safety of RELVAR®/BREQ® ELLIPTA® and ANORO® ELLIPTA® during the European Respiratory Society Annual Congress (ERS) that took place in September 2014 in Munich, Germany.
  
- *Respiratory Medicines* published positive results from a lung function study comparing the efficacy and safety of ANORO® ELLIPTA® with the LAMA, tiotropium, administered in the HandiHaler® inhaler, to patients with chronic obstructive pulmonary disease (COPD). In this study, ANORO® ELLIPTA® showed statistically significant improvement compared to tiotropium in measurement of lung function using trough forced expiratory volume in one second (FEV<sub>1</sub>) at the end of the treatment period (day 169). In addition, ANORO® ELLIPTA® showed a statistically significant improvement compared to tiotropium in measurement of lung function using weighted mean FEV<sub>1</sub> 0 - 6 hour, at the end of the treatment period (day 168). The most commonly reported side effects for both ANORO® ELLIPTA® and tiotropium included headache, nasopharyngitis, cough and back pain.
  
- GSK presented data from Phase 3 studies at CHEST 2014 in Austin, Texas, held from October 25, 2014 through October 30, 2014: (1) Efficacy and safety of umeclidinium/vilanterol (UMEC/VI) once daily (OD) versus fluticasone/salmeterol combination (FSC) twice daily (BD) in patients with moderate-to-severe COPD and infrequent COPD exacerbations; and (2) Efficacy and safety of once-daily umeclidinium added to fluticasone furoate/vilanterol in COPD: Results of two replicate randomized 12-week studies.

## **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. 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 bronchodilators) and FF (an inhaled corticosteroid), to be administered via the ELLIPTA® investigational dry powder inhaler, which triple therapy program GSK has referred to as Diamond. GSK recently announced its goal of advancing Diamond into Phase 3 in either 2014 or 2015. 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 2013 sales of approximately \$8.3 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2013 sales of approximately \$3.5 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.

In the event that a product containing VI was successfully developed and commercialized, we were obligated to make milestone payments to GSK totaling \$220.0 million if both a single-agent and a combination product or two different combination products were launched in multiple regions of the world. As of September 30, 2014, we have paid a total of \$210.0 million of these milestones and have a payable of \$10.0 million related to the launch and approval of BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe. The final milestone payment of \$10.0 million was made in October 2014, which completed our obligation to GSK related to these milestone payments. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, 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 Agreement, 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 capitalized as finite-lived intangible assets, is a reduction to royalty revenue. When amortization expense exceeds amounts recognized for royalty revenue, negative revenue would be reported in our consolidated statements of operations.

### ***2004 Strategic Alliance***



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

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. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party. GSK has no further option rights on any of our research or development programs under the strategic alliance.

In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the Additional MABAs). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to GSK961081 (081), the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to us, at which point we may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and we have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing 081 is successfully developed and commercialized, we are entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. If a MABA medicine containing 081 is commercialized as a combination product, such as a 081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, we are entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS combination, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing 081 is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$125.0 million for a single-agent medicine and up to \$250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total contingent payments of up to \$129.0 million.

***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 are 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 GSK entered into a governance agreement, a registration rights agreement and an extension agreement. The three-way master agreement is 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 an option to purchase these shares of Theravance Biopharma from us, but this option expired unexercised. Accordingly, at September 30, 2014, we owned 436,802 ordinary shares of Theravance Biopharma.

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.

***Purchases of Common Stock by GSK***

During the first nine months of 2014, GSK purchased 832,650 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 \$25.3 million.

***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.

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

Net revenue recognized under the GSK Agreements was as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Royalty revenue	\$ 3,962	\$	\$ 7,953	\$
Amortization of intangible assets	(3,233)		(7,611)	
Net royalty revenue	729		342	
LABA collaboration				1,814
Strategic alliance MABA program license	270	415	811	1,245
Total net revenue from GSK	\$ 999	\$ 415	\$ 1,153	\$ 3,059

Amortization expense resulting from the milestone fees paid to GSK, which are capitalized as finite-lived intangible assets, is a reduction to royalty revenue. When amortization expense exceeds amounts recognized for royalty revenue, negative revenue would be reported in our consolidated statements of operations. Estimated amortization expense of intangible assets is \$11.1 million for the year ended December 31, 2014.

Under the GSK Agreements, we are reimbursed for research and development expenses. These reimbursements have been reflected as a reduction of research and development expense and were not material for the three and nine months ended September 30, 2014. The reimbursement of research and development expense was \$0.2 million and \$0.5 million for the three and nine months ended September 30, 2013.

### 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. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

### Revenue Recognition

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

*Collaborative Arrangements and Multiple Element Arrangements*

We generate revenue from collaboration and license agreements for the development and commercialization of product candidates. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, supply arrangement, contingent payments based on the occurrence of specified events under our collaborative arrangements, license fees and royalties on sales of product candidates if they are successfully approved and commercialized. Our performance obligations under the collaborations may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and related materials, supply of active pharmaceutical ingredient ( API ) and/or drug product, and obligations to participate on certain development and/or commercialization committees with the collaborative partners. We make judgments that affect the periods over which we recognize revenue. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis.

