

THERAVANCE INC  
Form 10-Q  
November 01, 2013  
[Table of Contents](#)

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

WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2013

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: 0-30319

# THERAVANCE, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

**901 Gateway Boulevard**

**South San Francisco, CA 94080**

(Address of Principal Executive Offices)

**(650) 808-6000**

(Registrant's Telephone Number, Including Area Code)

---

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 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 23, 2013 was 110,558,092.



Table of Contents

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

Item 1. Financial Statements

Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012 3

Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2013 and 2012 4

Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2013 and 2012 5

Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012 6

Notes to Condensed Consolidated Financial Statements 7

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 25

Item 3. Quantitative and Qualitative Disclosures About Market Risk 38

Item 4. Controls and Procedures 39

**PART II. OTHER INFORMATION**

Item 1A. Risk Factors 39

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 57

Item 6. Exhibits 57

Signatures 58

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

(In thousands, except per share data)

	September 30, 2013 (Unaudited)	December 31, 2012 *
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 171,892	\$ 94,849
Short-term investments	334,261	153,640
Accounts receivable	450	
Receivables from collaborative arrangements (including amounts from a related party of \$517 at September 30, 2013 and \$123 at December 31, 2012)	2,489	1,064
Notes receivable	140	100
Prepaid expenses and other current assets	4,071	3,966
Inventories	9,038	7,514
Total current assets	522,341	261,133
Marketable securities	88,333	95,194
Restricted cash	833	833
Property and equipment, net	8,563	9,154
Intangible assets	40,000	
Other assets	5,946	2,268
Total assets	\$ 666,016	\$ 368,582
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 5,733	\$ 5,377
Accrued personnel-related expenses	8,362	9,002
Accrued clinical and development expenses	10,599	6,550
Other accrued liabilities	3,093	2,072
Accrued interest on convertible subordinated notes	1,273	2,372
Deferred revenue, current	9,601	4,593
Total current liabilities	38,661	29,966
Convertible subordinated notes	287,500	172,500
Deferred rent	4,658	5,074
Deferred revenue, non-current	5,148	6,014
Commitments and contingencies (Notes 3, 9 and 11)		
Stockholders equity:		
Common stock, \$0.01 par value; authorized: 200,000 shares; outstanding: 110,543 at September 30, 2013 and 98,379 at December 31, 2012	1,105	984
Additional paid-in capital	1,784,016	1,488,447

Edgar Filing: THERAVANCE INC - Form 10-Q

Accumulated other comprehensive income	202	99
Accumulated deficit	(1,455,274)	(1,334,502)
Total stockholders' equity	330,049	155,028
Total liabilities and stockholders' equity	\$ 666,016	\$ 368,582

---

\* Condensed consolidated balance sheet at December 31, 2012 has been derived from audited consolidated financial statements.

*See accompanying notes to condensed consolidated financial statements.*

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

(In thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
<b>Revenue:</b>				
Revenue from collaborative arrangements (including amounts from a related party: three months 2013-\$415; 2012-\$1,430; nine months 2013-\$3,059; 2012-\$4,291)	\$ 439	\$ 1,430	\$ 3,110	\$ 129,960
<b>Operating expenses:</b>				
Research and development	33,395	27,026	91,550	89,778
Selling, general and administrative	12,282	7,754	31,971	23,201
Total operating expenses	45,677	34,780	123,521	112,979
Income (loss) from operations	(45,238)	(33,350)	(120,411)	16,981
Other income (expense), net	(37)		6,734	
Interest income	192	158	567	304
Interest expense	(1,902)	(1,500)	(7,662)	(4,503)
Net income (loss)	\$ (46,985)	\$ (34,692)	\$ (120,772)	\$ 12,782
<b>Net income (loss) per share:</b>				
Basic net income (loss) per share	\$ (0.44)	\$ (0.37)	\$ (1.20)	\$ 0.14
Diluted net income (loss) per share	\$ (0.44)	\$ (0.37)	\$ (1.20)	\$ 0.14
Shares used to compute basic earnings per share	106,925	95,027	100,321	89,271
Shares used to compute diluted earnings per share	106,925	95,027	100,321	91,713

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents

**THERAVANCE, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

(In thousands, except per share data)

(Unaudited)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Net income (loss)	\$ (46,985)	\$ (34,692)	\$ (120,772)	\$ 12,782
<b>Other comprehensive loss:</b>				
Net unrealized gain on available-for-sale securities, net of tax	217	225	103	100
Comprehensive income (loss)	\$ (46,768)	\$ (34,467)	\$ (120,669)	\$ 12,882

*See accompanying notes to condensed consolidated financial statements.*



Table of Contents

## THERAVANCE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2013	2012
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ (120,772)	\$ 12,782
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	5,684	5,462
Stock-based compensation	19,704	18,044
Gain on marketable securities	(3)	(8)
Loss on disposal of assets	20	
Change in capped-call option valuation	1,422	
Changes in operating assets and liabilities:		
Receivables from collaborative arrangements	(1,425)	152
Prepaid expenses and other current assets	(35)	(247)
Inventories	(2,912)	(4,567)
Accounts payable	2,040	(452)
Accrued personnel-related expenses, accrued clinical and development expenses, and other accrued liabilities	4,472	(3,902)
Accrued interest on convertible subordinated notes	(1,099)	
Deferred rent expense	(416)	(546)
Deferred revenue	3,692	(129,979)
Net cash used in operating activities	(89,628)	(103,261)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(1,667)	(2,329)
Purchases of available-for-sale securities	(354,583)	(276,425)
Maturities of available-for-sale securities	155,396	38,670
Sales of available-for-sale securities	22,600	181,495
Increase in intangible assets	(40,000)	
Release of restricted cash		60
Issuances of notes receivable		(140)
Payments received on notes receivable	100	240
Net cash used in investing activities	(218,154)	(58,429)
<b>Cash flows from financing activities</b>		
Payments on note payable and capital lease		(69)
Proceeds from issuances of common stock, net	140,003	229,216
Payment for capped calls	(36,800)	
Proceeds from issuances of convertible subordinated notes, net	281,622	
Net cash provided by financing activities	384,825	229,147
Net increase in cash and cash equivalents	77,043	67,457
Cash and cash equivalents at beginning of period	94,849	44,778
Cash and cash equivalents at end of period	\$ 171,892	\$ 112,235
<b>Supplemental non-cash financing activities:</b>		

Edgar Filing: THERAVANCE INC - Form 10-Q

Conversion of convertible subordinated notes into common stock	\$	172,499	\$
----------------------------------------------------------------	----	---------	----

*See accompanying notes to condensed consolidated financial statements.*

Table of Contents

**Theravance, Inc.**

**Notes to Condensed Consolidated Financial Statements**

**(Unaudited)**

**1. DESCRIPTION OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Description of Operations**

Theravance, Inc. (the Company or Theravance) is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain.

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements of the Company 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 the opinion of the Company's management, 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 the Company's financial position, results of operations, comprehensive income (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, 2013 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, 2012 filed with the Securities and Exchange Commission (SEC) on February 26, 2013.

**Business Separation**

In April 2013, Theravance announced that its Board of Directors approved plans to separate its businesses into two independent publicly traded companies. The company to be spun-off, Theravance Biopharma, Inc., filed an initial Form 10 with the SEC on August 1, 2013 and filed amendments of its Form 10 with the SEC on September 27, 2013 and October 29, 2013. After the business separation, Theravance will focus on managing all development and commercial responsibilities under the LABA collaboration with Glaxo Group Limited (GSK) and associated potential royalty revenue from RELVAR ELLIPTA or BREO ELLIPTA, ANORO ELLIPTA and VI monotherapy, with the intention of

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

providing a consistent return of capital to its stockholders. Theravance Biopharma, Inc. will be a biopharmaceutical company focused on discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need. The result will be two independent, publicly traded companies with different business models enabling investors to align their investment philosophies with the strategic opportunities and financial objectives of the two independent companies. The accompanying unaudited condensed consolidated financial statements do not reflect any adjustments resulting from the planned business separation.

### **Principles of Consolidation**

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

### **Use of Management's Estimates**

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

### **Segment Reporting**

The Company has determined that it operates in a single segment, which is the discovery (research), development and commercialization of human therapeutics. Revenues are generated primarily from the Company's collaboration agreements with GSK, located in Great Britain, Astellas Pharma Inc. (Astellas) (through January 6, 2012), located in Japan, and Merck (which agreement

Table of Contents

will terminate in December 2013), located in the United States. All long-lived assets, which were comprised of property and equipment, are maintained in the United States.

**Investments in Marketable Securities**

The Company invests in short-term and long-term marketable securities, primarily corporate notes, government, government agency, and municipal bonds. The Company classifies its marketable securities as available-for-sale securities and reports them at fair value in cash equivalents, short-term investments or marketable securities on the condensed consolidated balance sheets with related unrealized gains and losses included as a component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the condensed consolidated statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

The Company regularly reviews all of its investments for other-than-temporary declines in estimated fair value. The Company's review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company's management determines that the decline in estimated fair value of an investment is below the amortized cost basis and the decline is other-than-temporary, the Company reduces the carrying value of the security and records a loss for the amount of such decline.

**Inventories**

Inventories consist of the Company's currently marketed product, VIBATIV® (telavancin). The Company values inventory at the lower of cost or net realizable value. The Company determines the cost of inventory using the average-cost method. The Company analyzes its inventory levels quarterly and writes down inventory that is expected to become obsolete, that has a cost basis in excess of its expected net realizable value or for inventory quantities in excess of expected requirements.

**Intangible Assets**

The Company capitalizes fees paid to licensors related to agreements for approved products or commercialized products. The Company capitalizes these fees as finite-lived intangible assets and amortizes these intangible assets on a straight-line basis over their estimated useful lives once the Company begins recognizing the related royalty revenue. Consistent with the Company's 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. The Company reviews its 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. The Company derives the required cash flow estimates from near-term forecasted product sales and long-term projected sales in

the corresponding market.

### **Revenue Recognition**

Revenue is recognized when the related costs are incurred and 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, the Company defers 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 the Company is recognized when such amounts are earned. If the Company has continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of continuing performance obligation.

The Company accounts for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with FASB ASC Subtopic 605-25, *Multiple Element Arrangements*. For new or materially amended multiple element arrangements, the Company identifies 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 the Company's control. The Company allocates revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determines 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, the Company uses 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.

Table of Contents

For multiple-element arrangements entered into prior to January 1, 2011, the Company's management determined the deliverables under its collaborative arrangements did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, the Company recognized revenue from non-refundable, upfront fees and development contingent payments ratably over the term of its performance 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 Company's consolidated balance sheet and amortized over the estimated period of performance. The Company periodically reviews the estimated performance periods of its contracts based on the progress of its 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 the Company's estimated performance period under the agreement. The Company's management determines 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, the Company has been reimbursed for a portion of its research and development expenses. These reimbursements have been reflected as a reduction of research and development expense in the Company's consolidated statements of operations, as the Company does not consider performing research and development services to be a part of its ongoing and central operations. Therefore, the reimbursement of research and developmental services and any amounts allocated to the Company's 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 all performance obligations have been satisfied.

The Company accounts for contingent payments in accordance with FASB Subtopic ASC 605-28 Revenue Recognition Milestone Method . The Company recognizes 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) the Company does 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 the Company's 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 the Company's 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. See Note 3, Collaborative Arrangements, for analysis of each milestone event deemed to be substantive or non-substantive.

In accordance with FASB Subtopic ASC 808-10, Collaborative Arrangements, and pursuant to the Company's agreement with Astellas, the Company recognized as revenue the net impact of transactions with Astellas related to VIBATIV® inventories including revenue specifically attributable to any sales, and cost of inventories either transferred or expensed as unrealizable.

***Product Revenues***

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

The Company sells VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers order VIBATIV® through these distributors. For all product shipped during the three months ended September 30, 2013, the Company is deferring the recognition of revenue until the product is sold through to healthcare providers, the end customers, due to the inherent uncertainties in estimating normal channel inventory at the distributors, and during which period the Company also provided extended payment terms and expanded return rights that allow distributors to return the product up to one year after the product launch. As of September 30, 2013, the Company had deferred revenue of \$0.5 million related to VIBATIV® shipments and recorded this amount as a current liability in the condensed consolidated balance sheet.



Table of Contents

Product sales are recorded net of estimated government-mandated rebates and chargebacks, distribution fees, estimated product returns and other deductions. Reserves are established for these deductions and actual amounts incurred are offset against applicable reserves. The Company reflects these reserves as either a reduction in the related account receivable from the distributor, or as an accrued liability, depending on the nature of the sales deduction. Sales reserves are based on management's estimates that consider payer mix in target markets, industry benchmarks and experience to date. The Company monitors inventory levels in the distribution channel, as well as sales of VIBATIV® by distributors to healthcare providers, using product-specific data provided by the distributors. Product return allowances are based on amounts owed or to be claimed on related sales. These estimates take into consideration the terms of the Company's agreements with customers, historical product returns of VIBATIV® experienced by 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. The Company updates its estimates and assumptions each quarter and if actual future results vary from the Company's estimates, the Company may adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment.

Sales Discounts: The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company expects its customers to comply with the prompt payment terms to earn the cash discount. The Company accounts for cash discounts by reducing accounts receivable by the full amount and recognizes 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., the Company estimates reductions to product sales for qualifying federal and state government programs including discounted pricing offered to PHS as well as government-managed Medicaid programs. The Company's reserve for PHS is based on actual chargebacks that distributors have claimed for reduced pricing offered to such health care providers. The Company's accrual for Medicaid is based upon statutorily-defined discounts, estimated payer mix, expected sales to qualified healthcare providers, and the Company's expectation about future utilization. The Medicaid accrual and government rebates that are invoiced directly to the Company are recorded in other accrued liabilities on the condensed consolidated balance sheet. For qualified programs that can purchase the Company's products through distributors at a lower contractual government price, the distributors charge back to the Company the difference between their acquisition cost and the lower contractual government price.