On January 1, 2011, we adopted an accounting standards update that amends the guidance on accounting for new or materially modified multiple-element arrangements that we enter into subsequent to January 1, 2011. This guidance removed the requirement for objective and reliable evidence of fair value of the undelivered items in order to consider a deliverable a separate unit of accounting. It also changed the allocation method such that the relative-selling-price method must be used to allocate arrangement consideration to all the units of accounting in an arrangement. This guidance established the following hierarchy that must be used in estimating selling price under the relative-selling-price method: (1) vendor-specific objective evidence of fair value of the deliverable, if it exists, (2) third-party evidence of selling price, if vendor-specific objective evidence is not available or (3) vendor's best estimate of selling price ( BESP ) if neither vendor-specific nor third-party evidence is available.

We may determine that the selling price for the deliverables within collaboration and license arrangements should be determined using BESP. The process for determining BESP involves significant judgment on our part and includes consideration of multiple factors such as estimated direct expenses and other costs, and available data. We have determined BESP for license units of accounting based on market conditions, similar arrangements entered into by third parties and entity-specific factors such as the terms of previous collaborative agreements, our pricing practices and pricing objectives, the likelihood that clinical trials will be successful, the likelihood that regulatory approval will be received and that the products will become commercialized. We have also determined BESP for services-related deliverables based on the nature of the services to be performed and estimates of the associated effort as well as estimated market rates for similar services.

For each unit of accounting identified within an arrangement, we determine the period over which the performance obligation occurs. Revenue is then recognized using either a proportional performance or straight-line method. We recognize revenue using the proportional performance method when the level of effort to complete our performance obligations under an arrangement can be reasonably estimated. Direct labor hours or full time equivalents are typically used as the measurement of performance. Any changes in the remaining estimated performance obligation periods under these collaborative arrangements will not have a significant impact on the results of operations, except for a change in estimated performance period resulting from the termination of a collaborative arrangement, which would result in immediate recognition of the related deferred revenue.

The GSK Agreements were entered into prior to January 1, 2011. The delivered items under these collaborative agreements did not meet the criteria required to be accounted for as separate accounting units for the purposes of revenue recognition. As a result, revenue from non-refundable, upfront fees and development contingent payments were recognized ratably over the expected term of our performance of research and development services under the agreements. These upfront or contingent payments received, pending recognition as revenue, were recorded as deferred revenue and recognized over the estimated performance periods.

Under the GSK Agreements, we recognized revenue of \$1.2 million and \$3.1 million for the nine months ended September 30, 2014 and 2013. The remaining deferred revenue under the GSK Strategic Alliance Agreement is \$5.1 million at September 30, 2014. Any change in the estimated performance period, which is predominantly based on GSK's development timeline, will not have a significant impact on the results of operations, except for a change in estimated performance period resulting from the termination of the MABA program that would result in immediate recognition of the deferred revenue.

On January 1, 2011, we also adopted an accounting standards update that provides guidance on revenue recognition using the milestone method. Payments that are contingent upon achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved. Milestones are defined as events that can be achieved based only on our performance and as to which, at the inception of the arrangement, there is substantive uncertainty about whether the milestone will be achieved. Events that are contingent only on the passage of time or only on third-party performance are not considered milestones subject to this guidance. Further, the amounts received must relate solely to prior performance, be reasonable relative to all of the deliverables and payment terms in the agreement and commensurate with our performance to achieve the milestone after commencement of the agreement. Total contingent payments that may become payable to us under our collaborative agreements were up to \$363.0 million at September 30, 2014 and are considered non-substantive.

Under the GSK Agreements, and in accordance with FASB Subtopic ASC 808-10, Collaborative Arrangements, royalty revenue earned is reduced by amortization expense resulting from the fees paid to GSK, which were capitalized as finite-lived intangible assets. When amortization expense exceeds amounts recognized for royalty revenues from GSK, negative revenue would be reported in our consolidated statements of operations.

Amounts related to research and development funding is recognized as the related services or activities are performed, in accordance with the contract terms. Payments may be made to us based on the number of full-time equivalent researchers assigned to the collaborative project and

the related research and development expenses incurred. Accordingly, reimbursement of research and development expenses pursuant to the cost-sharing provisions of our agreements with certain collaborative partners are recognized as a reduction of research and development expenses.

***Royalties***

We recognize royalty revenue on licensee net sales of products with respect to which we have royalty rights in the period in which the royalties are earned and reported to us and collectability is reasonably assured. Royalties are recognized net of amortization of intangible assets associated with any approval and launch milestone payments made to GSK.

**Intangible Assets**

We capitalize fees paid to licensors related to agreements for approved products or commercialized products. We capitalize these fees as finite-lived intangible assets and amortize these intangible assets on a straight-line basis over their estimated useful lives upon the commercial launch of the product, which is expected to be shortly after regulatory approval of such product. The estimated useful lives of these intangible assets are based on a country-by-country and product-by-product basis, as the later of the expiration or termination of the last patent right covering the compound in such product in such country and 15 years from first commercial sale of such product in such country, unless the agreement is terminated earlier. Consistent with our policy for classification of costs under the research and development collaborative arrangements, the amortization of these intangible assets will be recognized as a reduction of royalty revenue.

We review our intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The recoverability of finite-lived intangible assets is measured by comparing the asset's carrying amount to the expected undiscounted future cash flows that the asset is expected to generate. The determination of recoverability typically requires various estimates and assumptions, including estimating the useful life over which cash flows will occur, their amount, and the asset's residual value, if any. We derive the required cash flow estimates from near-term forecasted product sales and long-term projected sales in the corresponding market.

Our gross intangible assets of \$220.0 million at September 30, 2014 consist of registrational and launch-related to milestone fees paid or owed to GSK (see Collaborative Arrangements with GSK above for more information). These intangible assets are considered finite-lived intangible assets, which are amortized over their estimated useful lives using the straight-line method commencing upon commercial launch.

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

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2014	2013	\$	%	2014	2013	\$	%
Royalty revenue	\$ 3,962	\$	\$ 3,962	*%	\$ 7,953	\$	\$ 7,953	*%
Amortization of intangible assets	(3,233)		(3,233)	*	(7,611)		(7,611)	*
Net royalty revenue	729		729	*	342		342	*
Net revenue from collaborative arrangements	270	415	(145)	(35)%	811	3,059	(2,248)	(73)%
Total net revenue	\$ 999	\$ 415	\$ 584	141%	\$ 1,153	\$ 3,059	\$ (1,906)	(62)%

\*Not meaningful

Total net revenue increased for the third quarter and decreased for the first nine months of 2014 compared to the same periods a year ago. Revenue for the third quarter and first nine months of 2014 includes net royalty revenue and revenue from collaborative arrangements compared to the same periods in 2013, which only includes revenue from collaborative arrangements. Royalty revenue recognized under the LABA Collaboration Agreement with GSK is reduced by amortization expense for intangible assets. Revenue from collaborative arrangements decreased for the first nine months of 2014 compared to the same periods in 2013 primarily as a result of deferred revenue under the LABA Collaboration Agreement with GSK being fully recognized in 2013.

***Research and Development***

Research and development expenses from our continuing operations, as compared to the prior year periods, were as follows:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2014	2013	\$	%	2014	2013	\$	%
Research and development expenses	\$ 1,909	\$ 2,104	\$ (195)	(9)%	\$ 6,721	\$ 6,555	\$ 166	3%



Research and development expenses decreased in the third quarter of 2014 compared to the same period a year ago primarily due to our ongoing operations being significantly smaller as a result of the Spin-Off.

Research and development expenses in the first nine months of 2014 approximated the same period a year ago primarily due to an increase in stock-based compensation expense from new grants and the achievement of performance conditions under a special long-term retention and incentive equity awarded to certain employees in 2011, offset by fewer allocated costs as our ongoing operations are significantly smaller as a result of the Spin-Off.

### *General and Administrative*

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

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2014	2013	\$	%	2014	2013	\$	%
General and administrative expenses	\$ 8,632	\$ 6,018	\$ 2,614	43%	\$ 28,491	\$ 17,882	\$ 10,609	59%

General and administrative expenses increased in the third quarter and first nine months of 2014 compared to the same periods a year ago primarily due to higher stock-based compensation expense and employee-related costs. Stock-based compensation expense and employee-related costs increased 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, which resulted in additional stock-based compensation and cash bonus expense.

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

Interest and other income (expense), net, as compared to the prior year periods, were as follows:

(In thousands)	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2014	2013	\$	%	2014	2013	\$	%
Interest income	\$ 93	\$ 192	\$ (99)	(52)%	\$ 446	\$ 567	\$ (121)	(21)%
Other income (expense), net	255	(37)	292	789	335	6,734	(6,399)	(95)

Interest income in the third quarter and first nine months of 2014 decreased as compared to the same periods a year ago primarily due to lower average cash balances resulting from the cash contribution to Theravance Biopharma in June 2014.

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

The increase in other income (expense), net for the third quarter of 2014 as compared to the same period in 2013 is due to income received from Theravance Biopharma for transition services rendered as a result of the Spin-Off. The decrease during the first nine months of 2014 as compared to the same period in 2013 was primarily due to net cash received from the termination of the royalty participation agreement with Elan Corporation, plc in 2013, partially offset by \$1.4 million from the change in the fair value of the capped call instruments related to our convertible subordinated notes issued in 2013.