Distribution Fees and Product Returns: The Company has written contracts with its distributors that include terms for distribution-related fees. The Company records distribution-related fees based on a percentage of the product sales price. The Company offers its distributors a right to return product purchased directly from the Company, which is principally based upon the product's expiration date. Additionally, the Company has granted more expansive return rights to its distributors for a period of up to twelve months following its product launch of VIBATIV®. The Company will generally 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 the Company's distributors. Product returned is generally not resalable given the nature of the Company's products and method of administration. The Company has developed estimates for VIBATIV® product returns based upon historical VIBATIV® sales from the Company's former collaborative partner, Astellas.

The Company maintains a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of its customers to make required payments.

**Royalties**

The Company recognizes royalty revenue on licensee net sales of its products in the period in which the royalties are earned and reported to the Company and collectability is reasonably assured.

**Concentration of Risk**

The Company's accounts receivable at September 30, 2013, represent amounts due to the Company from distributors, including AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation. The Company performs ongoing credit

Table of Contents

evaluations of its customers and generally does not require collateral. For the three months ended September 30, 2013, the Company did not have any write-offs of accounts receivable.

The following table summarizes accounts receivable balances at September 30, 2013 by distributor:

<b>Distributor</b>	<b>Accounts Receivable Balance (In thousands)</b>	<b>Percentage of Total Accounts Receivable Balance</b>
AmerisourceBergen Drug Corporation	\$ 285	63%
Cardinal Health, Inc.	103	23
McKesson Corporation	59	13
Other	3	1
<b>Total</b>	<b>\$ 450</b>	<b>100%</b>

The Company depends on a single-source supplier of the active pharmaceutical ingredient, or API, in VIBATIV® and one supplier to provide fill-finish services related to the manufacturing of VIBATIV®. If any of the Company's suppliers were to limit or terminate production or otherwise fail to meet the quality or delivery requirements needed to supply VIBATIV® at levels to meet market demand, the Company could experience a loss of revenue, which could materially and adversely impact its results of operations.

**Fair Value of Stock-Based Compensation Awards**

The Company uses the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire stock granted under its employee stock purchase plan (ESPP). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected stock price volatility. The Company uses the simplified method as described in Staff Accounting Bulletin No. 107, Share-Based Payment, for the expected option term because the usage of its historical option exercise data is limited due to post-IPO exercise restrictions. Beginning April 1, 2011, the Company has used its historical volatility to estimate expected stock price volatility. Prior to April 1, 2011, the Company used peer company price volatility to estimate expected stock price volatility due to the Company's limited historical common stock price volatility since its initial public offering in 2004.

Restricted Stock Units (RSUs) and Restricted Stock Awards (RSAs) are measured based on the fair market values of the underlying stock on the dates of grant.

Stock-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. The Company's estimated annual forfeiture rates for stock options, RSUs and RSAs are based on its historical forfeiture experience.

The estimated fair value of stock options, RSUs and RSAs is expensed on a straight-line basis over the expected term of the grant and the estimated fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the term of the award once the

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

Company's management has determined that it is probable that performance milestones will be achieved. Compensation expense for RSUs and RSAs that contain performance conditions is based on the grant date fair value of the award. Compensation expense is recorded over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. The Company's management assesses the probability of the performance milestones being met on a continuous basis.

Compensation expense for purchases under the ESPP is recognized based on the fair value of the common stock on the date of offering, less the purchase discount percentage provided for in the plan.

The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance on the Company's deferred tax assets including deferred tax assets related to its net operating loss carryforwards.

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

In May 2013, the Company and Elan Corporation, plc (Elan) entered into a royalty participation agreement. The closing of the transaction was subject to closing conditions, including the approval of the transaction by Elan's shareholders. Elan's shareholders did not approve the transaction at an Extraordinary General Meeting. Subsequently, the Company terminated the agreement and as a result, Elan paid the Company a \$10.0 million termination fee in June 2013, which is reflected in other income. Non-operating

Table of Contents

expense is comprised of third party expenses related to the aforementioned royalty participation agreement and the change in the estimated fair value of the capped call instruments related to the Company's convertible subordinated notes issued in January 2013, which is reflected in other expense.

**2. NET INCOME (LOSS) PER SHARE**

Basic net income (loss) per share for each period presented was computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding, less RSAs subject to forfeiture.

For the three and nine months ended September 30, 2013, and the three months ended September 30, 2012, diluted net loss per share was identical to basic net loss per share since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

For the nine months ended September 30, 2012, diluted net income per share was computed by dividing net income by the weighted-average number of shares of common stock outstanding during the period, 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.

Dilutive potential common shares include the dilutive effect of the common stock underlying in-the-money stock options and ESPP shares and were calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option and the average amount of compensation cost, if any, for future service that the Company has not yet recognized when the option is exercised, are assumed to be used to repurchase shares in the current period. Dilutive potential common shares also reflect the dilutive effect of unvested restricted stock units.

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

<b>Numerator:</b>								
Net income (loss)	\$	(46,985)	\$	(34,692)	\$	(120,772)	\$	12,782
<b>Denominator:</b>								
Weighted-average common shares outstanding		109,343		97,590		102,739		91,834
Less: unvested RSAs		(2,418)		(2,563)		(2,418)		(2,563)
Weighted-average common shares outstanding basic		106,925		95,027		100,321		89,271
Dilutive effect of equity incentive plans and ESPP								2,442
		106,925		95,027		100,321		91,713

Edgar Filing: THERAVANCE INC - Form 10-Q

Weighted-average common shares  
outstanding and dilutive potential common  
shares - diluted

**Net income (loss) per share:**

Basic net income (loss) per share	\$	(0.44)	\$	(0.37)	\$	(1.20)	\$	0.14
Diluted net income (loss) per share	\$	(0.44)	\$	(0.37)	\$	(1.20)	\$	0.14 <sup>(1)</sup>

---

(1) In connection with the preparation of the Company's unaudited condensed consolidated financial statements for the quarter ended September 30, 2013, the Company determined that its convertible subordinated notes were incorrectly included as dilutive securities using the if-converted method in the calculation of diluted earnings per share for the nine months ended September 30, 2012. Accordingly, the Company has corrected its calculation of diluted earnings per share for the nine months ended September 30, 2012 as presented herein to report diluted earnings per share of \$0.14, which was previously reported in its quarterly report on Form 10-Q for the nine months ended September 30, 2012 as \$0.18 per diluted share.

Table of Contents*Anti-Dilutive Securities*

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

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Shares issuable under equity incentive plans and ESPP	3,590	5,098	4,161	2,915
Shares issuable upon the conversion of convertible subordinated notes	10,503	6,668	16,262	6,668
Total anti-dilutive securities	14,093	11,766	20,423	9,583

**3. COLLABORATIVE ARRANGEMENTS****Revenue from Collaborative Arrangements**

The Company has recognized revenue from its collaborative arrangements as follows:

(In thousands)	Three months Ended September 30,		Nine months Ended September 30,	
	2013	2012	2013	2012
GSK	\$ 415	\$ 1,430	\$ 3,059	\$ 4,291
Astellas				125,669
Other	24		51	
Total revenue	\$ 439	\$ 1,430	\$ 3,110	\$ 129,960

**Reimbursement of Research and Development (R&D) Costs**

Under the GSK, Merck, Alfa Wasserman and R-Pharm collaboration arrangements, the Company is entitled to reimbursement of certain R&D costs. The Company's policy is to account for the reimbursement payments by its collaboration partners as reductions to R&D expense.

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

Edgar Filing: THERAVANCE INC - Form 10-Q

(In thousands)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2013		2012		2013		2012	
GSK	\$	181	\$	40	\$	517	\$	116
Merck		1,501				4,579		
Alfa Wassermann		471				924		
R-Pharm						86		
Total reduction to R&D expense	\$	2,153	\$	40	\$	6,106	\$	116

**GSK**

***LABA collaboration***

In November 2002, the Company entered into its long-acting beta2 agonist (LABA) collaboration 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 is developing two combination products: (1) RELVAR ELLIPTA or BREO ELLIPTA (FF/VI), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO ELLIPTA (UMEC/VI), a once-daily investigational medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI.

In the event that a product containing VI is successfully developed and commercialized, the Company will be obligated to make future milestone payments to GSK, which could total as much as \$180.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments,



Table of Contents

\$30.0 million became payable in October 2013 due to the launch of BREO ELLIPTA in the U.S., and the Company estimates another \$70.0 million could become payable during the remainder of 2013 and all the milestone payments could be payable by the end of 2014. On May 10, 2013 the U.S. Food and Drug Administration (FDA) approved BREO ELLIPTA as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. On September 20, 2013 the Japanese Ministry of Health, Labour and Welfare (MHLW) approved RELVAR ELLIPTA for the treatment of bronchial asthma in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required. As a result of these approvals the Company paid GSK \$40.0 million for registrational milestone fees in the first nine months of 2013. These milestone payments to GSK were capitalized as finite-lived intangible assets and will be amortized over their estimated useful lives.

The Company is entitled to receive annual royalties from GSK of 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 the mid-single digits to 10%.

***2004 Strategic Alliance***

In March 2004, the Company entered into its strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of the Company's 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, the Company is 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, the Company retains 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 the Company's research or development programs under the strategic alliance.

In 2005, GSK licensed the Company's bifunctional muscarinic antagonist-beta2 agonist (MABA) program for the treatment of COPD, and in October 2011, the Company 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 the Company, at which point the Company may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and the Company 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, the Company is entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to \$3.5 billion, and 7.5% for all annual global net sales above \$3.5 billion. If a MABA medicine containing 081 is commercialized only as a combination product, such as 081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, the Company is entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to \$3.5 billion, and 10% for all annual global net sales above \$3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS combination, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing 081 is successfully developed and commercialized in multiple regions of the world, the Company 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, the Company could earn total contingent payments of up to \$129.0 million.

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

During the first nine months of 2013, the Company issued and Glaxo Group Limited, an affiliate of GSK, purchased 3,374,497 shares of the Company's common stock, for an aggregate purchase price of approximately \$121.1 million pursuant to its periodic top-up rights under the Company's governance agreement with GSK dated June 4, 2004, as amended.

*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

Table of Contents

performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

Revenue recognized from GSK under the LABA collaboration and strategic alliance agreements was as follows:

(In thousands)	Three Months Ended September 30,		Nine Months Ended September 30,					
	2013	2012	2013	2012				
LABA collaboration	\$	\$	907	\$	1,814	\$	2,722	
Strategic alliance MABA program license		415	523		1,245		1,569	
Total revenue from GSK Collaborations	\$	415	\$	1,430	\$	3,059	\$	4,291

**Merck***Research Collaboration and License Agreement*

In October 2012, the Company entered into a research collaboration and license agreement (the Research Collaboration and License Agreement) with Merck, known as MSD outside the United States and Canada, to discover, develop and commercialize novel small molecule therapeutics directed towards a target being investigated for the treatment of hypertension and heart failure. Under the agreement, the Company granted Merck a worldwide, exclusive license to the Company's therapeutic candidates. The Company received a \$5.0 million upfront payment in November 2012. Also, the Company received funding for research and was eligible for potential future contingent payments totaling up to \$148.0 million for the first indication and royalties on worldwide annual net sales of any products derived from the collaboration. The initial research term was twelve months, with optional extensions by mutual agreement. Merck had the right to terminate the agreement at any time and provided Theravance with notice of termination in September 2013. The agreement will terminate in December 2013.

Under the Research Collaboration and License Agreement, the significant deliverables were determined to be the license, committee participation and research services. The Company determined that the license represents a separate unit of accounting because the license has standalone value. The license, which includes rights to the Company's underlying technologies for its therapeutic candidates, permit Merck to perform all efforts necessary to use the Company's technologies to bring a therapeutic candidate through development and, upon regulatory approval, commercialization. The Company based the best estimate of selling price on potential future cash flows under the arrangement over the estimated development period. The Company determined that the committee participation represents a separate unit of accounting as Merck could negotiate for and/or acquire these services from other third parties and based the best estimate of selling price on the nature and timing of the services to be performed. The Company determined that the research services represent a separate unit of accounting and based the best estimate of selling price on the nature and timing of the services to be performed.

The \$5.0 million upfront payment received in November 2012 was allocated to the three units of accounting based on the relative selling price method as follows: \$4.4 million to the license, \$0.4 million to the research services and \$0.2 million to the committee participation. The Company recognized revenue of \$4.4 million from the license in 2012 as the technical transfer activities were complete and the associated unit of accounting was deemed delivered. The amount of the upfront payment allocated to the committee participation was deferred and recognized as revenue over the estimated performance period. The amount of the upfront payment allocated to the research services was deferred and is being recognized as a reduction of research and development expense as the underlying services are performed, as the nature of the research services is more appropriately characterized as research and development expense, consistent with the research reimbursements being received.

Due to the notice of termination, the Company revised the estimated performance period resulting in an increase in revenue of \$37,000 in the third quarter of 2013. Revenue recognized from Merck under the collaboration agreement was \$41,000 for the three months and \$51,000 for the nine months ended September 30, 2013.

## **Clinigen Group**

### *Commercialization Agreement*

In March 2013, the Company entered into a commercialization agreement (the *Clinigen Commercialization Agreement* ) with Clinigen Group plc (Clinigen) to commercialize VIBATIV® for the treatment of hospital acquired nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable. Under the agreement, the Company granted Clinigen exclusive commercialization rights in the European Union and certain other European countries (including Switzerland and Norway). The Company received a \$5.0 million

Table of Contents

upfront payment in March 2013. Also, the Company is eligible to receive tiered royalty payments on net sales of VIBATIV®, ranging from 20% to 30%. The Company is responsible, either directly or through its vendors or contractors, for supplying at Clinigen's expense both API and finished drug product for Clinigen's commercialization activities. The agreement has a term of at least 15 years, with an option to extend exercisable by Clinigen. However, Clinigen may terminate the agreement at any time after it has initiated commercialization upon 12 months advance notice.

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

The \$5.0 million upfront payment received in the first quarter of 2013 was allocated to two units of accounting based on the relative selling price method as follows: \$4.9 million to the license and \$0.1 million to the committee participation. The Company did not recognize any revenue from the license and committee participation as the technical transfer activities were not completed as of September 30, 2013 and the associated units of accounting were not delivered. The amount of the upfront payment allocated to the committee participation was deferred and will be recognized as revenue over the estimated performance period. Amounts received under a future separate supply agreement for API and finished goods, which will be manufactured by the Company's third party contract manufacturers, will be recognized as revenue to the extent of future API and finished goods inventory sales.

**R-Pharm CJSC**

*Development and Commercialization Agreements*

In October 2012, the Company entered into two development and commercialization agreements with R-Pharm CJSC (R-Pharm): one to develop and commercialize VIBATIV® (the VIBATIV® Development and Commercialization Agreement) and the other to develop and commercialize TD-1792 (the TD-1792 Development and Commercialization Agreement), one of the Company's investigational glycopeptide-cephalosporin heterodimer antibiotics for the treatment of Gram-positive infections. Under each agreement, the Company granted R-Pharm exclusive development and commercialization rights in Russia, Ukraine, other member countries of the Commonwealth of Independent States, and Georgia. The Company received \$1.1 million in upfront payments for each agreement. Also, the Company is eligible to receive potential future contingent payments totaling up to \$10.0 million for both agreements and royalties on net sales by R-Pharm of 15% from TD-1792 and 25% from VIBATIV®. The contingent payments are not deemed substantive milestones due to the fact that the achievement of the event underlying the payment predominantly relates to R-Pharm's performance of future development and commercialization activities.

*TD-1792*

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

Under the TD-1792 Development and Commercialization Agreement, the significant deliverables were determined to be the license, committee participation and a contingent obligation to supply R-Pharm with API compound at R-Pharm's expense, either directly or through the Company's contract manufacturer. The Company determined that the license represents a separate unit of accounting as the license, which includes rights to the Company's underlying technologies for TD-1792, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use the Company's technologies to bring the compounds through development and, upon regulatory approval, commercialization. Also, the Company determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties, and the Company based the best estimate of selling price on the nature and timing of the services to be performed. In March 2013, the Company entered into a supply agreement for TD-1792 API compound under which the Company will sell its existing API compound to R-Pharm. Upon execution of this supply agreement, the Company determined that the supply agreement represents a separate unit of accounting under the development and commercialization arrangement and based the best estimate of selling price for the supply agreement on its fully burdened cost to manufacture the underlying API.

The \$1.1 million upfront payment for the TD-1792 agreement was allocated to two units of accounting based on the relative selling price method as follows: \$0.9 million to the license and \$0.1 million to the committee participation. The amount allocated to the license was deferred and will be recognized as revenue upon completion of technical transfer for the underlying license. The amount allocated to committee participation was deferred and is being recognized as revenue over the estimated performance period.

Table of Contents

Amounts to be received under the supply agreement described above will be recognized as revenue to the extent R-Pharm purchases API compound from the Company.

*VIBATIV®*

Under the VIBATIV® Development and Commercialization Agreement, the significant deliverables were determined to be the license, committee participation and a contingent obligation to supply R-Pharm with API compound at R-Pharm's expense, subject to entering into a future supply agreement. The Company determined that the license represents a separate unit of accounting as the license, which includes rights to the Company's underlying technologies for VIBATIV®, has standalone value because the rights conveyed permit R-Pharm to perform all efforts necessary to use the Company's technologies to bring the compounds through development and, upon regulatory approval, commercialization. The Company based the best estimate of selling price for the license on potential future cash flows under the arrangement over the estimated performance period. The Company determined that the committee participation represents a separate unit of accounting as R-Pharm could negotiate for and/or acquire these services from other third parties, and the Company based the best estimate of selling price on the nature and timing of the services to be performed.

The \$1.1 million upfront payment for the VIBATIV® agreement was allocated to two units of accounting based on the relative selling price method as follows: \$1.0 million to the license and \$33,000 to the committee participation. The amount allocated to the license was deferred and will be recognized as revenue upon completion of technical transfer. The amount allocated to committee participation was deferred and is being recognized as revenue over the estimated performance period.

**Alfa Wassermann**

*Development and Collaboration Arrangement*

In October 2012, the Company entered into a development and collaboration arrangement with Alfa Wassermann società per azioni (S.p.A.) (Alfa Wassermann) for velusetrag under which the parties agreed to collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis (a medical condition consisting of a paresis (partial paralysis) of the stomach, resulting in food remaining in the stomach for a longer time than normal). Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while the Company retains full rights to velusetrag in the United States, Canada, Japan and certain other countries. The Company is entitled to receive funding for the Phase 2a study and a subsequent Phase 2b study if the parties agree to proceed. If Alfa Wassermann exercises its license option at the completion of the Phase 2 program, then the Company is entitled to receive a \$10.0 million option fee. If velusetrag is successfully developed and commercialized, the Company is entitled to receive potential future contingent payments totaling up to \$53.5 million, and royalties on net sales by Alfa Wassermann ranging from the low teens to 20%.

**Hikma Pharmaceuticals LLC**

*Commercialization Agreement*

In May 2013, the Company entered into a commercialization agreement with Hikma Pharmaceuticals LLC (Hikma) providing Hikma with the right to commercialize telavancin for the treatment of Gram-positive bacterial infections, including MRSA (the Hikma Commercialization Agreement). Under the agreement, the Company granted Hikma exclusive commercialization rights in the Middle East and North Africa (MENA) region to register, and upon regulatory approval, market and distribute telavancin in 16 countries across MENA. The Company received a \$0.5 million upfront payment in June 2013. Also, the Company is eligible to receive contingent payments of up to \$0.5 million related to the successful commercialization of telavancin. The Company is responsible, either directly or through its vendors or contractors, for supplying drug product for Hikma's commercialization activities for 15 years.

Under the Hikma Commercialization Agreement, the significant deliverables were determined to be the license and manufacturing supply. The Company determined that the license and manufacturing supply together represent a single unit of accounting. The license, which includes rights to the Company's underlying technologies for telavancin, does not have standalone value because the rights conveyed do not permit Hikma to perform all efforts necessary to use the Company's technologies to bring the compound through commercialization. The Company deferred the upfront payment and will recognize revenue over the term of the manufacturing supply period, which is 15 years, on a straight-line basis. Future contingent payments will be deferred and recognized over the remaining term of the agreement on a straight-line basis. Revenue will be recognized from the sale of drug product upon delivery to Hikma.



Table of Contents**Former Collaboration Arrangement with Astellas***License, Development and Commercialization Agreement*

In November 2005, the Company entered into a global collaboration arrangement with Astellas for the license, development and commercialization of VIBATIV®. Under this agreement, Astellas paid the Company non-refundable cash payments totaling \$191.0 million. In January 2012, Astellas exercised its right to terminate the collaboration agreement. The rights previously granted to Astellas ceased upon termination of the agreement, and Astellas stopped all promotional sales efforts. Pursuant to the terms of the agreement, Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV®. As such, the Company recognized into revenue \$125.8 million of deferred revenue related to Astellas in the first quarter of 2012, and the Company is no longer eligible to receive any further milestone payments from Astellas.

**4. AVAILABLE-FOR-SALE SECURITIES**

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, 2013				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	
U.S. government securities	\$ 42,169	\$ 60	\$ (1)	\$ 42,229	
U.S. government agencies	161,751	107	(1)	161,857	
U.S. corporate notes	103,773	43	(7)	103,809	
U.S. commercial paper	133,818			133,818	
Money market funds	146,459			146,459	
Total	\$ 587,970	\$ 210	\$ (8)	\$ 588,172	

(In thousands)	December 31, 2012				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	
U.S. government securities	\$ 27,197	\$ 10	\$ (2)	\$ 27,205	
U.S. government agencies	115,397	85	(16)	115,466	
U.S. corporate notes	91,544	32	(10)	91,566	
U.S. commercial paper	23,082			23,082	
Money market funds	78,646			78,646	
Total	\$ 335,866	\$ 127	\$ (28)	\$ 335,965	

The following table summarizes the classification of the available-for-sale securities on the Company's condensed consolidated balance sheets:

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

(In thousands)	September 30, 2013		December 31, 2012	
Cash and cash equivalents	\$	164,745	\$	86,298
Short-term investments		334,261		153,640
Marketable securities		88,333		95,194
Restricted cash		833		833
Total	\$	588,172	\$	335,965

At September 30, 2013, all of the marketable securities have contractual maturities within two years and the average duration of marketable securities was approximately eight months. The Company does not intend to sell the investments which are in an unrealized loss position, and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross unrealized losses on its marketable securities at September 30, 2013, were temporary in nature. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

### 5. FAIR VALUE MEASUREMENTS

The Company defines 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.

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

### Table of Contents

The Company's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect the Company's market assumptions. The Company classifies 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.

The Company's available-for-sale securities are measured at fair value on a recurring basis and the Company's convertible subordinated notes are not measured at fair value on a recurring 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, 2013:</i>					
U.S. government securities	\$ 42,229				\$ 42,229
U.S. government agency securities	114,180		47,677		161,857
U.S. corporate notes	85,302		18,507		103,809
U.S. commercial paper			133,818		133,818
Money market funds	146,459				146,459
Total assets measured at estimated fair value	\$ 388,170		\$ 200,002		\$ 588,172
<i>Liabilities at September 30, 2013:</i>					
Convertible subordinated notes due 2023			\$ 476,531		\$ 476,531

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 December 31, 2012:</i>					
U.S. government securities	\$ 27,205				\$ 27,205
U.S. government agency securities	56,969		58,497		115,466
U.S. corporate notes	40,472		51,094		91,566
U.S. commercial paper			23,082		23,082
Money market funds	78,646				78,646

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

Total assets measured at estimated fair value	\$	203,292	\$	132,673	\$	\$	335,965
<i>Liabilities at December 31, 2012:</i>							
Convertible subordinated notes due 2015	\$		\$	194,050	\$	\$	194,050

At September 30, 2013, securities with a total fair value of \$6.6 million were measured using Level 1 inputs in comparison to December 31, 2012, at which time the securities had a fair value of \$6.6 million and were measured using Level 2 inputs. The transfer to Level 1 from Level 2 was primarily the result of increased trading volume of the securities at and around September 30, 2013, compared to December 31, 2012.

At September 30, 2013, securities with a total fair value of \$8.5 million were measured using Level 2 inputs in comparison to December 31, 2012, at which time the securities had a fair value of \$8.5 million and were measured using Level 1 inputs. The transfer to Level 2 from Level 1 was primarily the result of decreased trading volume of the securities at and around September 30, 2013, compared to December 31, 2012.

Table of Contents

Due to their short-term maturities, the Company believes that the fair value of its bank deposits, receivables from collaborative arrangements, accounts payable and accrued expenses approximate their carrying value.

**6. INVENTORIES**

Inventories consist of raw materials, work-in-process and finished goods related to the production of VIBATIV® (telavancin). Raw materials include VIBATIV® active pharmaceutical ingredient (API). Work-in-process includes third party manufacturing and associated labor costs relating to the Company's personnel directly involved in the production process. Included in inventories are raw materials and work-in-process that may be used as clinical products, which are charged to research and development (R&D) expense when consumed. In addition, under certain commercialization agreements, the Company may sell VIBATIV® packaged in unlabeled vials that are recorded in work-in-process. Inventories are summarized as follows:

(In thousands)	September 30, 2013	December 31, 2012
Raw materials	\$ 4,081	\$ 5,668
Work-in-process	3,605	1,846
Finished goods	1,352	
Total inventories	\$ 9,038	\$ 7,514

Inventories as of September 30, 2013, include \$219,000 of raw materials and work-in-process related to the production of VIBATIV® (telavancin) manufactured using certain process and specification changes that have not yet received regulatory approval. The process and specification changes are required to be approved by the FDA before the product can be sold commercially, however, the Company expects to receive FDA approval and realize the costs of the inventories through future sales.

**7. INTANGIBLE ASSETS**

The Company's intangible assets at September 30, 2013 consist of a \$30.0 million registrational milestone fee paid to GSK for the FDA approval of BREO ELLIPTA in the U.S. and a \$10.0 million registrational milestone fee paid to GSK for the MHLW approval of RELVAR ELLIPTA (see Note 3 Collaborative Arrangements above for more information). Each of these intangible assets is considered a finite-lived intangible asset with an estimated amortization period of 15 years. The amortization expense, which will be a reduction in revenue from collaborative arrangements over the next five years, is estimated to be \$13.3 million. There was no amortization expense for the three months and nine months ended September 30, 2013.

**8. LONG-TERM DEBT**

Long-term obligations are as follows:

Edgar Filing: THERAVANCE INC - Form 10-Q

(In thousands)	September 30, 2013	December 31, 2012
Convertible Subordinated Notes Due 2015	\$	172,500
Convertible Subordinated Notes Due 2023	287,500	
Total	\$ 287,500	\$ 172,500

*Convertible Subordinated Notes Due 2015*

In January 2008, the Company completed an underwritten public offering of \$172.5 million aggregate principal amount of unsecured 3% Convertible Subordinated Notes due January 15, 2015 (2015 Notes). The financing raised proceeds, net of issuance costs, of \$166.7 million. On June 4, 2013, the Company called for the redemption of all outstanding 2015 Notes, \$172.5 million principal amount, pursuant to the redemption right in the indenture governing the 2015 Notes. Any 2015 Notes outstanding on July 5, 2013 were to be redeemed in cash for 100% of the principal amount, plus accrued and unpaid interest to, but excluding, the redemption date. The 2015 Notes were convertible at any time prior to 5:00 p.m. Eastern time on July 3, 2013 into shares of the Company's common stock at a conversion rate of 38.6548 shares per \$1,000 principal amount (equivalent to a conversion price of approximately \$25.87 per share). All of the convertible subordinated notes, \$172.5 million principal amount, were converted into 6,667,932 of the Company's common stock between June 30, 2013 and July 3, 2013 and none were redeemed for cash. As a result of the conversion, unamortized debt issuance costs of \$1.3 million was reclassified from other long-term assets to additional paid-in capital in the third quarter of 2013.

Table of Contents

Amortization of the debt issuance costs ceased upon the conversion of the 2015 Notes. Amortization expense was negligible in the three months ended September 30, 2013, \$0.2 million in the three months ended September 30, 2012, \$0.4 million in the nine months ended September 30, 2013 and \$0.6 million in the nine months ended September 2012.