### *Interest Expense*

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

(In thousands)	Three Months Ended September 30,				Nine months Ended September 30,			
	2014	2013	Change		2014	2013	Change	
	\$	\$	\$	%	\$	\$	\$	%
Interest expense	\$ 12,355	\$ 1,902	\$ 10,453	550%	\$ 24,326	\$ 7,662	\$ 16,664	217%

Interest expense increased in the third quarter and first nine months of 2014 compared to the same periods a year ago primarily due to the interest expense associated with the issuance of our 2029 Notes in April 2014.

**Discontinued Operations**

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 September 30,				Nine months Ended September 30,			
	2014	2013	Change	%	2014	2013	Change	%
Net revenue	\$ 24	\$	\$ (24)	*%	\$ 3,129	\$ 51	\$ 3,078	*%
Loss from discontinued operations		(37,531)	37,531	*	(94,934)	(99,003)	4,069	4

\*Not Meaningful

Net revenues primarily consist of revenue from collaborative arrangements and product sales. Revenue from collaborative arrangements was recognized from our agreement with R-Pharm CJSC, which was transferred to Theravance Biopharma as a part of the Spin-Off. Products 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.

Loss from discontinued operations decreased in the first nine months of 2014 compared to the same period a year ago primarily as there was no impact of discontinued operations during the third quarter of 2014 as a result of the Spin-Off occurring in June 2014. Included in the loss from discontinued operations 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.

**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. At September 30, 2014, we had \$310.9 million in cash, cash equivalents and marketable securities, excluding amounts classified as restricted cash.

On October 16, 2014, Theravance's Board of Directors declared a \$0.25 per share dividend for the fourth quarter of 2014 for all stockholders of record as of the close of business on November 25, 2014. The dividend was publicly announced by Theravance on October 30, 2014 and will be

paid on December 23, 2014.

On July 25, 2014, Theravance's Board of Directors declared a \$0.25 per share dividend for the third quarter of 2014 for all stockholders of record as of the close of business on August 28, 2014 and a total of \$28.3 million was paid to our stockholders on September 18, 2014.

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 the Spin-Off. 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 2029 Notes. The 2029 Notes are secured by a security interest in a segregated bank account established to receive 40% of 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. 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 September 30, 2014, the balance of the milestone reserve account and royalty collection account was \$4.0 million and \$1.6 million. Each of these accounts is a segregated bank account, which are classified as current restricted cash on our condensed consolidated balance sheets. We incurred approximately \$15.3 million in debt issuance costs, which are being amortized to interest expense over the estimated life of the 2029 Notes.

Pursuant to our LABA Collaboration Agreement with GSK, we are obligated to make milestone payments to GSK, which total \$220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. As of September 30, 2014, we have paid a total of \$210.0 million of these milestones and have accrued a liability of \$10.0 million as of September 30, 2014. The final milestone payment of \$10.0 million was made in October 2014, which completed our obligation to GSK related to these milestone payments. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon commercial launch.

*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. 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:

(In thousands)	Nine Months Ended			Change
	2014	September 30,	2013	
Net cash used in operating activities	\$	(126,113)	\$ (89,628)	\$ (36,485)
Net cash used in investing activities		(56,649)	(218,154)	161,505
Net cash provided by financing activities		158,827	384,825	(225,998)

*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 in the first nine months of 2014 of \$126.1 million was primarily due to:

- \$114.7 million used in operating expenses, after adjusting for \$37.8 million of non-cash related items, consisting primarily of stock-based compensation expense of \$26.0 million, depreciation and amortization expense of \$8.7 million, amortization on premium of marketable securities of \$1.5 million and amortization of debt issuance costs of \$1.6 million;
- \$16.2 million decrease in payable to Theravance Biopharma;
- \$16.7 million increase in interest payments on convertible subordinated notes payable;
- \$1.9 million used to increase inventories, all incurred prior to the Spin-Off

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

- \$7.1 million decrease in accounts payable primarily due to the timing of payments and our ongoing operations being significantly smaller due to the Spin-Off; and
- \$2.9 million from the decrease in deferred revenue.

Net cash used in operating activities in the first nine months of 2013 of \$89.6 million was primarily due to:

- \$93.9 million used in operating expenses, after adjusting for non-cash related items of \$26.8 million, consisting primarily of stock-based compensation expense of \$19.7 million, depreciation and amortization expense of \$2.0 million, amortization on premium of marketable securities of \$2.9 million, change in fair value of capped call derivative assets of \$1.4 million and amortization of debt issuance costs of \$0.8 million;
- \$8.8 million used for interest payments on convertible subordinated notes payable;
- \$2.9 million used to increase inventories;
- \$1.4 million used to increase receivable from collaborative arrangements related to reimbursement of research and development services;
- \$8.2 million increase for cash, net of third party expenses, for the termination of our royalty participation agreement;
- \$4.5 million increase in accrued liabilities primarily due to decreases in accrued personnel-related expenses, accrued clinical and development expense, and other accrued liabilities;
- \$2.0 million increase in accounts payable primarily due to the timing of payments; and
- \$6.5 million received in upfront fees from collaboration agreements with Clinigen, R-Pharm and Hikma.