*Convertible Subordinated Notes Due 2023*

In January 2013, the Company 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 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 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 issuance costs, which are included in other long-term assets, are being amortized over the life of the notes. Unamortized issuance costs totaled \$5.9 million as of September 30, 2013. Amortization expense was \$0.2 million for the three months and \$0.4 million for the nine months ended September 30, 2013.

The notes are convertible, at the option of the holder, into shares of the Company's common stock at an initial conversion rate of 35.9903 shares per \$1,000 principal amount of the 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 the Company 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. The Company may not redeem the notes prior to their stated maturity date.

In connection with the offering of the notes, the Company 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 its common stock purchased by the Company 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 the Company 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, the Company will receive from its hedge counterparty a number of the Company's common shares that will range from zero, if the stock price is 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 the Company's 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.

The terms of the capped call option agreements include a provision under which the Company would have been required to make cash payments to the counterparty if the debt offering did not close. As a result of this provision, the capped calls were recorded as derivative assets between the trade dates and the date of the closing of the debt offering, at which time the cash settlement provision was no longer applicable. Upon the closing of the debt offering, the capped call transactions met the criteria for classification as an equity instrument, and the Company reclassified the carrying value of the capped call derivative assets to stockholders' equity. The change in fair value between the trade dates and the date at which the capped call derivative assets were reclassified to stockholders' equity was \$1.4 million, which was recorded as other income (expense), net, in the Company's condensed consolidated statement of operations in the first quarter of 2013.

**9. STOCK-BASED COMPENSATION**

*Equity Incentive Plan*

The 2012 Equity Incentive Plan (2012 Plan) provides for the granting of stock options, time-based and performance-contingent restricted stock units, time-based and performance-contingent restricted stock awards, and stock appreciation rights to employees, officers, directors and consultants of the Company. As of September 30, 2013, total shares remaining available for issuance under the 2012 Plan were 3,666,342.

*Employee Stock Purchase Plan*

The 2004 Employee Stock Purchase Plan (ESPP) provides for the purchase of the Company's common stock to the Company's non-officer employees. As of September 30, 2013, total shares remaining available for issuance under the ESPP were 343,233.

*Performance-Contingent Restricted Stock Awards*

In 2013, the Compensation Committee of the Company's Board of Directors approved the grant of 44,500 performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of one of three



Table of Contents

possible performance goals by December 31, 2014, as well as a requirement for continued employment through early 2017. In the second quarter of 2013, one of the performance goals was deemed achieved and time-based vesting commenced with respect to these awards. As a result, compensation expense was \$317,000 for the nine months ended September 30, 2013, and the remaining unrecognized expense will be recognized over the remaining vesting period through early-2017 using the graded vesting expense attribution method.

In 2012, the Compensation Committee of the Company's Board of Directors approved the grant of 44,500 performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of one of three possible performance goals by December 31, 2013, as well as a requirement for continued employment through early 2016. In the fourth quarter of 2012, one of the performance goals was deemed achieved and time-based vesting commenced with respect to these awards. Compensation expense was \$158,000 for the nine months ended September 30, 2013 and was \$286,000 for the nine months ended September 30, 2012. The remaining unrecognized expense will be recognized over the remaining vesting period through early-2016 using the graded vesting expense attribution method.

In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of 1,290,000 special long-term retention and incentive performance-contingent RSAs to senior management. These awards have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011-2016 and continued employment, both of which must be satisfied in order for the RSAs to vest. Expense associated with these RSAs would be recognized, if at all, during these years depending on the probability of meeting the performance conditions. The maximum potential expense associated with the RSAs could be up to approximately \$28.2 million (allocated as \$6.3 million for research and development expense and \$21.9 million for general and administrative expense) if all of the performance conditions are achieved on time. As of September 30, 2013, the Company had determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. As the RSAs are dependent upon the achievement of certain performance conditions, the expense associated with the RSAs may vary significantly from period to period. If sufficient performance conditions are achieved in the remainder of 2013, then the Company would recognize up to \$6.7 million in stock-based compensation expense associated with these RSAs.

In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of a 25,000 performance-contingent RSA to a non-executive officer that has dual triggers of vesting based upon the achievement of a performance condition over a timeframe from 2012-2013 and continued employment through 2014, both of which must be satisfied in order for the award to vest in full. The maximum potential expense associated with this award is approximately \$475,000, which would be recognized in increments based on the achievement of the performance condition. In the second quarter of 2013, the performance goal was deemed achieved and time-based vesting commenced with respect to this award. As a result, compensation expense was \$404,000 for the nine months ended September 30, 2013, and the remaining unrecognized expense will be recognized over the remaining vesting period through mid-2014 using the graded vesting expense attribution method.

*Performance-Contingent Restricted Stock Units*

In 2010, the Compensation Committee of the Company's Board of Directors approved the grant of 210,000 performance-contingent RSUs to senior management. These awards have dual triggers of vesting based upon the successful achievement of certain corporate operating milestones during 2010 and 2011, as well as a requirement for continued employment through early 2014. In the first quarter of 2011, both performance milestones were deemed achieved, and time-based vesting commenced with respect to all of the performance-contingent RSU shares. Compensation expense was \$49,000 for the nine months ended September 30, 2013 and was \$244,000 for the nine months ended September 30, 2012. The remaining unrecognized expense will be recognized over the remaining vesting period through early-2014 using the graded vesting expense attribution method.



Table of Contents*Stock-Based Compensation Expense*

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,	
	2013	2012	2013	2012
Research and development	\$ 4,191	\$ 3,259	\$ 12,496	\$ 10,329
Selling, general and administrative	2,255	2,571	7,208	7,715
Total stock-based compensation expense	\$ 6,446	\$ 5,830	\$ 19,704	\$ 18,044

Total stock-based compensation expense capitalized to inventory was nil for the three months and \$170,000 for the nine months ended September 30, 2013. Total stock-based compensation expense capitalized to inventory was \$198,000 for both the three months and nine months ended September 30, 2012.

As of September 30, 2013, unrecognized compensation expense, net of expected forfeitures, was as follows: \$8.7 million related to unvested stock options; \$18.8 million related to unvested RSUs; and \$25.3 million related to unvested RSAs (excludes performance-contingent RSAs).

*Valuation Assumptions*

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
<b>Employee stock options</b>				
Risk-free interest rate	1.68%-2.02%	0.83%-0.86%	0.76%-2.02%	0.74%-1.17%
Expected term (in years)	6	6	5-6	5-6
Volatility	60%	57%	58%-60%	55%-60%
Dividend yield	%	%	%	%
Weighted-average estimated fair value of stock options granted	\$ 21.63	\$ 14.31	\$ 18.11	\$ 11.41

*Stockholders Equity*

For the nine months ended September 30, 2013, approximately 1,312,000 shares were exercised at a weighted-average exercise price of \$15.11 per share, for total cash proceeds of approximately \$19,834,000.

## 10. INCOME TAXES

The Company did not record a provision for income taxes for both of the three months and nine months ended September 30, 2013 and September 30, 2012, because it expected to generate a taxable net operating loss for the fiscal year ended December 31, 2013 and 2012. In addition, the deferred tax assets continue to be treated as having no current value and remain fully offset by a valuation allowance or uncertain tax position liabilities.

## 11. COMMITMENTS AND CONTINGENCIES

### *Special Long-Term Retention and Incentive Equity Awards Program*

In 2011, the Company 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. The maximum potential cash bonus expense associated with this program is \$38.2 million, which would be recognized in increments based on achievement of the performance conditions. As of September 30, 2013, the Company's management determined that the achievement of the requisite performance conditions was not probable and, as a result, no bonus expense has been recognized. If sufficient performance conditions are achieved in the remainder of 2013, then the Company would recognize up to \$9.5 million cash bonus expense in 2013.

### *Guarantees and Indemnifications*

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of September 30, 2013.

Table of Contents

**12. SUBSEQUENT EVENT**

*Sale of Stock*

On October 29, 2013, the Company and Glaxo Group Limited, an affiliate of GSK, entered into an agreement to purchase 130,473 shares of the Company's common stock at \$37.66 per share, for an aggregate purchase price of approximately \$4.9 million, pursuant to its rights under the Company's governance agreement with GSK dated June 4, 2004, as amended.

Table of Contents

**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 is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. We are focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Our key programs include: RELVAR ELLIPTA or BREO ELLIPTA (fluticasone furoate/vilanterol), ANORO ELLIPTA (umeclidinium bromide/vilanterol) and MABA (Bifunctional Muscarinic Antagonist-Beta2 Agonist), each partnered with GlaxoSmithKline plc (GSK), and our oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging our proprietary insight of multivalency to drug discovery, we are pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.

In the third quarter of 2013, our net loss was \$47.0 million, an increase of 35.4% from \$34.7 million in the third quarter of 2012. In the first nine months of 2013, our net loss was \$120.8 million, compared with net income of \$12.8 million in the first nine months of 2012. Net income in the nine months ended September 30, 2012 reflects the recognition of deferred revenue of \$125.7 million from our global collaboration arrangement with Astellas Pharma Inc. (Astellas) for the development and commercialization of VIBATIV®. This recognition resulted from Astellas January 6, 2012 termination of our agreement with them. In the third quarter of 2013, our research and development expenses were \$33.4 million, an increase of 23.7% from \$27.0 million in the third quarter of 2012. In the first nine months of 2013, our research and development expenses were \$91.6 million, an increase of 2% from \$89.8 million in the first nine months of 2012. Cash, cash equivalents, short-term investments, and marketable securities totaled \$594.5 million at September 30, 2013, an increase of \$250.8 million from December 31, 2012. The increase was primarily due to net proceeds of \$281.2 million received from the January 2013 issuance of convertible subordinated notes, net proceeds of \$121.1 million received from our private placements of common stock to an affiliate of GSK and net proceeds of \$18.9 million received from employee stock transactions. These increases were partially offset by cash used in operations of \$89.6 million and by

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

\$36.8 million of payments on privately-negotiated capped call option transactions in connection with the issuance of the convertible subordinated notes.

In 2012, our total operating expenses were \$148.8 million. We anticipate total operating expenses for 2013 to increase relative to 2012.

### **Recent Developments**

#### ***Business Separation Announcement***

In April 2013, we announced that our Board of Directors approved plans to separate our businesses into two independent publicly traded companies. The company to be spun-off, Theravance Biopharma, Inc., filed an initial Form 10 with the SEC on August 1, 2013 and filed amendments of its Form 10 with the SEC on September 27, 2013 and October 29, 2013. After the business separation, Theravance will focus on managing all development and commercial responsibilities under the LABA

Table of Contents

collaboration with GSK and associated potential royalty revenue from RELVAR ELLIPTA or BREO ELLIPTA , ANORO ELLIPTA and VI monotherapy, with the intention of providing a consistent return of capital to stockholders. Theravance Biopharma, Inc. will be a biopharmaceutical company focused on discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need. The result will be two independent, publicly traded companies with different business models enabling investors to align their investment philosophies with the strategic opportunities and financial objectives of the two independent companies.

***Conversion of Convertible Subordinated Notes Due 2015***

On June 4, 2013, we called for the redemption of all of our outstanding 3% Convertible Subordinated Notes due 2015 (the 2015 Notes ), pursuant to the redemption right in the indenture governing the 2015 Notes. Any 2015 Notes outstanding on July 5, 2013 were to be redeemed in cash for 100% of the principal amount, plus accrued and unpaid interest to, but excluding, the redemption date. The 2015 Notes were convertible at any time prior to 5:00 p.m. Eastern time on July 3, 2013 into shares of our common stock at a conversion rate of 38.6548 shares per \$1,000 principal amount (equivalent to a conversion price of approximately \$25.87 per share). All of the convertible subordinated notes, \$172.5 million principal amount, were converted into 6,667,932 of our common stock between June 30, 2013 and July 3, 2013 and none were redeemed for cash.

***Reintroduction of VIBATIV® to the U.S. Market***

On August 14, 2013, we announced that we commenced shipments of VIBATIV® (telavancin) into the U.S. wholesaler channel.

**Program Highlights**

***Respiratory Programs with GlaxoSmithKline plc (GSK)***

***RELVAR ELLIPTA or BREO ELLIPTA (Fluticasone Furoate/Vilanterol, FF/VI)***

In September 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved RELVAR ELLIPTA for the treatment of bronchial asthma (in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist (LABA) is required). RELVAR ELLIPTA is not indicated for the treatment of chronic obstructive pulmonary disease (COPD) in Japan. RELVAR is a combination of the inhaled corticosteroid (ICS), fluticasone furoate FF , and the LABA, vilanterol VI . The MHLW has approved two doses of FF/VI - 100/25 mcg and 200/25 mcg. Both strengths will be administered once-daily using the ELLIPTA , a new dry powder inhaler (DPI). Under the terms of the 2002 LABA collaboration agreement, Theravance made a milestone payment of \$10 million (USD) to GlaxoSmithKline plc (GSK) following MHLW approval of RELVAR ELLIPTA in Japan. It is anticipated RELVAR ELLIPTA will be made available in Japan by GSK during the fourth quarter of 2013.



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

In addition, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion recommending marketing authorization for FF/VI under the proposed brand name RELVAR ELLIPTA for:

**Asthma:** the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (LABA and ICS) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and as needed inhaled short acting beta2-agonists

**COPD:** the symptomatic treatment of adults with COPD with a FEV1<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy

Two strengths of FF/VI are proposed for asthma (92/22 mcg and 184/22 mcg) and one strength is proposed for COPD (92/22 mcg). All strengths will be administered once-daily using the ELLIPTA . The FF/VI doses of 92/22 mcg and 184/22 mcg are specified as the delivered doses (emitted from the inhaler). The lower strength is equivalent to the 100/25 mcg pre-dispensed doses (contained inside the inhaler) approved in the U.S. for COPD.

A CHMP positive opinion is one of the final steps before marketing authorization is granted by the European Commission, but does not always result in marketing authorization. A final decision by the European Commission is anticipated during the fourth quarter of 2013.