*Cash Flows from Investing Activities*

Net cash used in investing activities in the first nine months of 2014 of \$56.6 million was due to \$125.0 million used for intangible assets for the payments to GSK for registrational and launch-related milestone fees, partially offset by \$68.8 million from the sale and maturities of marketable securities, net of purchases.

Net cash used in investing activities in the first nine months of 2013 was \$218.2 million, which was primarily due to \$176.6 million in cash balances being invested in marketable securities and \$40.0 million used for a registrational milestone payment to GSK.

*Cash Flows from Financing Activities*

Net cash provided by financing activities in the first nine months of 2014 of \$158.8 million was due to net proceeds of \$434.7 million received from the private placement of our 2029 Notes and \$35.6 million received from the issuance of our common stock. These increases were partially offset by \$277.5 million of cash and cash equivalents contributed to Theravance Biopharma in connection with the Spin-Off and payments of cash dividends of \$28.3 million to our stockholders.

Net cash provided by financing activities in the first nine months of 2013 of \$384.8 million was due to net proceeds of \$281.6 million received from the January 2013 issuance of 2.125% convertible subordinated notes due in 2023 and net proceeds from the issuance of common stock of \$140.0 million, partially offset by \$36.8 million of payments on privately-negotiated capped call option transactions in connection with the issuance of the notes.

*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 September 30, 2014, the total lease payments for the duration of the lease, which runs through May 2020, are approximately \$34.6 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 September 30, 2014 related to the estimated fair value of this guarantee.

*Commitments and Contingencies*

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

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

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 May 2014, the Compensation Committee approved the modification of the remaining tranches related to these awards contingent upon the Spin-Off as the performance conditions associated with 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 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 outstanding under this equity award remain subject to performance and service conditions. In addition, the remaining RSAs outstanding under these awards are entitled to the pro rata dividend distribution made by Theravance on June 2, 2014 of one ordinary share of Theravance Biopharma for every three and one half shares of Theravance common stock, which will also be subject to the same performance and service conditions as the RSAs. The maximum amount payable by us under these modified cash bonus awards is \$0.5 million and the remaining tranches of the cash bonus awards were forfeited.

### **Contractual Obligations and Commercial Commitments**

Pursuant to our LABA Collaboration Agreement with GSK, we were obligated to make milestone payments to GSK totaling as much as \$220.0 million if both a single-agent and a combination product or two different combination products were launched in multiple regions of the world. As of September 30, 2014, we have paid a total of \$210.0 million of these milestones, and have a payable of \$10.0 million related to the launch and approval of BREO® ELLIPTA® and ANORO® ELLIPTA® in the U.S., Japan and Europe. The final milestone payment of \$10.0 million was made in October 2014, which completed our obligation to GSK related to these milestone payments. These milestone fees paid or owed to GSK were capitalized as finite-lived intangible assets, which are being amortized over their estimated useful lives commencing upon commercial launch.



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

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 issued by our wholly-owned subsidiary.

	Total	Payments Due by Period as of September 30, 2014			After 5 Years
		Less Than 1 Year	1-3 Years	3-5 Years	
2023 Notes	255,109				255,109
2029 Notes	450,000	*	*	*	*
<b>Total</b>	<b>\$ 705,109</b>				

\* 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. In addition, 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 interest shortfall amount for that period. Since the principal and interest payments on the 2029 Notes are based on royalties from product sales recorded by GSK, which can vary from quarter to quarter and are unknown to us, these amounts are not included in the above table. See Note 9, Long-Term Debt of the accompanying consolidated financial statements for further information.

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

#### *Equity Market Risk*

As of September 30, 2014, we hold ordinary shares of Theravance Biopharma with a fair value of \$10.1 million. These equity securities are restricted securities and can only be resold pursuant to a registration statement or an exemption from registration under the Securities Act of 1933, as amended (the Securities Act). We expect to be able to sell these shares pursuant to Rule 144 promulgated under the Securities Act after the satisfaction of a six-month holding period. The fair value of the equity securities could be adversely affected as ordinary shares are susceptible to stock market fluctuations and to volatile increases and decreases in value. A 10% decrease in the fair value of this equity security would result in a loss in fair value of approximately \$1.0 million.

#### *Interest Rate Risk*

As of September 30, 2014, the fair value of our convertible notes due in 2023 was estimated to be \$239.3 million, based on available pricing information. The 2023 Notes bear interest at a fixed rate of 2.125% and are subject to interest rate risk because the fixed interest rates under this obligation may exceed current interest rates. The effective interest rate by year of expected maturity for our convertible notes or the earliest in which the note holders may put the debt to us is 2.38% each year.

As of September 30, 2014, the fair value of our non-recourse notes due 2029 was estimated to be \$454.5 million, based on available pricing information. The 2029 Notes bear interest at a fixed rate of 9% per annum. This obligation is subject to interest rate risk because the fixed interest rates under this obligation may exceed current interest rates. The effective interest rate by year of expected maturity for our non-recourse

notes due 2029 is 9.78% each year.

**Item 4. Controls and Procedures.**

*Evaluation of Disclosure Controls and Procedures*

We conducted an evaluation as of September 30, 2014, 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) (i) is recorded, processed, summarized and reported within required time periods and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

*Limitations on the Effectiveness of Controls*

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Theravance 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*

On June 2, 2014, we completed the Spin-Off of Theravance Biopharma, Inc. Since the Spin-Off of Theravance Biopharma, Inc., we have significantly downsized our operations and, as of October 31, 2014, we had nine employees managing our intellectual property, licensing operations and late-stage partnered respiratory assets with GSK as well as providing for certain essential reporting and management functions of a public company. Under a transition services agreement, Theravance Biopharma, Inc. continues to support the financial reporting function for Theravance, Inc. during a transition period. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during our most recent fiscal quarter which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 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. Our current revenues consist, and future revenues will consist, almost entirely of royalties from the sale of products in the respiratory programs partnered with GSK, although we may receive milestone payments from GSK if certain development milestones are achieved in our MABA program licensed to GSK. The amount and timing of revenue from such royalties and milestones is unknown and highly uncertain. Our future success depends primarily upon the performance by GSK of its commercial obligations under the GSK Agreements. The initial sales performance for both BREO<sup>®</sup> ELLIPTA<sup>®</sup> and ANORO<sup>®</sup> ELLIPTA<sup>®</sup> is currently below our expectations. We have no control over GSK's marketing and sales efforts, and GSK might not be successful, which would harm our business and the price of our securities could fall.

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

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

- the competitive landscape for approved products and developing therapies that compete with our partnered products, including other products owned by GSK (such as Advair®) but which are not partnered with us and pricing pressure in the respiratory markets targeted by our partnered products;
- the ability of patients to be able to afford our partnered products or obtain health care coverage that covers our partnered products;
- acceptance of, and ongoing satisfaction with, our partnered products by the medical community, patients receiving therapy and third party payors;
- a satisfactory efficacy and safety profile as demonstrated in a broad patient population;
- the size of the market for our partnered products;
- the extent and effectiveness of the sales and marketing and distribution support GSK provides 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;
- 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;
- 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.



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

Under our agreements with our collaborative partner GSK, GSK has full responsibility for commercialization of BREO® ELLIPTA® and RELVAR® ELLIPTA®. GSK launched BREO® ELLIPTA® into the U.S. and Canadian markets in October 2013 and January 2014, respectively. GSK launched RELVAR® ELLIPTA® in Japan during December 2013 and in the United Kingdom, Germany and Denmark during January 2014. It has since been launched in other countries. BREO® ELLIPTA® is the proprietary name in the United States (U.S.) and Canada and RELVAR® ELLIPTA® is the proprietary name outside the U.S. and Canada. The commercial launch of BREO® ELLIPTA® has been relatively slow, as this is a primary care product and we believe it will take time to obtain payor coverage and increase physician awareness. In addition, 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 BREO® ELLIPTA® and RELVAR® ELLIPTA®. As a result, some 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® in the countries in which RELVAR®/BREO® ELLIPTA® has received regulatory approval, including if sales or payor coverage do not meet investor or our expectations, will significantly harm our business and the price of our securities could fall.

***If the commercialization of ANORO® ELLIPTA® (UMEC/VI) in the countries in which it has received regulatory approval encounter any delays or adverse developments, or perceived delays or adverse developments, or if sales or payor coverage do not meet investor or our expectations, our business will be harmed, and the price of our securities could fall.***

ANORO® ELLIPTA® (UMEC/VI) was launched by GSK in the U.S. in April 2014 and in Japan in September 2014 and made available for purchase in Canada in April 2014 and in the European Union (EU) in June 2014. ANORO® ELLIPTA® is the proprietary name in the U.S. and Canada and Japan and ANORO® is the proprietary name in Europe. Although it is still early in the launch cycle, the ANORO® ELLIPTA® launch has also been slow, as this is also a primary care product and we believe it will take time to obtain payor coverage and increase physician awareness. In addition, 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 ANORO® ELLIPTA®. Any delays or adverse developments or perceived delays or adverse developments with respect to the commercialization of ANORO® ELLIPTA® in countries in which ANORO® ELLIPTA® has received regulatory approval, including if sales or payor coverage do not meet investor or our expectations, will significantly harm our business and the price of our securities could fall.