FF/VI 100/25 mcg was approved by the FDA for use in patients with COPD in May 2013 under the trade name BREO ELLIPTA . It was also approved for the treatment of COPD by Health Canada in July 2013 under the same trade name. It is not

Table of Contents

indicated for the relief of acute bronchospasm or the treatment of asthma in the U.S. or Canada. BREO ELLIPTA 100/25 mcg was made available in the U.S. during the fourth quarter of 2013.

Regulatory applications for FF/VI are planned for submission in a number of other countries worldwide.

*ANORO ELLIPTA (Umeclidinium Bromide/Vilanterol, UMEC/VI)*

On September 10, 2013, the Pulmonary-Allergy Drugs Advisory Committee (PADAC) to the FDA recommended approval of UMEC/VI, 62.5/25 mcg dose, for the treatment of COPD. The FDA Advisory Committee provides non-binding recommendations for consideration by the FDA, with the final decision on approval made by the FDA. The Prescription Drug User Fee Act (PDUFA) goal date for UMEC/VI is December 18, 2013.

ANORO ELLIPTA is the proposed proprietary name for UMEC/VI, a combination of two investigational bronchodilator molecules umeclidinium, a long-acting muscarinic antagonist (LAMA) and VI, a LABA, administered using the ELLIPTA inhaler.

UMEC/VI is an investigational medicine, which is not currently approved anywhere in the world. UMEC/VI is under regulatory review by the FDA, European Medicines Agency and the Japanese Ministry of Health, Labor and Welfare. Regulatory submissions for UMEC/VI have also been submitted in a number of countries worldwide.

*Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA) GSK961081*

GSK961081 ( 081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activities. In July 2013, Theravance announced that GSK had initiated preclinical Phase 3-enabling studies with the combination 081/FF, supporting development as a once-daily medicine delivered in the ELLIPTA inhaler.

***Bacterial Infections Program***

*VIBATIV® (telavancin)*

In August 2013, Theravance reintroduced VIBATIV® (telavancin) into the U.S. VIBATIV® is approved in the U.S. for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable, and for the treatment of complicated skin and skin structure infections (cSSSI) caused by

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

susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains. VIBATIV®, discovered and developed by Theravance, is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function.

### ***Central Nervous System (CNS)/Pain Programs***

#### *Norepinephrine and Serotonin Reuptake Inhibitor TD-9855*

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor for the treatment of central nervous system conditions such as Attention-Deficit/Hyperactivity Disorder (ADHD) and chronic pain. TD-9855 is being evaluated in an ongoing Phase 2 study in adult patients with ADHD and in an ongoing Phase 2 study in patients with fibromyalgia. Both studies are progressing and results from the Phase 2 study in ADHD and fibromyalgia are anticipated to be reported late this year and during the first half of 2014, respectively.

### ***Theravance Respiratory Program***

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

In September 2013, Theravance announced positive topline results from a dose-ranging 7-day cross-over design Phase 2b study of TD-4208, an investigational LAMA, administered once-a-day as a nebulized aqueous solution in patients with moderate to severe COPD. All doses met the primary and secondary efficacy endpoints. The primary efficacy endpoint in this study was change from baseline in trough FEV1 (forced expiratory volume in one second) at the end of Day 7. TD-4208 demonstrated significant bronchodilation over 24 hours. All doses of TD-4208 were generally well tolerated in the study with rates of adverse events comparable to placebo.

Table of Contents

**Collaboration Arrangements with GSK**

*LABA collaboration*

In November 2002, we entered into our long-acting beta2 agonist (LABA) collaboration 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 is developing two combination products: (1) RELVAR ELLIPTA or BREO ELLIPTA (FF/VI), a once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF) and (2) ANORO ELLIPTA (UMEC/VI), a once-daily investigational medicine combining a long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI. 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 2012 sales of approximately \$8.0 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2012 sales of approximately \$3.2 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 2012 sales of approximately \$4.6 billion.

In the event that a product containing VI is successfully developed and commercialized, we will be obligated to make future milestone payments to GSK, which could total as much as \$180.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. Of these potential milestone payments, \$30.0 million became payable in October 2013 due to the launch of BREO ELLIPTA in the U.S. and we estimate another \$70.0 million could become payable during the remainder of 2013 and all the milestone payments could be payable by the end of 2014. On May 10, 2013 the U.S. Food and Drug Administration (FDA) approved BREO ELLIPTA as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. On September 20, 2013 the Japanese Ministry of Health, Labour and Welfare (MHLW) approved RELVAR ELLIPTA for the treatment of bronchial asthma in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required. As a result of these approvals we paid GSK \$40.0 million for registrational milestone fees in the first nine months of 2013. These milestone payments to GSK were capitalized as finite-lived intangible assets and will be amortized over their estimated useful life.

We are entitled to receive annual royalties from GSK of 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 the mid-single digits to 10%.

*2004 Strategic Alliance*

In March 2004, we entered into our strategic alliance with GSK. Under this alliance, 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 bifunctional muscarinic antagonist-beta2 agonist (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 only as a combination product, such as 081/FF, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, 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

Table of Contents

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.

***Purchases of Common Stock under our Governance Agreement and Common Stock Purchase Agreement with GSK***

During the first nine months of 2013, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 3,374,497 shares of our common stock for an aggregate purchase price of approximately \$121.1 million pursuant to its periodic top-up rights under our governance agreement with GSK dated June 4, 2004, as amended.

***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.

Revenue recognized from GSK under the LABA collaboration and strategic alliance agreements was as follows:

(In millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012		2013	2012	
LABA collaboration	\$	\$	0.9	\$	\$	2.7
Strategic alliance MABA program license		0.4	0.5		1.3	1.6
Total revenue from GSK Collaborations	\$	0.4	1.4	\$	3.1	4.3

Under the GSK collaborative arrangements, we are reimbursed for research and development (R&D) expenses. These reimbursements have been reflected as a reduction of R&D expense. Reduction of R&D expense was \$0.2 million for the three months and \$0.5 million for the nine months ended September 30, 2013. Reduction of R&D expense was less than \$0.1 million for the three months and \$0.1 million for the nine months ended September 30, 2012.

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

**Product Revenues:** We sell VIBATIV® in the U.S. through a limited number of distributors, and title and risk of loss transfer upon receipt by these distributors. Healthcare providers order VIBATIV® through these distributors. For all product shipped during the three months ended September 30, 2013, we are deferring the recognition of revenue until the product is sold through to healthcare providers, the end customers, due to the inherent uncertainties in estimating normal channel inventory at the distributors, and during which period we also provided extended payment terms and expanded return rights that allow distributors to return the product up to one year after the product launch. As of September 30, 2013, we had deferred revenue of \$0.5 million related to VIBATIV® shipments and recorded this amount as a current liability in the condensed consolidated balance sheet.

Table of Contents

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

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

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

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

We maintain a policy to record allowances for potentially doubtful accounts for estimated losses resulting from the inability of our customers to make required payments.

*Concentration of Credit Risk:* Financial instruments which potentially subject us to concentrations of credit risk include accounts receivable. At September 30, 2013, 99% of our accounts receivable balance represents amounts due to us from three distributors, AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation. Despite the significant concentration of distributors, the demand for VIBATIV® is driven primarily by patient therapy requirements and we are not dependent upon any individual distributor with respect to VIBATIV® sales.



**Collaborative Arrangements.** We generate revenue from collaboration and license agreements for the development and commercialization of our 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

Table of Contents

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. The total amount of deferred revenue based on BESP at September 30, 2013 was \$7.3 million. 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.

For multiple element arrangements entered into prior to January 1, 2011, we determined whether the elements had stand-alone value and whether there was objective and reliable evidence of fair value. When the delivered element did not have stand-alone value or there was insufficient evidence of fair value for the undelivered element(s), we recognized the consideration for the combined unit of accounting ratably over the estimated period of performance, which was the same manner in which the revenue was recognized for the final deliverable. Our collaborative agreements with GSK and our former collaborative arrangement with Astellas were entered into prior to January 1, 2011. The deliverables 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 term of our performance periods under the agreements. These upfront or contingent payments received, pending recognition as revenue, were recorded as deferred revenue and amortized over the estimated performance periods.

We recognized revenue from our GSK collaborative arrangements of \$3.1 million in the nine months ended September 30, 2013 and \$4.3 million in the nine months ended September 30, 2012. The remaining deferred revenue under the GSK strategic alliance agreement is \$6.2 million at September 30, 2013. 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, which would result in immediate recognition of the deferred revenue. The collaborative arrangement with Astellas was terminated on January 6, 2012. The termination resulted in the recognition of deferred revenue of \$125.8 million in the nine months ended September 30, 2012.

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

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

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. Under this guidance, total contingent payments that may become payable to us under our collaborative agreements with R-Pharm and Hikma were \$10.5 million at September 30, 2013 and are considered non-substantive.

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 Merck, Alfa Wassermann, GSK and R-Pharm are recognized as a reduction of research and development expenses. For the nine months ended September 30, 2013, we recorded a

Table of Contents

reduction in our research and development expenses of \$6.1 million for reimbursement of research and development expenses received from Merck, Alfa Wassermann, GSK, and R-Pharm.

*Accrued Research and Development Expenses*

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves the following:

- communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with preclinical and toxicology studies and clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to CMOs in connection with the production of product and clinical study materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical studies on our behalf. The financial terms of

these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical study milestones. Our service providers invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies and other research activities.

***Fair Value of Stock- Based Compensation Awards***

We use the Black-Scholes-Merton option pricing model to estimate the fair value of options at the date of grant. The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected stock price volatility. We use the simplified method as described in Staff Accounting Bulletin No. 107, Share Based Payment, for the expected option term because the usage of our historical option exercise data is limited due to post-IPO exercise restrictions. Beginning April 1, 2011, we have used our historical volatility to estimate expected stock price volatility. Prior to April 1, 2011, we used our peer company price volatility to estimate expected stock price volatility due to our limited historical common stock price volatility since our initial public offering in 2004. The estimated fair value of the option is expensed on a straight-line basis over the expected term of the grant.

We estimated the fair value of restricted stock units (RSUs) and restricted stock awards (RSAs) based on the fair market values of the underlying stock on the dates of grant. The estimated fair value of time-based RSUs and RSAs is expensed on a straight-line basis over the expected term of the grant. The estimated fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the requisite service period based on management's best estimate as to whether it is probable that the shares awarded are expected to vest. We assess the probability of the performance indicators being met on a continuous basis.

Table of Contents

Stock-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. The estimated annual forfeiture rates for stock options, RSUs and RSAs are based on our historical forfeiture experience.

In 2011, we granted special long-term retention and incentive performance-contingent RSAs to members of senior management, which 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. The maximum potential expense associated with these RSAs is \$28.2 million, which would be recognized in increments based on achievement of the performance conditions. As of September 30, 2013, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in 2013, then we would recognize up to \$6.7 million in stock-based compensation expense associated with these RSAs in 2013.

We do not expect to recognize in the near future any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance on our deferred tax assets including deferred tax assets related to our net operating loss carry forwards.

***Inventories***

Inventories are stated at the lower of cost or market value. Inventories include VIBATIV® API and other raw materials of \$4.1 million, work-in-process of \$3.6 million and finished goods of \$1.4 million at September 30, 2013. Work-in-process consists of third party manufacturing costs and associated labor costs relating to our personnel directly involved in the production process. Included in inventories are raw materials and work-in-process that may be used as clinical products, which are charged to R&D expense when consumed. If information becomes available that suggests the inventories may not be realizable, we may be required to expense a portion or all of the previously capitalized inventories.

***Impairment of Finite-lived Intangible Assets***

We review 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 intangible assets at September 30, 2013 consist of a \$30.0 million registrational milestone fee paid to GSK for the FDA approval of BREO ELLIPTA in the U.S. and a \$10.0 million registrational milestone fee paid to GSK for the MHLW approval of RELVAR ELLIPTA (see Collaboration Arrangements with GSK above for more information). Each of these intangible assets is considered a finite-lived intangible asset, which will be amortized over its estimated useful life of 15 years using the straight-line method.

**RESULTS OF OPERATIONS***Revenue*

Revenue, as compared to the prior year periods, was as follows:

(In millions, except percentages)	Three months Ended September 30,		Change		Nine months Ended September 30,		Change	
	2013	2012	\$	%	2013	2012	\$	%
Collaborative arrangements								
GSK Collaborative arrangement	\$ 0.4	\$ 1.4	\$ (1.0)	(71)%	\$ 3.1	\$ 4.3	\$ (1.2)	(28)%
Astellas Collaborative arrangement				%		125.7	(125.7)	(100)%
Other Collaborative arrangements	*		*	**	0.1		0.1	**
Total Revenue	\$ 0.4	\$ 1.4	\$ (1.0)	(71)%	\$ 3.2	\$ 130.0	\$ (126.8)	(98)%

\* Amount is less than \$50,000.

\*\* Calculation not meaningful.

Table of Contents

Revenue decreased 71% to \$0.4 million in the third quarter of 2013 and decreased 98% to \$3.2 million in the first nine months of 2013, from the comparable periods in 2012. The decrease in the first nine months of 2013 was primarily due to the January 6, 2012 termination of our global collaboration arrangement with Astellas for the development and commercialization of VIBATIV®, which resulted in the recognition of the remaining deferred revenue under that agreement of \$125.7 million.

A portion of our upfront fees and certain contingent payments received from our collaborative arrangements other than with Astellas have been deferred and are being amortized ratably into revenue or research and development expense over the estimated performance period. Future revenue will include the ongoing amortization of upfront and contingent payments earned. We periodically review and, if necessary, revise the estimated periods of our performance pursuant to these contracts.

**Research & Development**

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

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

Our R&D expenses incurred during the periods presented were as follows:

(In millions, except percentages)	Three months Ended September 30,				Nine months Ended September 30,			
	2013	2012	Change \$	%	2013	2012	Change \$	%
Employee-related	\$ 9.0	\$ 9.0	\$	%	\$ 26.9	\$ 28.7	\$ (1.8)	(6)%
External-related	14.5	8.8	5.7	65%	34.2	32.9	1.3	4%
Stock-based compensation	4.2	3.3	0.9	27%	12.5	10.3	2.2	21%
Facilities, depreciation and other allocated	5.7	5.9	(0.2)	(3)%	18.0	17.9	0.1	1%
Total expenses	\$ 33.4	\$ 27.0	\$ 6.4	24%	\$ 91.6	\$ 89.8	\$ 1.8	2%



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

R&D expenses increased 24% to \$33.4 million in the third quarter and increased 2% to \$91.6 million in the first nine months of 2013 from the comparable periods in 2012. The increase in the first nine months of 2013 was primarily due to higher external costs of \$5.7 million. The key Phase 2 clinical trials we were conducting in the first nine months of 2013 were our Phase 2 clinical studies in our MARIN program with TD-9855 and a Phase 2b study in our LAMA program with TD-4208. In the comparable period in 2012 our key Phase 2 clinical trials primarily consisted of our Phase 2b studies in our program for opioid induced constipation with TD-1211 and one Phase 2 study in our MARIN program with TD-9855. Under certain of our collaborative arrangements we received partial reimbursement of external costs and employee-related costs, which have been reflected as a reduction of R&D expenses of \$2.2 million in the third quarter of 2013 compared to a nominal amount in the same period of 2012 and \$6.1 million in the first nine months of 2013 compared to \$0.1 million in the same period of 2012.

### *Selling, general and administrative*

Selling, general and administrative (SG&A) expenses, as compared to the prior year periods, were as follows:

(In millions, except percentages)	Three months Ended September 30,		Change		Nine months Ended September 30,		Change	
	2013	2012	\$	%	2013	2012	\$	%
Selling, general and administrative expense	\$ 12.3	\$ 7.8	\$ 4.5	58%	\$ 32.0	\$ 23.2	8.8	38%

SG&A expenses increased 58% to \$12.3 million in the third quarter and 38% to \$32.0 million in the first nine months of 2013 from the comparable periods in 2012. The increases in 2013 were primarily due to an increase in external legal and accounting

Table of Contents

fees in connection with our separation strategy. Total external expenses related to the proposed company separation were \$3.9 million for the three months and \$6.2 million for the nine months ended September 30, 2013. Stock-based compensation expense was \$2.3 million in the third quarter of 2013, compared to \$2.6 million in the same period of 2012 and \$7.2 million in the nine months ended September 30, 2013, compared to \$7.7 million in the same period of 2012.

***Interest and other income (expense), net***

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

(In millions, except percentages)	Three months Ended		Change		Nine months Ended		Change	
	September 30, 2013	September 30, 2012	\$	%	September 30, 2013	September 30, 2012	\$	%
Interest income	\$ 0.2	\$ 0.2	\$	%	\$ 0.6	\$ 0.3	\$ 0.3	100%
Other income (expense), net	*		*	**	6.7		6.7	**
Interest and other income (expense), net	\$ 0.2	\$ 0.2	\$	**	\$ 7.3	\$ 0.3	\$ 7.0	**

\* Amount is less than \$50,000.

\*\* Calculation not meaningful.

Interest and other income (expense), net remained relatively flat in the third quarter and increased from \$0.3 million to \$7.3 million in the first nine months of 2013, compared to the same periods in 2012. The increase in the first nine months of 2013 was primarily related to other income of \$10.0 million resulting from the termination of our royalty participation agreement with Elan in the second quarter of 2013. The increase was partially offset by other expense of \$1.8 million in third party expenses relating to the aforementioned royalty participation agreement in the second quarter of 2013 and \$1.4 million related to the change in fair value of the capped call instruments related to our convertible subordinated notes issued in January 2013 in the first quarter of 2013.

***Interest expense***

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

(In millions, except percentages)	Three months Ended		Change		Nine months Ended		Change	
	September 30, 2013	September 30, 2012	\$	%	September 30, 2013	September 30, 2012	\$	%
Interest expense	\$ 1.9	\$ 1.5	\$ 0.4	27%	\$ 7.7	\$ 4.5	\$ 3.2	71%

Interest expense increased 27% to \$1.9 million in the third quarter of 2013 and increased 71% in the first nine months of 2013 from the comparable periods of 2012. The increases were primarily due to the interest expense and amortization of debt issuance costs from our 2.125% convertible subordinated notes due 2023 issued in January 2013. Interest expense is primarily comprised of interest expense and amortization of debt issuance costs from our convertible subordinated notes issued in January 2008 and January 2013.

## LIQUIDITY AND CAPITAL RESOURCES

### *Liquidity*

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under corporate collaborative arrangements. At September 30, 2013, we had \$594.5 million in cash, cash equivalents, short-term investments and marketable securities, excluding \$0.8 million in restricted cash that was pledged as collateral for certain of our leases. On January 24, 2013, we completed an underwritten public offering of \$287.5 million aggregate principal amount of unsecured 2.125% convertible subordinated notes due 2023. The financing raised proceeds, net of issuance costs, of approximately \$281.2 million, less \$36.8 million of payments on privately-negotiated capped call option transactions in connection with the issuance of the notes. In connection with the offering of the notes, we entered into privately-negotiated capped call option transactions with an aggregate cost of \$36.8 million. Also, during the first nine months of 2013, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 3,374,497 shares of our common stock for an aggregate purchase price of approximately \$121.1 million pursuant to its periodic top-up rights under our governance agreement with GSK dated June 4, 2004, as amended.

Table of Contents

On June 4, 2013, we called for the redemption of all of our outstanding 3% Convertible Subordinated Notes due 2015 (the 2015 Notes), pursuant to the redemption right in the indenture governing the 2015 Notes. Any 2015 Notes outstanding on July 5, 2013 were to be redeemed in cash for 100% of the principal amount, plus accrued and unpaid interest to, but excluding, the redemption date. The 2015 Notes were convertible at any time prior to 5:00 p.m. Eastern time on July 3, 2013 into shares of our common stock at a conversion rate of 38.6548 shares per \$1,000 principal amount (equivalent to a conversion price of approximately \$25.87 per share). All of the convertible subordinated notes, \$172.5 million principal amount, were converted into 6,667,932 of our common stock between June 30, 2013 and July 3, 2013 and none were redeemed for cash.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, TD-9855 in our MARIN program is in Phase 2 studies for ADHD and fibromyalgia, and our LAMA compound TD-4208 recently completed a Phase 2b study in the third quarter of 2013. Also, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. In addition, we reintroduced VIBATIV® in the U.S. during the third quarter of 2013, which involves outside services costs associated with manufacturing and distribution capabilities. Furthermore, as we commercialize VIBATIV® in the United States without a partner, we incur costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery.

As part of the business separation announced in April 2013, we currently anticipate funding the new company with a minimum of \$300 million at separation. We expect this initial cash will fund the new company's operations through significant potential corporate milestones for approximately the next two to three years after the completion of the spin-off, based on current operating plans and financial forecasts. Changes in our development or operating plans, the timing of, and our cash balance at the time of the spin-off, however, could affect the amount of cash available for the two companies at the time of separation and the initial cash funding needed to adequately capitalize both companies.

Pursuant to our LABA collaboration with GSK, we are obligated to make milestone payments to GSK, which could total as much as \$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. Of these potential milestone payments, we paid GSK \$40.0 million in registrational milestone fees in the first nine months of 2013, \$30.0 million became payable in October 2013 due to the launch of BREO ELLIPTA in the U.S., and we estimate another \$70.0 million could become payable during the remainder of 2013 and the remaining milestone payments could be payable by the end of 2014.

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 September 30, 2013, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in 2013, then we would recognize up to \$9.5 million related to cash bonus expense in 2013.

**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 financial 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

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

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 year period, were as follows:

(In millions)	Nine Months Ended			
	September 30,		September 30,	
	2013		2012	
Net cash used in operating activities	\$	(89.6)	\$	(103.3)
Net cash used in investing activities	\$	(218.2)	\$	(58.4)
Net cash provided by financing activities	\$	384.8	\$	229.1

Table of Contents

*Cash Flows from Operating Activities*

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

Net cash used in operating activities in the nine-months ended September 30, 2013 was \$89.6 million, which was primarily due to:

- \$98.5 million used in operating expenses, after adjusting for non-cash related items of: \$25.0 million consisting primarily of stock-based compensation expense of \$19.7 million, depreciation and amortization expenses of \$5.7 million, and, partially offset by rent expense of \$0.4 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 R&D services;
- \$8.2 million increase for cash, net of third party expenses, for the termination of our royalty participation agreement;
- \$6.5 million increase in accrued liabilities due to \$4.5 million increase in accrued personnel-related expenses, accrued clinical and development expense, and other accrued liabilities, and \$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.

Net cash used in operating activities in the nine-months ended September 30, 2012 was \$103.3 million, which was primarily due to:

- \$90.0 million used in operating expenses, after adjusting for non-cash related items of \$23.0 million consisting primarily of stock-based compensation expense of \$18.0 million, depreciation and amortization expenses of \$5.5 million, partially offset by a reduction of

rent expense of \$0.5 million;

- \$5.4 million used for interest payments on convertible subordinated notes payable;
- \$4.6 million used to increase inventories; and
- \$4.4 million used to decrease accrued liabilities due to a \$3.9 million decrease in accrued personnel-related expenses, accrued clinical and development expense, and \$0.5 million decrease in accounts payable primarily due to timing of payments.

*Cash Flows from Investing Activities*

Net cash used in investing activities in the nine-months ended September 30, 2013 was \$218.2 million, which was primarily due to \$176.6 million in cash balances being invested in short-term investments and long-term marketable securities and \$40.0 million used for milestone payments to GSK.

Net cash used in investing activities in the nine months ended September 30, 2012 was \$58.4 million, which was primarily due to \$56.3 million in cash balances being invested in short-term investments and long-term marketable securities.

Table of Contents

*Cash Flows from Financing Activities*

Net cash provided by financing activities in the nine months ended September 30, 2013 was \$384.8 million, which was primarily due to the net proceeds of \$281.2 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.

Net cash provided by financing activities in the nine months ended September 30, 2012 was \$229.1 million, which was primarily due to \$212.5 million, net of issuance costs, received from the sale of our common stock to an affiliate of GSK.

**OFF-BALANCE SHEET ARRANGEMENTS**

We lease various real properties under an operating lease that generally requires us to pay taxes, insurance, maintenance, and minimum lease payments. This lease has options to renew.

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

**Commitments and Contingencies**

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements at September 30, 2013.

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. The maximum potential expense associated with this program is \$28.2 million related to stock-based compensation expense and \$38.2 million related to cash bonus expense, which would be recognized in increments based on achievement of the performance conditions. As of September 30, 2013, we determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation expense has been recognized. If sufficient performance conditions are achieved in the remainder of 2013, then we would recognize up to \$6.7 million in stock-based compensation expense associated with these RSAs and \$9.5 million related to cash bonus expense in 2013.



**Contractual Obligations and Commercial Commitments**

There have been no significant changes in our payments due under contractual obligations, compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

Pursuant to our LABA collaboration with GSK, we will be obligated to make milestone payments to GSK, which could total as much as \$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. Of these potential milestone payments, we paid GSK \$40.0 million in registrational milestone fees in the first nine months of 2013, \$30.0 million became payable in October 2013 due to the launch of BREO ELLIPTA in the U.S., and we estimate another \$70.0 million could become payable during the remainder of 2013 and all the milestone payments could be payable by the end of 2014. We have not recognized any liabilities relating to this agreement at September 30, 2013.

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

During the first nine months of 2013, there have been no significant changes in our market risk or how our market risk is managed, compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012.

Table of Contents

**Item 4. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.*

We conducted an evaluation as of September 30, 2013, 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*

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**

*If the commercialization of BREO ELLIPTA and RELVAR 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 do not meet investor expectations, our business will be harmed, and the price of our securities could fall.*

In May 2013, the U.S. Food and Drug Administration (FDA) approved BREO ELLIPTA (FF/VI 100/25 mcg) as an inhaled long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. In July 2013, Health Canada approved BREO ELLIPTA (100/25mcg) for the long-term, once-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema, and for the reduction of exacerbations of COPD in patients with a history of exacerbations. In addition, in September 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved RELVAR ELLIPTA (two doses, FF/VI - 100/25 mcg and 200/25 mcg) for the treatment of bronchial asthma in cases where concurrent use of inhaled corticosteroid and long-acting inhaled beta2 agonist is required. Under our agreements with our collaborative partner GSK, GSK has full responsibility for commercialization of BREO ELLIPTA and RELVAR ELLIPTA. In October 2013, GSK began shipping BREO ELLIPTA into the U.S. market. Following the MHLW approval, it is also anticipated that RELVAR ELLIPTA will be made available by GSK in Japan during the fourth quarter of 2013. Any delays or adverse developments or perceived delays or adverse developments with respect to the commercialization of BREO ELLIPTA in the U.S. or Canada, or RELVAR ELLIPTA in Japan, including if sales do not meet investor expectations, will significantly harm our business and could cause the price of our securities to fall.

Table of Contents

*If regulatory authorities determine that the Phase 3 programs for FF/VI in asthma and/or outside the U.S. for COPD do not demonstrate adequate safety and efficacy, the continued development of FF/VI may be significantly delayed, it 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.*

During the first quarter of 2012, we announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma. In July 2012, GSK submitted a regulatory application for FF/VI (proposed brand name RELVAR ELLIPTA ) in Europe for both COPD and asthma, as well as to other regulatory agencies throughout the world, which applications have been accepted for review. In September 2012, GSK announced that it was commencing an additional Phase 3 study to complete the U.S. asthma filing package. The Phase 3b program for FF/VI in COPD commenced in February 2011. In September 2013, GSK and we announced that the European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive opinion recommending marketing authorization for FF/VI. Any adverse developments or results or perceived adverse developments or results with respect to the FF/VI regulatory submissions, such as the recent withdrawal of the COPD submission from the current Japanese New Drug Application, the asthma Phase 3 study or the Phase 3b program will significantly harm our business and could cause the price of our securities to 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;
- inability to gain, or delay in gaining, regulatory approval outside the U.S., Canada and Japan, for the new ELLIPTA investigational dry powder inhaler used in these programs;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs. For example, GSK is investigating seven cases of fatal pneumonia in the Phase 3 FF/VI COPD program, six of which were at a dose that is higher than the dose being pursued for approval and a majority of which occurred at one clinical site;
- safety, efficacy or other concerns arising from clinical or non-clinical studies with umeclidinium bromide/vilanterol (proposed brand name ANORO ELLIPTA ) (UMEC/VI) having to do with the LABA VI, which is also a component of FF/VI;
- regulatory authorities determining that the Phase 3 program in asthma, or outside the U.S., in COPD, raises safety concerns or does not demonstrate adequate efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs to treat asthma.