***If the U.S. Food and Drug Administration ( FDA ) does not approve the supplemental New Drug Application ( sNDA ) for a fixed dose combination of FF/VI as a once-daily treatment for asthma in patients aged 12 years and older, or if the PDUFA date is extended, or if the approval contains restrictions or limitations on usage, our business will be significantly harmed, and the price of our securities could fall.***

In June 2014, we and GSK announced the submission of a sNDA 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. The FDA determined the action target date under the Prescription Drug User Fee Act (PDUFA-V) to be April 30, 2015. Any adverse developments, results or delays or perceived adverse developments, results or delays with respect to the asthma sNDA or the FF/VI Phase 3 program will significantly harm our business and could cause the market price of our securities to decline. Examples of such adverse developments include, but are not limited to:

- not every study, nor every dose in every study, in the Phase 3 asthma program for FF/VI achieved its primary endpoint and regulatory authorities may determine that additional clinical studies are required;

Edgar Filing: THERAVANCE INC - Form 10-Q

- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs, other studies of FF/VI, or previous studies with other LABAs; and
- any change in FDA policy or guidance regarding the use of LABAs to treat asthma.

On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and 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 Phase 3 programs 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, additional studies of FF/VI are underway. The Phase 3b program for FF/VI in COPD commenced in February 2011. Any adverse developments or perceived adverse developments with respect to the asthma sNDA, the COPD Phase 3b program or any 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 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:



- 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 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 United States 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 these products 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 and the associated assignment of most of our economic rights in these programs to Theravance Biopharma, Inc, 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. As a result of the transactions effected by the Spin-Off, however, we are now only entitled to receive 15% of the royalties payable by GSK from sales of UMEC/VI/FF (and MABA, and MABA/FF). 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 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

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

MABA /FF) receives regulatory approval in either the United States or the European Union, 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

***Restrictions or reductions on pricing and reimbursement from governments, payors, or other healthcare cost containment initiatives, may negatively impact royalties generated under the GSK Agreements.***

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

- GSK's ability to set a price we believe is fair for our partnered products, if approved; and
- GSK's ability to generate revenues and the resulting royalties owed to us.

The Patient Protection and Affordable Care Act and other potential legislative or regulatory action regarding healthcare and insurance matters, along with the trend toward managed healthcare in the United States, could influence the purchase of healthcare products and reduce demand and prices for our partnered products. This could harm GSK's ability to market our partnered products and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of the Patient Protection and Affordable Care Act and further agency regulations that are have and are expected to emerge in connection with this act could significantly reduce potential revenues from the sale of our partnered products. For example, while GSK launched BREO® ELLIPTA® for the treatment of COPD in the United States in October 2013 and launched RELVAR® ELLIPTA® in certain countries in the European Union in early 2014, GSK has experienced significant challenges in gaining acceptance for RELVAR®/BREO® ELLIPTA® for treatment of COPD by some of the largest healthcare payors and providers. Additionally, recent actions by pharmaceutical benefit management organizations in the US have increased discount levels for respiratory products resulting in lower net sales pricing realized for product 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®/BREO® ELLIPTA® could become more difficult. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the state and federal level, as well as internationally, will continue and may increase, which may make it difficult for GSK to sell our partnered products that have been or may be approved in the future at a price acceptable to us or GSK, which may cause the price of our securities to fall.

***We are relying significantly upon Theravance Biopharma for a variety of services during a six to nine-month post-separation transition period during which time we are required to establish our own separate administrative infrastructure, systems and controls to enable us to function as an independent public company and, if we fail to do so in timely manner, our business will be harmed and the price of our securities could fall.***

Under the terms of a transition services agreement entered into between us and Theravance Biopharma, Theravance Biopharma will provide us with a variety of administrative services for a period of approximately six to nine-months following the Spin-Off, including (i) record keeping support, (ii) finance, tax and accounting support to assist us in a secondary capacity to our own personnel, (iii) legal support, (iv) human resources support and (v) facilities support to the extent we continue to occupy separate space at our current South San Francisco, California facilities. We will be relying on Theravance Biopharma for execution of these administrative activities through this transition period, which is a period when Theravance Biopharma personnel will be highly focused on supporting its own newly public company operations. If there is any disruption in the provision of these services to us, or if the services provided to us are not provided in a timely or satisfactory manner, our business operations could be adversely affected. Further, we must design, build, test and implement our own stand-alone (i) finance, tax, accounting and IT systems, controls and capabilities, and (ii) legal, human resources and administrative functions that are properly suited to our new post-spin business operations. All of these will need to be sufficiently rigorous to support our ongoing operations as an independent public company. Failure to do so could cause us to be unable to comply with the accounting and legal standards required of publicly traded companies, which would harm our business and our reputation and could cause the price of our securities to fall.

*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 and ongoing process to separate the two businesses has and will continue to divert the attention of our management and employees, may disrupt our operations, and has and will continue to increase our professional services expenses through the balance of 2014 and in 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.

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

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 is currently effective and the other agreements became effective upon the Spin-Off.

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 United States or the European Union 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.

The process of planning for and effecting the business separation demanded a significant amount of time and effort from our management and certain employees, and we anticipate that it will continue to do so for the balance of 2014. The diversion of our management's and employees' attention to the business separation process and the post-separation transition has disrupted and may continue to disrupt our operations and may adversely impact our relationship with GSK and increase employee turnover.

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.

We have incurred and will 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 and after the Spin-Off with respect to (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 United States. 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

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

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 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 ). Prior to the Spin-Off, we conducted an analysis to determine whether an ownership change had occurred since inception through December 31, 2013, and concluded that we had undergone two ownership changes in prior years. We had approximately \$1.1 billion of net operating loss carryforward as of September 30, 2014. We currently expect our net operating loss carryforward and current projected losses for the 2014 taxable year will generally fully offset the U.S. federal income tax resulting from the gains we will realize in connection with the pre Spin-Off restructuring and distribution of Theravance Biopharma ordinary shares. However, the amount of our net operating loss carryforward that will be used is uncertain in part due to subjective nature of a valuation of the transferred assets as described above. There may be alternative minimum tax federal tax liability to the extent such gains are offset with net operating loss carryforwards from prior years. Because U.S. tax law limits the time during which carryforwards may be applied against future taxes, we may not be able to take full advantage of the carryforwards for federal income tax purposes. In addition, federal and state tax laws pertaining to net operating loss carryforwards may be changed from time to time such that the net operating loss carryforwards may be reduced or eliminated. If the net operating loss carryforwards become unavailable to us or are fully utilized, our future income will not be shielded from federal and state income taxation, and the funds otherwise available for general corporate purposes would be reduced.

***Our stockholders who received ordinary shares of Theravance Biopharma in the Spin-Off could incur significant U.S. federal income tax liabilities as a result of the distribution.***

All or a portion of the Theravance Biopharma ordinary shares received by our stockholders in the Spin-Off is expected to be taxable to them as a dividend. An amount equal to the fair market value of Theravance Biopharma ordinary shares received (including any fractional shares deemed to be received) on the distribution date will be treated as a taxable dividend to the extent of each Theravance stockholder's ratable share of any current and accumulated earnings and profits of Theravance, measured as of the end of 2014, with the excess treated as a non-taxable return of capital to the extent of such stockholder's tax basis in our common stock and any remaining excess treated as a capital gain. Accordingly, Theravance stockholders who received ordinary shares of Theravance Biopharma in the Spin-Off could incur significant U.S. federal income tax liabilities as a result of the distribution.

***The Spin-Off resulted in substantial changes in our Board and management. 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 recently 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 United States. 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.

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.

***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.

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 September 30, 2014, 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.

*We intend to reserve from time to time a certain amount of cash in order to satisfy the obligations relating to our debt, which could adversely affect the amount or timing of distributions to our stockholders.*

As of September 30, 2014 we had approximately \$710 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 \$450 million in principal that remains outstanding under our 9% fixed rate term notes due 2029 (the 2029 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. This could adversely affect the amount or timing of any distributions to our stockholders.

We intend to reserve from time to time a certain amount of cash in order to satisfy these obligations relating to Notes, which could materially affect the amount or timing of any distribution to our stockholders. We may also finance such repurchase through public or private equity or debt financings if we deem such financings available on favorable terms. If any or all of 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. 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.

#### **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

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

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 26.7% of our outstanding capital stock as of October 31, 2014, 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 its 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 the stock price of the Company. 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 European Union, 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 (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 October 31, 2014, GSK beneficially owned approximately 26.7% 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.

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

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 October 31, 2014, GSK beneficially owned approximately 26.7% 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 our stockholder rights plan, 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.

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 of directors 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 United States 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. 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

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

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®;
- 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 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;

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

- 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;
- 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 United States 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 35.7% of our outstanding capital stock as of October 31, 2014 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.

***We may be unable to or elect not to pay our quarterly dividend payment.***

We currently plan to pay a regular quarterly dividend, subject to quarterly board of director approval. The payment of, or continuation of, the quarterly dividend 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 dividends in the United States, potential future contractual restrictions contained in credit agreements and other agreements and other factors deemed relevant by our board of directors. Future dividends 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 dividend payments may change from time to time, and we cannot provide assurance that we will continue to declare dividends at all or in any particular amounts. A reduction or suspension in our dividend payments could have a negative effect on our stock price.

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

As of October 31, 2014, GSK beneficially owned approximately 26.7% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 0.7% of our outstanding capital stock. Based on our review of publicly available filings as of October 31, 2014, our three largest stockholders other than GSK collectively owned approximately 35.7% 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 of directors or for proposing matters that can be acted on by stockholders at meetings.

In addition, our board of directors 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 August 11, 2014, we completed the sale of 172,651 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of \$22.66 per share, resulting in aggregate gross proceeds of \$3.9 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.

**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)		
10.1+	Offer Letter with Michael W. Aguiar dated August 5, 2014		
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 September 30, 2014, 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 (v) the Notes to the Condensed Consolidated Financial Statements		

---

+ Management contract or compensatory plan or arrangement.



**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: November 4, 2014

/s/ Michael W. Aguiar  
**Michael W. Aguiar**  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 4, 2014

/s/ Eric d Esparbes  
**Eric d Esparbes**  
Senior Vice President and Chief Financial Officer  
(Principal Financial Officer and Principal Accounting Officer)