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

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, on March 10 and 11, 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 United States (U.S.) for FF/VI and increase the overall risk for FF/VI for the treatment of asthma in the U.S.

Table of Contents

***If the FDA does not approve UMEC/VI on the December 18, 2013 PDUFA goal date, if FDA's action on UMEC/VI is delayed beyond the PDUFA goal date, or if regulatory authorities determine that the Phase 3 program for UMEC/VI for the treatment of COPD does not demonstrate adequate safety and efficacy, continued development of UMEC/VI will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.***

The Phase 3 program for UMEC/VI with the combination of a LAMA umeclidinium bromide (UMEC), and a LABA, VI, for the treatment of COPD commenced in February 2011. In July 2012, GSK and we reported top-line results from four pivotal studies in this Phase 3 program and in August 2012, GSK and we announced the completion of this Phase 3 program and reported certain top-line data from the remaining studies in the registrational program. GSK submitted regulatory applications for UMEC/VI (proposed brand name ANORO ELLIPTA ) for the treatment of COPD in December 2012 in the U.S. and in January 2013 in Europe and both submissions have been accepted for review. In September 2013, the FDA's Pulmonary-Allergy Drugs Advisory Committee discussed the New Drug Application for UMEC/VI, sponsored by GSK, for the for the long-term, once-daily, maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema. The Committee voted that the efficacy and safety data provide substantial evidence to support approval of UMEC/VI (62.5/25mcg dose) for the long-term, once-daily, maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema, that the safety of the investigational medicine had been adequately demonstrated at the 62.5/25mcg dose for the proposed indication , and that the efficacy data provided substantial evidence of a clinically meaningful benefit for UMEC/VI (62.5/25mcg) once daily for the long-term, maintenance treatment of airflow obstruction in COPD .Despite these favorable votes, the FDA is not bound by the recommendation of the advisory committee, and could decide not to approve, or delay approval of, the UMEC/VI NDA on the December 18 PDUFA goal date. GSK plans to make regulatory submissions in other countries. Any adverse developments or results or perceived adverse developments or results with respect to these regulatory submissions or the UMEC/VI program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- any unfavorable action or decision by the FDA on the UMEC/VI December 18, 2013 PDUFA goal date;
- the FDA and/or other regulatory authorities determining that additional clinical studies are required with respect to the Phase 3 program in COPD;
- inability to gain, or delay in gaining, regulatory approval outside the U.S. for the new ELLIPTA investigational dry powder inhaler used in the program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies with FF/VI having to do with the LABA, VI, which is also a component of UMEC/VI;
- regulatory authorities determining that the Phase 3 program in COPD raises safety concerns or does not demonstrate adequate efficacy; or

- any change in FDA policy or guidance regarding the use of LABAs combined with a LAMA to treat COPD.

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

The lead compound, GSK961081 ( 081), in the bifunctional muscarinic antagonist-beta2 agonist (MABA) program with GSK has completed a Phase 2b study, a Phase 1 study in combination with fluticasone propionate (FP), an inhaled corticosteroid (ICS), and a number of Phase 3-enabling non-clinical studies. GSK recently initiated preclinical Phase 3 enabling studies in the combination 081/FF program. GSK has informed us that the Phase 3 study will not be initiated for 081 monotherapy in 2013. GSK made a decision to move away from twice-daily option with fluticasone propionate (FP) in the Diskus® inhaler to the combination of 081/FF delivered once-daily in the ELLIPTA inhaler which requires additional work on non-clinical studies, manufacturing and a Phase 1 bioequivalence study. We are in further discussions with GSK regarding the 081 monotherapy program but we believe it is unlikely that a Phase 3 study with 081 monotherapy will commence in 2014. Any further delays or adverse developments or results or perceived adverse developments or results with respect to the MABA program will harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- GSK deciding to further delay or halt development of 081 monotherapy or the combination 081/FF;
- the FDA and/or other regulatory authorities determining that any of these studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the MABA program;
- the inability to gain, or delay in gaining, regulatory approval outside the U.S. for the ELLIPTA dry powder inhaler used in the program;

Table of Contents

- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program; or
- any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

***In April 2013 we announced our intention to separate our businesses into two independent publicly traded companies by separating our late-stage partnered respiratory assets from our biopharmaceutical operations, and the ongoing process to separate the two businesses may divert the attention of our management and employees, may disrupt our operations, will increase our professional services expenses and is subject to other risks.***

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, Inc. (Theravance Biopharma), filed a preliminary Form 10 with the SEC, and subsequent amendments on September 27, 2013 and October 29, 2013. Theravance will continue to manage all development and commercial responsibilities under the LABA collaboration with GSK and associated potential royalty revenues from FF/VI (RELVAR ELLIPTA or BREO ELLIPTA ), UMEC/VI (ANORO ELLIPTA ) and VI monotherapy, and Theravance Biopharma, will be a biopharmaceutical company focusing on the discovery, development and commercialization of small-molecule medicines in areas of significant unmet medical need. Our ability to effect the business separation is subject to the completion of numerous tasks, including but not limited to the preparation of audited financial statements for the new company, the completion of required regulatory filings, the receipt of a private letter ruling from the Internal Revenue Service (should we determine to proceed on a tax-free basis), and obtaining the consent of third parties to the transfer of contractual rights to the new company. The failure to obtain necessary approvals and consents could delay or make impractical our plan to effect the business separation. In addition, other transactions or developments could delay, prevent the completion of, or otherwise adversely affect the planned business separation. If the business separation is delayed or not consummated for any reason, we will not realize the anticipated benefits of the business separation as expected or at all.

The process of planning for and effecting the business separation will continue to demand a significant amount of time and effort from our management and certain employees. The diversion of our management's and employees' attention to the business separation process may disrupt our operations and may adversely impact the progress of our discovery and development efforts, disrupt our relationships with collaborators and increase employee turnover.

We currently anticipate funding the new company with approximately \$300 million at separation. We expect this initial cash will fund the new company's operations through significant potential corporate milestones for approximately the next two to three years after the completion of the spin-off, based on current operating plans and financial forecasts. Changes in our development or operating plans, the timing of, and our cash balance at the time of, the spin-off, however, could affect the amount of cash available for the two companies at the time of separation and the initial cash funding needed to adequately capitalize both companies. In addition, any delays in completion of the planned separation may increase the amount of time, effort, and expense that the Company devotes to the transaction and reduce the amount of funding available to both companies.

We cannot assure you that we will not undertake additional restructuring activities, that the planned business separation will be completed or if completed will succeed, or that the actual results will not differ materially from the results that the Company anticipates.



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

We will continue to incur significant expenditures for professional services in connection with our planning and implementation of the business separation, including financial advisory, accounting and legal fees.

Under the terms of a separation and distribution agreement to be 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.

Under the terms of a transition services agreement to be entered into between us and Theravance Biopharma, Theravance Biopharma will provide us with a variety of administrative services for a period of time 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 space at our current South San Francisco, California facilities. We will be relying on Theravance Biopharma for execution of these administrative activities through the

Table of Contents

transition period, which is a period when Theravance Biopharma personnel will be highly focused on supporting their own newly public company. 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.

***The amount of our net operating losses that will be used as a result of pre-spin-off restructuring is uncertain.***

As a part of the overall spin-off transaction, it is anticipated that certain assets that are transferred by us to Theravance Biopharma will result 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 recognized by us attributable to the transfer of certain assets to Theravance Biopharma will equal the excess of the fair market value of each asset transferred over our adjusted tax basis in such asset. While our basis in the cash we transfer to Theravance Biopharma will be equal to the amount of cash (and, therefore, we will recognize no gain on the transfer of such cash), our basis in some assets (other than cash) transferred to Theravance Biopharma may be significantly less than their associated fair market values, which could result in substantial taxable gain to us. The determination of the fair market value of non publicly traded 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, and thus U.S. federal income tax, realized by us as a result of the transfer. Our U.S. federal income tax resulting from any gain realized 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 of the transferred assets), may be reduced by our net operating loss carryforward. While federal and state tax laws impose restrictions on the utilization of net operating losses in the event of an ownership change, as defined in Section 382 of the Code, we conducted an analysis to determine whether an ownership change had occurred since inception through December 31, 2012, and has concluded that we had not undergone an ownership change. We had approximately \$1.2 billion of net operating loss as of December 31, 2012 and estimated additional losses in 2013 (excluding any spin-off related gains) exceeding \$100 million. We expect our net operating loss carryforward and current projected losses will fully offset the U.S. federal income tax resulting from the gains we will realize in connection with the pre spin-off restructuring. However, the amount of our net operating loss carryforward that will be used is uncertain as we are not seeking a pre-spin-off appraisal of the fair market value of our transferred assets, but instead will be determining fair market values after the spin-off in significant part on the trading prices of Theravance Biopharma shares following the spin-off.

***If the distribution is determined to be taxable for U.S. federal income tax purposes, our shareholders could incur significant U.S. federal income tax liabilities.***

We intend to seek a private letter ruling from the IRS regarding the U.S. federal income tax consequences of the distribution of the Theravance Biopharma common shares to our stockholders substantially to the effect that the distribution, except for cash received in lieu of a fractional share of the Theravance Biopharma common shares, will qualify as tax free under Sections 368(a)(1)(D) and 355 of the Code and, that, for U.S. federal income tax purposes, no gain or loss will be recognized by a holder of our common stock upon the receipt of the Theravance Biopharma common shares pursuant to the distribution. As part of the IRS' general policy with respect to rulings on spin-off transactions (including the distribution), the private letter ruling expected to be received by us will not be based upon a determination by the IRS that certain conditions which are necessary to obtain tax free treatment under Section 355 of the Code have been satisfied. Rather, the private letter ruling relies or will rely on certain facts and assumptions, and certain representations and undertakings, from us and Theravance Biopharma regarding the past and future conduct of our respective businesses and other matters. Notwithstanding the private letter ruling, the IRS could determine on audit that the distribution or certain related transactions should be treated as taxable transactions if it determines that any of these facts, assumptions, representations or undertakings is not correct or has been violated or that the distributions should be taxable for other reasons, including as a result of significant changes in stock or asset ownership after the distribution. In addition, the receipt of a private letter ruling is not a condition to the distribution, and the spin-off may occur prior to the receipt of such ruling. If the distribution ultimately is determined to be taxable for U.S. federal income tax purposes, the distribution could be treated as a taxable dividend or capital gain to you for U.S. federal income tax purposes, and you could incur significant U.S. federal income tax liabilities.

*Completion of the Proposed Spin-off of Theravance Biopharma will result in substantial changes in our Board and management.*

After the spin-off, our Chief Executive Officer is expected to work part time for us and part time for Theravance Biopharma and this arrangement is expected to last until the recruitment and transition of a new chief executive officer for Theravance. While we will benefit from his deep knowledge of our business, as well as his familiarity with our systems, policies, procedures and mode of operation, the lack of his full time focus on our business may dilute his effectiveness on our behalf and therefore hurt our business. In addition, we also anticipate that some or all of the other senior officers remaining at Theravance may become officers of Theravance Biopharma following the spin-off as we recruit and integrate new officers for our royalty management business. Some of these senior officer transitions may occur quickly after the spin-off depending in part on our success in recruiting and integrating new officers into our management. We also anticipate that substantially all of the current members of our Board of Directors other than Mr. Winningham

Table of Contents

and Mr. Waltrip will resign from our Board of Directors prior to the spin-off. We are currently engaged in a search to locate additional independent board members and we expect our Board to have at least four continuing directors prior to the spin-off. At the time of the spin-off and for a period of time thereafter, these senior officer and board level changes could be disruptive to our operations, present significant management challenges and could harm our business.

***If we cannot identify a suitable commercialization partner for VIBATIV® in the U.S. we will bear the full cost of developing the capability to market, sell and distribute the product.***

Our general strategy is to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products. We may not be able to establish these sales and distribution relationships on acceptable terms, or at all. For any of our product candidates that receive regulatory approval in the future and are not covered by our current collaboration agreements, we will need a partner in order to commercialize such products unless we establish independent sales, marketing and distribution capabilities with appropriate technical expertise and supporting infrastructure. VIBATIV® was returned to Theravance by Astellas Pharma Inc. (Astellas) (our former VIBATIV® collaboration partner) in January 2012. On August 14, 2013 we announced the reintroduction of VIBATIV® to the U.S. market with the commencement of shipments into the wholesaler channel. While we have contracted a small sales force and expanded our medical affairs presence, other commercialization alternatives for the U.S. market are being evaluated. The risks of commercializing VIBATIV® in the U.S. without a partner include:

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

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

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

Each of our product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. Non-clinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies or decisions to terminate programs.

The commencement and completion of clinical studies for our product candidates may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;

Table of Contents

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

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

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

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

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

***If any product candidates, in particular those in any respiratory program with GSK, are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.***

Although VIBATIV®, discovered and developed by us, is approved in the U.S. and Canada, and BREO ELLIPTA™, developed in collaboration with GSK, is approved in the U.S. and Canada, and RELVAR ELLIPTA™ is approved in Japan, none of our other product candidates have been approved by regulatory authorities. We are uncertain whether any of our other product candidates and our collaborative partners' product candidates will prove effective and safe in humans or meet applicable regulatory standards. In addition, our approach to applying our expertise in multivalency to drug discovery may not result in the creation of successful medicines. The risk of failure for our product candidates is high. For example, in late 2005, we discontinued our overactive bladder program based upon the results of our Phase 1 studies with compound TD-6301, and GSK discontinued development of TD-5742, the first LAMA compound licensed from us, after completing a single-dose Phase 1 study. In addition, although we believe the results of our Phase 2b program with TD-1211, our investigational mu-opioid antagonist, support progression into Phase 3 development, the FDA appears to be exploring whether there is evidence of a potential cardiovascular class effect related to opioid

Table of Contents

withdrawal associated with mu-opioid antagonists. Accordingly, we are currently evaluating our Phase 3 strategy due to the potentially evolving FDA requirements in this area. The data supporting our drug discovery and development programs is derived solely from laboratory experiments, non-clinical studies and clinical studies. A number of other compounds remain in the lead identification, lead optimization, preclinical testing or early clinical testing stages.

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 (REMS) at the FDA's discretion. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our and our collaborative partner's product candidates.

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

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

Our previous VIBATIV® commercialization partner failed to maintain a reliable source of drug product supply which resulted in critical product shortages and, eventually, suspension of commercialization. In addition, the E.U. marketing authorization for VIBATIV® has been suspended since May 2012 because our previous VIBATIV® commercialization partner's single-source VIBATIV® drug product supplier at that time did not meet cGMP requirements for the manufacture of VIBATIV®. Theravance has filed the first of several anticipated submissions to support the removal of the suspension, and we currently believe the suspension could be lifted sometime in the first half of 2014, and possibly sooner. Manufacturing of E.U. approved VIBATIV® finished drug product currently is scheduled for late 2013. Any failure to remove the E.U. marketing authorization suspension or manufacture E.U. approved drug product on a timely basis will continue to delay the commercial introduction of VIBATIV® in the E.U. and Canada. In May 2012, we entered into an agreement with Hospira Worldwide, Inc. (Hospira) to supply VIBATIV® drug product. In June 2013 the FDA approved Hospira as a VIBATIV® drug product manufacturer. Although we believe that Hospira will be a reliable supplier of VIBATIV® drug product, if it cannot perform or if its performance does not meet regulatory requirements, including maintaining cGMP compliance, and if commercial manufacture of VIBATIV® drug product cannot be arranged elsewhere on a timely basis, the commercialization of VIBATIV® in the U.S. could be adversely affected and the commercial introduction of VIBATIV® in the E.U. and Canada will be further delayed.

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



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

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

Our manufacturing strategy presents the following additional risks:

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

Table of Contents

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

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

Even if we receive regulatory approval for our product candidates, this approval may include limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive disadvantage relative to alternative therapies. For example, the U.S. labeling for VIBATIV® contains a number of boxed warnings. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. In addition, the VIBATIV® labeling for hospital-acquired and ventilator associated bacterial pneumonia (HABP/VABP) in the U.S. and the E.U. specifies that VIBATIV® should be reserved for use when alternative treatments are not suitable. These restrictions make it more difficult to market VIBATIV®. With VIBATIV® approved in certain countries, we are subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing.

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

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies with respect to VIBATIV®, as well as governmental authorities in those foreign countries in which any of our product candidates are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising,

dissemination of information and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition, which may cause the price of our securities to fall.

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

Table of Contents

***We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future.***

We have been engaged in discovering and developing compounds and product candidates since mid-1997. We may never generate sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve profitability. As of September 30, 2013, we had an accumulated deficit of approximately \$1.5 billion.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, TD-9855 in our MARIN program is in Phase 2 studies for both attention deficit/hyperactivity disorder and fibromyalgia and in September 2013 we reported positive top line data from a Phase 2b study with TD-4208, our LAMA compound. Also, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid induced constipation. Though we are seeking to partner these programs, we may choose to progress one or more of these programs into later stage clinical studies by ourselves, which could increase our anticipated operating expenses substantially. Furthermore, should we decide to continue to commercialize VIBATIV® in the United States without a partner, we will incur costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise, supporting infrastructure and distribution capabilities. As a result, we expect to continue to incur substantial losses for the foreseeable future. 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 and our ability to raise capital and continue operations.

***If we fail to maintain or obtain the capital necessary to fund our operations, we may be unable to develop our product candidates or commercialize VIBATIV® and we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.***

We need large amounts of capital to support our research and development efforts. If we are unable to maintain or to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans and financial forecasts, we believe that our cash and cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. If our current operating plans and financial forecasts change, we may seek additional funding sooner in the form of public or private equity offerings or debt financings. For example, if we chose to conduct Phase 3 studies with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation, or progress TD-4208 in our LAMA program or TD-9855 in our MARIN program into later stage development and we chose to progress any of these programs on our own, our capital needs would increase substantially. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. In addition, under our LABA collaboration with GSK, in the event that a product containing vilanterol (VI), which is the LABA product candidate in FF/VI, UMEC/VI and UMEC/VI/FF and which was discovered by GSK, is successfully developed and commercialized in multiple regions of the world as both a single-agent and a combination product or two different combination products, we will be obligated to pay GSK future milestone payments that could total as much as \$180.0 million. Of these potential milestone payments, \$30.0 million became payable in October due to the launch of BREO ELLIPTA in the U.S., and we estimate another \$70.0 million could become payable during the remainder of 2013 and that all the milestone payments could be payable by the end of 2014. We are not entitled to receive any further milestone payments from GSK under the LABA collaboration. Future financing to meet our capital needs may not be available in sufficient amounts or on terms acceptable to us, if at all. Even if we are able to raise additional capital, such financing may result in significant dilution to existing security holders. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery and development efforts and exploiting other corporate opportunities. This could harm our business, prospects and financial condition and cause the price of our securities to fall.

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

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

- the demonstration of the clinical efficacy and safety of VIBATIV®;
- the experiences of physicians, patients and payors with the use of VIBATIV® in the U.S.;

Table of Contents

- potential negative perceptions of physicians related to product shortages and regional supply outages that halted commercialization of VIBATIV®, stemming from the manufacturing issues at the previous drug product supplier;
- potential negative perceptions of physicians related to the European Commission's suspension of marketing authorization for VIBATIV® because our previous VIBATIV® commercialization partner's single-source VIBATIV® drug product supplier did not meet the cGMP requirements for the manufacture of VIBATIV®;
- the advantages and disadvantages of VIBATIV® compared to alternative therapies;
- our ability to educate the medical community about the appropriate circumstances for use of VIBATIV®;
- the reimbursement policies of government and third party payors; and
- the market price of VIBATIV® relative to competing therapies.

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

We entered into our LABA collaboration agreement with GSK in November 2002, our strategic alliance agreement with GSK in March 2004, and our VIBATIV® collaboration agreement with Astellas in November 2005, which was terminated by Astellas in January 2012. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for velusetrag, our lead compound in the 5-HT4 program, covering the European Union (EU), Russia, China, Mexico and certain other countries, and we entered into a research collaboration and license agreement with Merck to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease on an exclusive, worldwide basis. In March 2013, we entered into a commercialization agreement with Clinigen Group plc for VIBATIV® in the European Union and certain other European countries (including Switzerland and Norway). In connection with these agreements, we have granted to these parties certain rights regarding the use of our patents and technology with respect to compounds in our development programs, including development and marketing rights. Under our GSK agreements, GSK has full responsibility for development and commercialization of FF/VI, UMEC/VI, UMEC/VI/FF, VI monotherapy and any product candidates in the MABA program. Any future milestone payments or royalties to us from these programs will depend on the extent to which GSK advances the product candidate through development and, if approved, commercialization. The Merck and Alfa Wassermann agreements provide us with research and development funding, respectively, for the programs under license, and if either partner decides not to progress the licensed program, we may not be able to develop or commercialize the program on our own. In September 2013, Merck provided Theravance notice of its termination of the Research Collaboration and License Agreement. The termination is expected to be effective in December 2013.

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

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

We have active collaborations with GSK for FF/VI, UMEC/VI, UMEC/VI/FF, VI monotherapy and the MABA program, with Alfa Wassermann for velusetrag, with Clinigen for VIBATIV® for the EU, and with other companies for regional development and commercialization of VIBATIV®. Additional collaborations will be needed to fund later-stage development of our product candidates that have not been licensed to a collaborator or for territory that is not covered by the collaboration, and to commercialize these product candidates if approved by the necessary regulatory authorities. Velusetrag, our lead compound in the 5 HT4 program, and TD-1792, our investigational antibiotic have successfully completed a Phase 2 proof of concept study. In July 2012 we reported positive results from a Phase 2b study with TD-1211, the lead compound in our Peripheral Mu Opioid Receptor Antagonist program

Table of Contents

for opioid induced constipation and in September 2013 we reported positive top line results from a Phase 2b study with TD-4208 LAMA compound. In addition, in connection with the expansion of the MABA program under the strategic alliance with GSK in October 2011, GSK relinquished its right to option our MARIN program with TD-9855 and our ARNI program. We currently intend to seek additional third parties with which to pursue collaboration arrangements for the development and commercialization of our development programs and for the future commercialization of VIBATIV® in regions where it is not currently partnered. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to prioritize alternative programs. Our inability to successfully collaborate with third parties would increase our development costs and would limit the likelihood of successful commercialization of our product candidates which may cause the price of our securities to fall.

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

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

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

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

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

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



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

our ability to leverage our experience in drug discovery and development to:

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

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

Table of Contents

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

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

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

We are highly dependent on principal members of our management team and scientific staff 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 development and commercialization activities, which may cause the price of our securities to fall.

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

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

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

Our principal facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore is vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our research activities and of much of our equipment could make it difficult for us to recover from this type of disaster. We may not

have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition, which could cause the price of our securities to fall.

**Risks Related to our Alliance with GSK**

*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 26.9% of our outstanding capital stock as of September 30, 2013, it is also a strategic partner with rights and obligations under our collaboration and strategic alliance agreements with GSK that cause its interests to differ from the interests of us and our other stockholders. In particular, GSK has a substantial respiratory product portfolio, and only some of its products are covered by our 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 own respiratory products and/or delay or terminate the development or commercialization of the respiratory programs covered by our GSK agreements. Also, given the potential future royalty payments GSK may be obligated to pay under our GSK agreements, GSK may seek to acquire us in order to effectively terminate 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 our GSK agreements that has not been publicly disclosed. 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, GSK could also seek to challenge the spin-off or the post-spin-off operation of the limited liability company to be jointly owned by us and Theravance Biopharma as violating or allowing it to terminate the GSK agreements, including by violating the assignment or confidentiality provisions of those agreements, or otherwise violating its legal rights. While we believe the spin-off and planned operation of the limited liability company fully complies with our GSK agreements and applicable law, there can be no assurance that we will prevail against any such claims by GSK. Moreover, regardless of the merit of any claims by GSK, we may incur significant cost and diversion of resources in defending them. In addition, any uncertainty about the our respiratory programs partnered with GSK or the enforceability of our GSK agreements could result in significant reduction in the market price of our securities and other material harm to our business.

Table of Contents

***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 September 30, 2013, GSK beneficially owned approximately 26.9% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock in certain circumstances. GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business.

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

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

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

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

The procedures governing GSK offers to ours stockholders to acquire outstanding voting stock set forth in the preceding two paragraphs are applicable until the termination of the governance agreement 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 September 30, 2013, GSK beneficially owned approximately 26.9% 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.

Table of Contents

***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.

**Risks Related to Legal and Regulatory Uncertainty**

***If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.***

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of September 30, 2013, we owned 367 issued United States patents and 1338 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

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

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

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

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

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

Table of Contents

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

The risks identified in the two preceding risk factors also apply to the intellectual property protection efforts of our partner, GSK. To the extent the intellectual property protection of any of the assets in the LABA collaboration are successfully challenged or encounter problems with the United States Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset arising from the LABA collaboration could harm our business and cause the price of our securities to fall.

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

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

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

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

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

- our or our collaborators' ability to set a price we believe is fair for our products, if approved;



- our ability to generate revenues and achieve profitability; and
- the availability of capital.

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

Table of Contents

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with these and other applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

**Risks 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 development or commercialization 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;
- any adverse developments or results or perceived adverse developments or results with respect to the 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 or an unfavorable outcome on the December 18, 2013 PDUFA goal date;
- any adverse developments or results or perceived adverse developments or results with respect to the MABA program with GSK, including, without limitation, any further delays encountered in progressing the MABA program or a decision by GSK to halt the program or any further development of certain drug candidates in the program, any difficulties or delays encountered with regard to the regulatory path for GSK961081, either alone or in combination with other therapeutically active ingredients, or any indication from non-clinical studies of GSK961081 that the compound is not safe or efficacious;

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

- any further adverse developments or perceived adverse developments with respect to the commercialization of VIBATIV®;
- 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;
- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development or have commercialized;
- our incurrence of expenses in any particular quarter that are different than market expectations;

Table of Contents

- 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;
- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners other than GSK, including, without limitation, disagreements that may arise between us and any of those partners;
- any adverse developments or perceived adverse developments with respect to our partnering efforts with VIBATIV®, velusetrag, TD-1211, TD-9855, TD-4208, TD-1792 or our cardiovascular program;
- announcements regarding GSK generally;
- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;
- developments concerning any collaboration we undertake with companies other than GSK;
- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;
- regulatory developments in the United States and foreign countries;
- 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;

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

- relative illiquidity in the public market for our common stock (our three largest stockholders other than GSK collectively owned approximately 30.9% of our outstanding capital stock as of September 30, 2013 based on our review of publicly available filings);
- any adverse developments or perceived adverse developments with respect to the proposed business separation; and
- potential sales or purchases of our capital stock by GSK.

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

As of September 30, 2013, GSK beneficially owned approximately 26.9% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 4.4% of our outstanding capital stock. Based on our review of publicly available filings as of September 30, 2013, our three largest stockholders other than GSK collectively owned approximately 30.9% 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.



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

On August 2, 2013, we completed the sale of 3,064,407 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of \$36.50 per share, resulting in aggregate gross proceeds of \$111.9 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 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)		
10.8*	Collaboration Agreement between the registrant and Glaxo Group Limited, dated as of November 14, 2002		
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 quarter and first three quarters ended September 30, 2013, formatted in XBRL: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Income (Loss), (iv) the Condensed Consolidated Statements of Cash Flows and (v) the Notes to the Condensed Consolidated Financial Statements

---

\* Application has been made to the Securities and Exchange Commission to seek confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.



Table of Contents

**SIGNATURES**

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

Theravance, Inc.  
(Registrant)

November 1, 2013  
Date

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

November 1, 2013  
Date

/s/ Michael W. Aguiar  
Michael W. Aguiar  
Senior Vice President, Finance  
and Chief Financial Officer